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Form Approved: OMB No. 0945-0002
Expiration Date: 11/30/2022

COMPLAINANT CONSENT FORM

The Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) has the authority to collect and receive material and information about you, including personnel and medical records, when they are relevant to its investigation of your complaint.

To investigate your complaint, OCR may need to reveal your identity or identifying information about you to persons at the entity or agency under investigation or to other persons, agencies, or entities. In some circumstances, OCR may refer your complaint to another government agency, as warranted.

The Privacy Act of 1974 protects certain federal records that contain personally identifiable information about you and, with your consent, allows OCR to use your name or other personal information, if necessary, to investigate your complaint.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

Additionally, OCR may disclose information, including medical records and other personal information, which it has gathered during the course of its investigation in order to comply with a request under the Freedom of Information Act (FOIA) and may refer your complaint to another appropriate agency.

Under FOIA, OCR may be required to release information regarding the investigation of your complaint; however, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

OCR will use any applicable protections in that law to safeguard information which could identify you, or other individuals, or that, if released, could constitute a clearly unwarranted invasion of personal privacy. OCR may be required to release some information regarding the investigation of your complaint under the Freedom of Information Act (FOIA), however, information concerning your complaint which could reveal your identity is protected from disclosure to third party requesters under FOIA.

Please read and review the documents entitled *Notice to Complainants and Other Individuals Asked to Supply Information to the Office for Civil Rights* and *Protecting Personal Information in Complaint Investigations* for further information regarding how OCR may obtain, use, and disclose your information while investigating your complaint.

In order to expedite the investigation of your complaint if it is accepted by OCR, please read, sign, and return one copy of this consent form to OCR with your complaint. Please make one copy for your records.

- As a complainant, I understand that in the course of the investigation of my complaint it may become necessary for OCR to reveal my identity or identifying information about me to persons at the entity or agency under investigation or to other persons, agencies, or entities.

- I am also aware of the obligations of OCR to honor requests under the Freedom of Information Act (FOIA). I understand that it may be necessary for OCR to disclose general information which it has gathered as part of its investigation of my complaint, excluding personally identifiable information.

- In addition, I understand that, as a complainant, I may be covered by the Department of Health and Human Services' (HHS) regulations which protect any individual from being intimidated, threatened, coerced, retaliated against, or discriminated against because he/she has made a complaint, testified, assisted, or participated in any manner in any mediation, investigation, hearing, proceeding, or other part of HHS's investigation, conciliation, or enforcement process.

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NOTICE TO COMPLAINANTS AND OTHER INDIVIDUALS ASKED TO SUPPLY INFORMATION TO THE OFFICE FOR CIVIL RIGHTS

Privacy Act

The Privacy Act of 1974 (5 U.S.C. §552a) requires OCR to notify individuals whom it asks to supply information that:

— OCR is authorized to solicit information under:
(i) Federal laws barring discrimination by recipients of Federal financial assistance on grounds of race, color, national origin, disability, age, sex, religion under programs and activities receiving Federal financial assistance from the U.S. Department of Health and Human Services (HHS), including, but not limited to, Title VI of the Civil Rights Act of 1964 (42 U.S.C. §2000d *et seq.*), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. §794), the Age Discrimination Act of 1975 (42 U.S.C. §6101 *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. §1681 *et seq.*), Sections 794 and 855 of the Public Health Service Act (42 U.S.C. §§295m and 296g); and Section 1557 of the Affordable Care Act (42 U.S.C. §18116);
(ii) Federal laws protecting rights of conscience and religious freedom in health and human services programs, such as Sections 1303(b)(4) and 1553 of the Affordable Care Act (42 U.S.C. §§18113, 18023(b)(4)), the Church Amendments (42 U.S.C. § 300a-7), the Coats-Snowe Amendment (42 U.S.C §238n), the Religious Freedom Restoration Act (42 U.S.C. § 2000bb *et seq.*), and the Weldon Amendment (*e.g.*, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019, Pub. L. No. 115-245, Div. B., §507(d)), and applicable regulations;
(iii) Titles VI and XVI of the Public Health Service Act (42 U.S.C. §§291 *et seq.* and 300s *et seq.*) and 42 C.F.R. Part 124, Subpart G (Community Service obligations of Hill-Burton facilities);
(iv) 45 C.F.R. Part 85, as it implements Section 504 of the Rehabilitation Act in programs conducted by HHS; and
(v) Title II of the Americans with Disabilities Act (42 U.S.C. §12131 *et seq.*) and Department of Justice regulations at 28 C.F.R. Part 35, which give HHS "designated agency" authority to investigate and resolve disability discrimination complaints against certain public entities, defined as health and service agencies of state and local governments, regardless of whether they receive federal financial assistance.

HIPAA Standards for the Privacy of Individually Identifiable Health Information (The Privacy Rule), 45 C.F.R. Part 160 and Subparts A and E of Part 164, Health Insurance Reform: Security Standards (The Security Rule), 45 C.F.R. Part 160 and Subparts A and C of Part 164, Breach Notification for Unsecured Protected Health Information (The Breach Rule), 45 C.F.R. Part 160 and Subparts A and D of Part 164, and Administrative Simplification: Enforcement, 45 C.F.R. Part 160, Subparts C, D, and E, which contains provisions relating to compliance and investigations, the imposition of civil money penalties, and procedures for hearings related to violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. §1320d-2).

OCR will request information for the purpose of determining and securing compliance with the Federal laws listed above. Disclosure of this requested information to OCR by individuals who are not recipients of federal financial assistance is voluntary; however, even individuals who voluntarily disclose information are subject to prosecution and penalties under 18 U.S.C. § 1001 for making false statements.

Additionally, although disclosure is voluntary for individuals who are not recipients of federal financial assistance, failure to provide OCR with requested information may preclude OCR from making a compliance determination or enforcing the laws above.

OCR has the authority to disclose personal information collected during an investigation without the individual's consent for the following routine uses:

(i) to make disclosures to OCR contractors who are required to maintain Privacy Act safeguards with respect to such records;
(ii) for disclosure to a congressional office from the record of an individual in response to an inquiry made at the request of the individual;
(iii) to make disclosures to the Department of Justice to permit effective defense of litigation; and
(iv) to make disclosures to the appropriate agency in the event that records maintained by OCR to carry out its functions indicate a violation or potential violation of law.

Under 5 U.S.C. §552a(k)(2) and the HHS Privacy Act regulations at 45 C.F.R. §5b.11 OCR complaint records have been exempted as investigatory material compiled for law enforcement purposes from certain Privacy Act access, amendment, correction and notification requirements.

Freedom of Information Act

A complainant, the recipient or any member of the public may request release of OCR records under the Freedom of Information Act (5 U.S.C. §552) (FOIA) and HHS regulations at 45 C.F.R. Part 5. Generally, most records will be available only to the complainant if they are not privileged. Most or all records from a complaint file will be withheld to protect privacy.

Fraud and False Statements

Federal law, at 18 U.S.C. §1001, authorizes prosecution and penalties of fine or imprisonment for conviction of "whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry."

Form Approved: OMB No. 0945-0002
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PROTECTING PERSONAL INFORMATION IN COMPLAINT INVESTIGATIONS

To investigate your complaint, the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) will collect information from different sources. Depending on the type of complaint, we may need to get copies of your medical records, or other information that is personal to you. This Fact Sheet explains how OCR protects your personal information that is part of your case file.

HOW DOES OCR PROTECT MY PERSONAL INFORMATION?

OCR is required by law to protect your personal information. The Privacy Act of 1974 protects Federal records about an individual containing personally identifiable information, including, but not limited to, the individual's medical history, education, financial transactions, and criminal or employment history that contains an individual's name or other identifying information.

Under the Privacy Act, OCR will disclose your name or other personal information with a signed consent from you, and only when it is necessary to complete the investigation of your complaint or to enforce civil rights laws or when it is otherwise permitted by law.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

CAN I SEE MY OCR FILE?

Under the Freedom of Information Act (FOIA), you can request a copy of your case file once your case has been closed; however, OCR can withhold information from you in order to protect the identities of witnesses and other sources of information. Additionally, some records may be withheld to protect OCR's deliberative process privilege or any other legally protected privilege.

CAN OCR GIVE MY FILE TO ANY ONE ELSE?

If a complaint indicates a violation or a potential violation of law, OCR can refer the complaint to another appropriate agency without your permission.

If you file a complaint with OCR, and we decide we cannot help you, we may refer your complaint to another agency, such as the Department of Justice.

CAN ANYONE ELSE SEE THE INFORMATION IN MY FILE?

Public access to OCR's files and records is controlled by the Freedom of Information Act (FOIA). Under FOIA, OCR may be required to release general information about this case upon public request. In the event that OCR receives such a request, we will apply every legal protection to information that identifies individuals.

If OCR receives protected health information about you in connection with a HIPAA investigation or compliance review, we will only share this information with individuals outside of HHS if necessary for our compliance efforts or if we are required to do so by another law.

DOES IT COST ANYTHING FOR ME (OR SOMEONE ELSE) TO OBTAIN A COPY OF MY FILE?

In most cases, the first two hours spent searching for document(s) you request under the Freedom of Information Act and the first 100 pages are free. Additional search time or copying time may result in a cost for which you will be responsible. If you wish to limit the search time and number of pages to a maximum of two hours and 100 pages; please specify this in your request. You may also set a specific cost limit, for example, cost not to exceed $100.00. For details, see HHS's FOIA page.

If you have any questions about this complaint and consent package, please contact OCR at www.hhs.gov/ocr/office/about/contactus/index.html.

OR

Contact the Customer Response Center at (800) 368-1019 (see contact information on page 2 of the Complaint Form).

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STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Van Mitchell, Secretary

Office of Health Services
Medical Care Programs

MARYLAND MEDICAL ASSISTANCE PROGRAM
Managed Care Organizations Transmittal No. 110
March 10, 2016

TO: Managed Care Organizations

FROM: Susan J. Tucker, Executive Director
Office of Health Services

RE: Gender Transition: Covered Services, Coverage Criteria, Limitations and Exclusions

NOTE: Please ensure that appropriate staff members in your organization are informed of the contents of this transmittal

****

The purpose of this transmittal is to reinforce that, in addition to hormone therapy, HealthChoice Managed Care Organizations (MCOs) are now responsible for covering medically necessary gender transition services including gender reassignment surgery. The Department promulgated regulations effective December 10, 2015 to COMAR 10.09.02.05 to add coverage for gender reassignment surgery. The Department is also amending COMAR 10.09.02.05, .06, 10.09.03.06, 10.09.06.06, 10.09.09.05, 10.09.67.26-2 and 10.90.67.27 to reflect current policy.

When reviewing requests for gender transition services, MCOs will be responsible for the attached list of services. Gender reassignment surgery requires a behavioral health diagnosis of gender dysphoria. MCOs should verify that behavioral health treatment has taken place prior to gender reassignment surgery in accordance with the attached authorization criteria.

Please see the attached optional templates for providers that may be used prior to authorizing gender transition services.

If you have questions regarding this transmittal, please contact Dr. Tiffany Wedlake, Physician Specialist for Managed Care, at Tiffany.wedlake@maryland.gov or (410)767-6250.

Attachments

GENDER TRANSITION SERVICES UNDER
THE MARYLAND MEDICAID PROGRAM
Covered Services and Limitations
Effective 12/10/15

Covered Services:

1) **Outpatient psychotherapy/mental health services for gender dysphoria and associated co-morbid psychiatric diagnoses**. The benefits are the same as any other outpatient mental health service covered by Behavioral Health.

2) **Continuons hormone replacement therapy.** Includes hormones injected by a medical provider in an office setting and oral and self-injected hormones covered under the pharmacy benefit.

3) **Ontpatient Laboratory testing to monitor continuons hormone therapy**.

4) **Gender reassignment snrgery:**

Male-to-Female Transition	Female-to-Male Transition
Orchiectomy	Vaginectomy
Penectomy	Hysterectomy
Clitoroplasty	Mastectomy
Labiaplasty	Salpingo-oophorectomy
Vaginoplasty	Ovariectomy
Thyroid Chondroplasty	Metoidioplasy
	Phalloplasty
	Scrotoplasty
	Placement of Testicular Protheses
Urethroplasty for both types of transition	

For individuals planning to undergo gender reassignment snrgery, all of the following criteria must be met:

a. The individual is at least 18 years of age; and

b. The individual has capacity to make fully informed decisions and consent for treatment; and

c. The individual has been **diagnosed with gender dysphoria** and exhibits all of the following:

   1. The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatment; and

Source: STATE OF MARYLAND EMPLOYEE AND RETIREE HEALTH AND WELFARE BENEFITS PROGRAM

2. The gender dysphoria (pre and post diagnosis) has been present persistently for at least two years; and

3. The gender dysphoria is not a symptom of another mental disorder; and

4. The gender dysphoria causes clinically significant distress or impairment in social, occupational, or other important areas of functioning; and

d. The individual regularly participates in psychotherapy and/or ongoing clinical treatment throughout the real-life experience may be required when recommended by a treating medical or behavioral health practitioner or when medically necessary; and

e. If the individual has significant medical or mental health issues present, they must be reasonably well controlled. If the individual is diagnosed with severe psychiatric disorders and impaired reality testing (e.g., psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated; and

f. The individual will require two referrals from qualified mental health professionals who have independently assessed the individual. If the first referral is from the individual's psychotherapist, the second referral should be from a person who has only had an evaluative role with the individual. Two separate letters, or one letter signed by both (e.g., if practicing within the same clinic) are required; and

g. At least one of the professionals submitting a letter must have a doctoral degree (Ph.D., M.D., Ed.D., D.Sc., D.S.W., or Psy.D) and be capable of adequately evaluating co-morbid psychiatric conditions. One letter is sufficient if signed by two providers, one of whom has met the doctoral degree specifications, in addition to the specifications set forth above. One letter signed by an appropriate provider is sufficient to support benefits for a mastectomy. The medical documentation should include the start date of living full time in the new gender, when applicable; and

h. The individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician, unless the individual has a medical contraindication; and

i. Documentation that the individual is required to have completed 12 months of continuous hormonal therapy prior to hysterectomony/salpingo-oophorectomy, orchiectomy, vaginectomy or vaginoplasty procedures; and

j. Hormonal therapy **is not required** as a prerequisite to a mastectomy.

5) **Augmentation mammoplasty**. Provided the criteria above for gender reassignment surgery have been satisfied, augmentation mammoplasty (including breast prosthesis if necessary) may be covered for male-to-femal transgender individuals if the Physician prescribing hormones and the treating surgeon have documented that, after undergoing hormone treatment for 12 months, breast size continues to cause clinically significant distress in social, occupational, or other areas of functioning.

Post Transition Services. Gender-specific services may be medically necessary for transgender persons appropriate to their anatomy. Examples include:

- **Breast cancer screening** may be medically necessary for female to male transgender persons who have not undergone a mastectomy;
- **Prostate cancer screening** may be medically necessary for male to female transgender individuals who have retained their prostate.

Coverage Limitations and Exclusions

The surgeries and procedures identified below are excluded from coverage. (This list may not be all-inclusive):

1) Abdominoplasty
2) Blepharoplasty
3) Breast enlargement procedures, except in connection with a covered augmentation mammoplasty
4) Brow lift
5) Cheek implants
6) Chin/nose implants
7) Collagen injections
8) Cryopreservation, storage, and thawing of reproductive tissue (i.e., oocytes, ovaries, testicular tissue) and the charged associated therewith (e.g., office, hospital, ultrasounds, laboratory test, etc.)
9) Electrolysis
10) Face/forehead lifts
11) Hair removal/hairplasty/hair transplantation
12) Facial bone reconstruction
13) Hair removal/hairplasty/hair transplantation
14) Jaw shortening/sculpturing/facial bone reduction
15) Laryngoplasty
16) Lip reduction/enhancement
17) Liposuction
18) Mastopexy
19) Neck tightening
20) Nipple/areola reconstruction, except in connection with a covered augmentation Mammoplasty or mastectomy
21) Penile prosthesis (non-inflatable/inflatable), except in connection with a covered phalloplasty (implantation of the prosthesis shall not be considered a second state

phalloplasty) in a female-to-male transition (subsequent replacement or correction of such prosthesis subject to rules and limitations applicable to all prosthetic devises)

22) Removal or redundant skin, except in connection with a covered surgery
23) Replacement of tissue expander with permanent prosthesis testicular insertion, except as a component of a covered placement of a testicular prosthesis
24) Reversal of genital or breast surgery or reversal of surgery to revise secondary sex characteristics
25) Rhinoplasty
26) Second stage phalloplasty
27) Surgical correction of hydraulic abnormality of inflatable (multi-component) prosthesis including pump and/or cylinders and/or reservoir
28) Testicular prostheses, except as a component of a covered placement of a testicular Prosthesis (subsequent replacement or correction of such prosthesis subject to rules and Limitations applicable to all prosthetic devises)
29) Testicular expanders, except as a component of a covered placement of a testicular prosthesis
30) Voice modification surgery
31) Voice therapy/voice lessons

Prior Authorization of Gender Transition Surgery
Medical Provider Check List
(Optional Template for MCOs)

The patient must meet **ALL** of the following:

☐ Must be at least 18 years of age and has the capacity to make fully informed decisions and consent to treatment.

☐ Has no contraindicating medical diagnosis to treatment.

☐ Has completed 12 months of continuous hormonal therapy prior to gender reassignment surgery (e.g., hysterectomy/salpingo-oophorectomy, orchiectomy, vaginectomy or vaginoplasty procedures) [1].

☐ Has been informed of non-covered related medical procedures/care and expected future medical procedures/care and any costs associated with them[2].

☐ Has provided evidence of two independent psychological assessments[3].

The psychological assessment must indicate that the patient:

- Has a clear diagnosis of gender dysphoria with presence of symptoms > 2 years;
- Has lived for 12 months or more as opposite sex (desired gender) prior to the mental health professional recommending surgery; start date of living full time in the new gender;
- Has no contraindicating mental health conditions; if the patient is diagnosed with severe psychiatric disorders and impaired reality testing(e.g., psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), the patient must be reasonably well controlled with psychotropic medications and/or psychotherapy before surgery is contemplated; and
- Has expressed full understanding of the psychological, social, medical and financial implications of treatment, for now and the future, prior to referring for treatment or surgery.

[1] Not required for mastectomy

[2] See *Coverage Limitations and Exclusions* on Addendum

[3] At least one of the professionals must have a doctoral degree (Ph.D., M.D., Ed.D., D.Sc., D.S.W., or Psy.D). Two separate letters, or one letter signed by two providers, if both providers are in the same practices or clinics.

Prior Authorization of Gender Reassignment Surgery
Medical Provider Check List
(Optional Template for MCOs)

Addendum

Coverage Limitations and Exclusions – The surgeries and procedures identified below are excluded from coverage. (This list may not be all-inclusive)

1) Abdominoplasty
2) Blepharoplasty
3) Breast enlargement procedures, except in connection with a covered augmentation mammoplasty
4) Brow lift
5) Cheek implants
6) Chin/nose implants
7) Collagen injections
8) Cryopreservation, storage, and thawing of reproductive tissue (i.e., oocytes, ovaries, testicular tissue) and the charged associated therewith (e.g., office, hospital, ultrasounds, laboratory test, etc.)
9) Electrolysis
10) Face/forehead lifts
11) Hair removal/hairplasty/hair transplantation
12) Facial bone reconstruction
13) Hair removal/hairplasty/hair transplantation
14) Jaw shortening/sculpturing/facial bone reduction
15) Laryngoplasty
16) Lip reduction/enhancement
17) Liposuction
18) Mastopexy
19) Neck tightening
20) Nipple/areola reconstruction, except in connection with a covered augmentation Mammoplasty or mastectomy
21) Penile prosthesis (non-inflatable/inflatable), except in connection with a covered phalloplasty (implantation of the prosthesis shall not be considered a second state phalloplasty) in a female-to-male transition (subsequent replacement or correction of such prosthesis subject to rules and limitations applicable to all prosthetic devices)
22) Removal or redundant skin, except in connection with a covered surgery
23) Replacement of tissue expander with permanent prosthesis testicular insertion, except as a component of a covered placement of a testicular prosthesis
24) Reversal of genital or breast surgery or reversal of surgery to revise secondary sex characteristics
25) Rhinoplasty
26) Second stage phalloplasty
27) Surgical correction of hydraulic abnormality of inflatable (multi-component) prosthesis including pump and/or cylinders and/or reservoir
28) Testicular prostheses, except as a component of a covered placement of a testicular Prosthesis (subsequent replacement or correction of such prosthesis subject to rules and Limitations applicable to all prosthetic devices)
29) Testicular expanders, except as a component of a covered placement of a testicular prosthesis
30) Voice modification surgery
31) Voice therapy/voice lessons

Mental Health Provider Certification for Gender Transition Treatment or Surgery (Optional Template)

Patient Name:
MA #:

I certify that:

☐ The patient is at least 18 years of age and has the capacity to make fully informed decisions and consent to treatment; The patient must provide evidence of two independent psychological assessments; at least one of the professionals must have a doctoral degree (Ph.D., M.D., Ed.D., D.Sc., D.S.W., or Psy.D).

The psychological assessment must indicate that the patient:

☐ Has a clear diagnosis of gender dysphoria with presence of symptoms > 2 years:

☐ The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatment;
☐ The gender dysphoria is not a symptom of another mental disorder; and
☐ The gender dysphoria causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

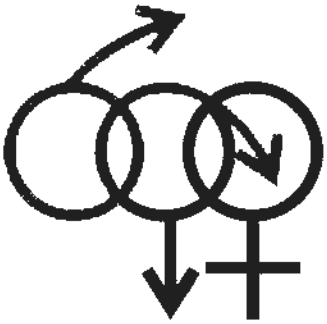
☐ Has lived for 12 months or more as opposite sex (desired gender) prior to the mental health professional recommending surgery; start date of living full time in the new gender-___/___/_____.

☐ Has no contraindicating mental health conditions; if the patient is diagnosed with severe psychiatric disorders and impaired reality testing (e.g., psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), the patient must be reasonably well controlled with psychotropic medications and/or psychotherapy before surgery is contemplated.

☐ Has expressed full understanding of the psychological, social, medical and financial implications of treatment, for now and the future, prior to referring for treatment or surgery.

_____ _____
Signature Date

_____ _____
Signature Date



WPATH WORLD PROFESSIONAL ASSOCIATION for TRANSGENDER HEALTH

21 December 2016

Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A.

The World Professional Association for Transgender Health (WPATH) is an international, interdisciplinary, professional association devoted to the understanding and treatment of individuals with Gender Dysphoria (GD). Founded in 1979, and currently with over 1500 medical, mental health, social scientist, and legal professional members, all of whom are engaged in clinical practice and/or research that affects the lives of transgender and transsexual people, WPATH is the oldest professional association in the world that continuously has been concerned with this clinical specialty.

Gender Dysphoria (GD), often associated with transsexualism, is a condition recognized in the Diagnostic and Statistical Manual of Mental Disorders, (DSM-5, 2013), published by the American Psychiatric Association. Previous nomenclature for gender dysphoria includes transsexualism and gender identity disorder (GID), conditions which are also recognized in the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, published by the World Health Organization, of which the United States is a member. Nomenclature is subject to changes, and new terminology and classifications may be arrived at by various medical organizations or administrative bodies, but these events shall not in themselves change the meaning or intent of this WPATH statement.

The criteria currently listed for GD are descriptive of many people who experience dissonance between their sex as assigned at birth and their gender identity. Gender identity is common to all human beings, is developed in early childhood, and is thought to be firmly established in most people—transgender or not—by age 4,[1] though for some transgender individuals, gender identity may remain somewhat fluid for many years,[2] while for others, conditions specific to individual lives may constrain a person from acknowledging or even recognizing any gender dysphoria they may experience until they

[1] American Academy of Pediatrics, 1999.

[2] Fraser L and De Cuypere G, 2016.

are well into adulthood. The various The DSM-5 descriptive criteria for gender dysphoria were developed to aid in diagnosis and treatment to alleviate the clinically significant distress and impairment that is frequently, though not universally, associated with transsexual and transgender conditions.

The WPATH Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People (SOC) were first issued in 1979, and articulate the "professional consensus about the psychiatric, psychological, medical and surgical management of GD." Periodically revised to reflect evolution in evidence-based clinical practice and scientific research, the Standards also unequivocally reflect this Association's conclusion that treatment is medically necessary. The most recent version of the SOC (Version 7) was published in 2012.[3] WPATH recommends that medical and mental health providers and administrators check www.wpath.org regularly to ensure they are working with the most up-to-date revision of the SOC.

MEDICAL NECESSITY is a term common to health care coverage and insurance policies in the United States. A common definition of medical necessity as used by insurers is:

> "[H]ealth care services that a Physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury, or disease; and (c) not primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.
>
> "Generally accepted standards of medical practice means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors."[4]

The current Board of Directors of the WPATH herewith expresses its considered opinion based on clinical and peer reviewed evidence that gender affirming/confirming treatments and surgical procedures, properly indicated and performed as provided by the Standards of Care, have proven to be beneficial and effective in the treatment of individuals with transsexualism or gender dysphoria. Gender affirming/confirming surgery, also known as sex reassignment surgery, plays an undisputed role in contributing toward favorable outcomes. Treatment includes legal name and sex or gender change on identity

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[3] Coleman E, Bockting W, Botzer M, et al. 2012.

[4] Definition from Blue Cross Blue Shield Settlement (Section 7.16(a)) available at www.hmosettlements.com

documents, as well as medically necessary hormone treatment, counseling, psychotherapy, and other medical procedures required to effectively treat an individual's gender dysphoria. Neither genital appearance nor reconstruction is required for social gender recognition, and so no surgery should be a prerequisite for identity document or record changes; changes to documentation so that identity documents reflect the individual's current lived expression and experience are crucial aids to social functioning, and can be a necessary component of the social transition and/or pre-surgical process. Delay of document changes may have a deleterious impact on a patient's social integration and personal safety.

In addition to hormonal balancing, medically necessary gender affirming/confirming surgical procedures are described in section XI of the SOC. These procedures include complete hysterectomy, bilateral mastectomy, chest reconstruction or augmentation as appropriate to each patient, including nipple resizing or placement of breast prostheses, as necessary; genital reconstruction by various techniques which must be appropriate to each patient, including, for example, skin flap hair removal, scrotoplasty, and penile and testicular prostheses, as necessary; facial hair removal, certain facial plastic reconstruction, voice therapy and/or surgery, and gender affirming counseling or psychotherapeutic treatment, as appropriate to the patient.

> "Non-genital surgical procedures are routinely performed… notably, subcutaneous mastectomy in female-to-male transsexuals, and facial feminization surgery, and/or breast augmentation in male-to-female transsexuals. These surgical interventions are often of greater practical significance in the patient's daily life than reconstruction of the genitals."[5]

It is important to understand that every patient will not have a medical need for identical procedures. Clinically appropriate treatments must be determined on an individualized and contextual basis, in consultation with the patient's medical providers.

The medical procedures attendant to gender affirming/confirming surgeries are not "cosmetic" or "elective" or "for the mere convenience of the patient." These reconstructive procedures are not optional in any meaningful sense, but are understood to be medically necessary for the treatment of the diagnosed condition.[6] In some cases, such surgery is the **only** effective treatment for the condition, and for some people genital surgery is essential and life-saving.

These medical procedures and treatment protocols are not experimental: Decades of both clinical experience and medical research show they are essential to achieving well-being for the transsexual patient. For example, a recent study of female-to-male transsexuals

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[5] Monstrey S, De Cuypere G, Ettner R (eds). (2007).

[6] Victoria L. Davidson v. Aetna Insurance. (1979). Judicial finding that "…the treatment and surgery…is of a medical nature and is feasible and required for the health and well-being of the patient."

found significantly improved quality of life following cross-gender hormonal therapy.[7] Moreover, those who had also undergone chest reconstruction had significantly higher scores for general health, social functioning, as well as mental health.[8]

> "[Hormone therapy and surgical] SRS [sex reassignment surgery] is an effective treatment for transsexualism and the only treatment that has been evaluated empirically with large clinical case series."[9]

Available routinely in the United States and in many other countries, these treatments are cost effective rather than cost prohibitive. In the United States, numerous large employers (e.g., City and County of San Francisco, University of California, Emory University, University of Michigan, IBM, Johnson & Johnson, Bank of America, Apple, and hundreds more[10]) have negotiated contracts with their insurance carriers to enable medically necessary treatment for transsexualism and/or GD to be provided to covered individuals. As more carriers realize the validity and effectiveness of treatment (Aetna, Cigna, United Healthcare, and many others now have medical guidelines for transgender care), coverage is being offered, often at very low or no additional premium cost.[11] More than 15 states currently have regulations in place prohibiting insurance carriers from offering policies that contain exclusions restricting transgender people from accessing needed healthcare.[12] Further, in a decision rendered 30 May 2014, the US Department of Health and Human Services Departmental Appeals Board found that "transsexual surgery" should not be considered experimental or dangerous as it has been proven to be an effective treatment for gender dysphoria when properly diagnosed and administered, lifting a longstanding Medicare program ban on this treatment.[13] More recently, in June, 2016, the Department of Defense lifted its ban on transgender military service, and will offer medically necessary hormone and surgical therapies for transgender active duty and reserve servicemen and women.[14]

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[7] Keo-Meier C L, et al. (2014).

[8] Newfield E, et al. (2006).

[9] Gijs L & Brewaeys A. (2007).

[10] See the latest Corporate Equality Index, maintained by the Human Rights Campaign Workplace Project at www.hrc.org for the list of companies that have scored 100% in current and past years (since 2002).

[11] Herman JL. (2013).

[12] See http://www.transequality.org/blog/pennsylvania-makes-17-states-dc-banning-trans-health-exclusions-hawaii-likely-next-0 for further information.

[13] www.hhs.gov/dab/decisions/dabdecisions/dab2576.pdf; last accessed 11-03-2016.

[14] Department of Defense Instruction (DoDI) 1300.28, "In-Service Transition for Transgender Service Members," June 30, 2016, and Directive-Type Memorandum (DTM) 16-005, "Military Service of Transgender Service Members," June 30, 2016.

> "Professionals who provide services to patients with gender conditions understand the necessity of SRS, and concur that it is reconstructive, and as such should be reimbursed, as would any other medically necessary treatment."[15]

Professional associations that have issued statements in support of the WPATH Standards of Care include the American Medical Association, the Endocrine Society, the American Psychiatric Association, the American Psychological Association, the American Academy of Family Physicians, the National Commission of Correctional Health Care, the American Public Health Association, the National Association of Social Workers, the American College of Obstetrics and Gynecology, the American Society of Plastic Surgeons, and the World Health Organization.

The WPATH Board of Directors urges health insurance carriers and healthcare providers in the United States to eliminate transgender or transsexual exclusions from their policy documents and medical guidelines, and to provide coverage for transgender patients; also to include in their policy documents and medical guidelines the medically prescribed sex reassignment or gender affirming/confirming services necessary for subscribers' treatment and well-being; and to ensure that ongoing healthcare, both routine and specialized, is readily accessible and affordable to all their subscribers on an equal basis.

[15] Monstrey S, De Cuypere G, Ettner R (eds). (2007).

This position statement constitutes the professional and clinical opinions of the signers below, comprising all members of the WPATH Board of Directors and Executive Officers as of this date, 21 December 2016.

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August 23, 2022

VIA ELECTRONIC MAIL

Centralized Case Management Operations
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Washington, D.C. 20201
OCRComplaint@hhs.gov

Re: (b)(6) v. Florida Department of Management Services and CVS Caremark

To Whom it May Concern,

The (b)(6) family submits this complaint to the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (the Department), the entity which is responsible for enforcing Section 1557 of the Affordable Care Act and which has vowed to protect the civil rights of individuals who seek to access healthcare services free from

discrimination. As set forth below, the Florida Department of Management Services (DMS) and CVS Caremark have violated Section 1557 of the Affordable Care Act by discriminating against (b)(6) and his transgender child, A.B., on the basis of sex.

Introduction

On May 10, 2021, the Department announced that the Office of Civil Rights would interpret and enforce Section 1557 and Title IX's prohibitions on discrimination based on sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs or activities. *(Notification of Interpretation and Enforcement of the Affordable Care Act and Title IX of the Education Amendments of 1972,* Effective 05/20/2021, Published 05/25/2021, available at: https://www.federalregister.gov/documents/2021/05/25/2021-10477/notification-of-interpretation-and-enforcement-of-section-1557-of-the-affordable-care-act-and-title.) This brought the Department's interpretation and enforcement of Section 1557 into alignment with the U.S. Supreme Court's decision in *Bostock v. Clayton County, GA*, 140 S. Ct. 1731 (2020) and subsequent court decisions making clear that discrimination on the basis of "sex" includes discrimination on the basis of sexual orientation or gender identity.

An important component of the ACA is the anti-discrimination mandate in section 1557. *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs.*, 485 F. Sup. 3d 1, 11 (D.D.C. 2020). This section provides that "[e]xcept as otherwise provided... an individual shall not, on the ground prohibited under title VI of the Civil Rights Act...[and] title IX...be excluded from participation in, be denied the benefits of, or be subjected to

discrimination under, any health program or activity, any part of which is receiving Federal financial assistance…". 42 U.S.C. § 18116. Because the ACA explicitly incorporates Title IX, and courts look to Title VII to guide the evaluation of claims under Title IX, the test announced in *Bostock* is the appropriate test to determine whether a policy discriminates in violation of the ACA. To prevail on a section 1557 claim, a plaintiff must show that: (1) the defendant is a health program or activity that receives federal funds, and (2) the plaintiff was subjected to discrimination in healthcare services on the basis of sex. As illustrated below, (b)(6) has met both prongs of this test.

By enforcing a discriminatory exclusion for coverage of medically necessary treatment of gender dysphoria, DMS and CVS Caremark have discriminated on the basis of sex in a covered health program or activity. DMS and CVS are both "covered health programs or activities" subject to the nondiscrimination provisions of Section 1557 of the Affordable Care Act. 42 U.S.C. 18116(a). DMS is the executive branch agency responsible for administering the State Group Insurance Program. §§20.22, 110.123(5), Fla. Stat. (2020). To implement the insurance program, DMS determines the benefits to be provided and the contributions to be required for the state group insurance program. §110.123(5)(a). DMS selects and contracts with Third Party Administrators to administer the State Plan, and CVS is the health plan administrator or all pharmacy benefits provided to state employees.

Statement of Facts

(b)(6) is the parent of a transgender child, (b)(6) who is a minor and has been clinically diagnosed with gender dysphoria. Gender dysphoria, which is a clinical condition that is marked by distress due to an incongruence between a patient's gender identity

and sex assigned at birth, is a formal diagnosis under the American Psychiatric Association's Diagnostic and Statistical Manual (DSM-5). If untreated or inadequately treated, gender dysphoria can cause depression, anxiety, self-harm, and suicidality. The widely accepted view of the professional medical community is that gender-affirming care is the appropriate treatment for gender dysphoria, including medical interventions such as puberty blockers for some adolescents with gender dysphoria.[1] (*See* Exhibit 1, Brief of *Amici Curiae* American Academy of Pediatrics (and 21 other Major Medical Associations) in Support of Plaintiffs' Motion for Temporary Restraining Order and Preliminary Injunction (Doc. 91-1), in *Eknes-Tucker v. Ivey,* Case No. Case 2:22-cv-00184 (M.D. Ala. May 13, 2022)). The treatment of gender dysphoria has been developed and is set out in the following established, evidence-based clinical guidelines: (a) the Endocrine Society's "Clinical Practice Guideline for Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons;" and (b) the World Professional Association for Transgender Health (WPATH) "Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People."[2] These Guidelines provide that youth with gender dysphoria should be evaluated, diagnosed, and treated by a qualified mental health professional and that all gender-affirming care should be tailored to the patient's individual needs.

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[1] Endocrine Soc'y, *Transgender Health: An Endocrine Society Position Statement* (2020) (hereinafter, "Endocrine Soc'y Position Statement"), https://www.endocrine.org/advocacy/ position-statements/transgender-health; see also *Healthcare Amici Br.* (Doc. 91-1), *Eknes-Tucker v. Ivey,* Case 2:22-cv-00184 (M.D. Ala. May 13, 2022).

[2] Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons*, 102(11) J. Clinical Endocrinology & Metabolism 3869 (Nov. 2017) (hereinafter, "Endocrine Society Guidelines"), https://academic.oup.com/jcem/article/102/11/3869/4157558; WPATH, *Standards of Care* (7th Version), https://www.wpath.org/media/cms/ Documents/SOC%20v7/SOC%20V7_English.pdf (hereinafter, "WPATH Guidelines").

Because of a blanket exclusion for gender-affirming care in the health insurance plan at issue, (b)(6) child has been denied access to medically-necessary care that has been recommended and prescribed by (b)(6) treating physicians.

(b)(6) is an employee of the state of Florida. He works for the Division of Retirement and, like all state of Florida employees, receives health insurance through his employer as part of his compensation. The only health insurance plan options available to state employees, including (b)(6) contain a blanket exclusion prohibiting coverage of gender-affirming care. The exclusions prohibit coverage of this care regardless of whether it is deemed medically necessary by the individuals' treating physician(s). The HMO Plans available to state employees, including (b)(6) contain exclusions for "gender reassignment or modification services and supplies," and "sexual deviations, disorders or psychosexual dysfunctions services and supplies." The PPO Plan available to state employees, including (b)(6) contains an exclusion for "sexual reassignment, or modification services and supplies, including, but not limited to, any healthcare service related to such treatment, such as services necessary to treat sexual deviations and disorders, psychosexual dysfunction or services or supplies provided in connection with intersex surgery." The pharmacy benefits for state employees are administered through the Third Party Administrator, CVS Caremark. (b)(6) child, (b)(6), is a dependent on his health insurance plan, and as such (b)(6) medical needs are subjected to the exclusions for gender-affirming care contained in the state plans. If employees of the State of Florida need medical care for any reason *other* than treatment of gender dysphoria, the treatment will be covered under the State Plans as long as it is medically necessary. However, for transgender state employees, or employees with

transgender dependents, like [redacted] the very same care is excluded solely because the person seeking the care is transgender.

After years of providing mental health and medical care for [redacted] a licensed clinical psychologist and a pediatric endocrinologist recommended that [redacted] begin Lupron Depot. (*See* Exhibit 2, Letter from Dr. Kristin Dayton, MD; Exhibit 3, Letter from Dr. Evans, PsyD). In accordance with the guidelines referenced above, both the mental health provider and physician deemed [redacted] met the required criteria for the recommended gonadotropin-releasing hormone (GnRH) analogues, or "puberty blockers." *Id.* Ex. 2 and Ex. 3. Thus, the treating physician sought authorization of Lupron Depot-Ped injections, a GnRH agonist, to suppress pubertal development and the progression of endogenous estrogen exposure. The purpose of puberty blockers is to delay pubertal development until adolescents are old enough and have had sufficient time to make more informed decisions about whether to pursue further treatments. Puberty blockers have well-known efficacy and side-effect profiles, their effects are reversible, and they have been used by pediatric endocrinologists for decades for the treatment of precocious puberty.[3]

[redacted] treating physicians requested authorization of puberty blockers, and on November 3, 2021, [redacted] received a denial letter from CVS Caremark, the administrator of the prescription drug plan for all state of Florida employees. On December 3, 2021, [redacted] submitted a Level I Appeal of the denial of medically-necessary care. On December 18, 2021, [redacted] received a letter from CVS Caremark

[3] WPATH Guidelines at 18; Simona Martin et al., *Criminalization of Gender-Affirming Care—Interfering with Essential Treatment for Transgender Children and Adolescents*, 385 New Eng. J. Med. 579, Note 29 at 2 (2021), https://www.nejm.org/doi/full/10.1056/NEJMp2106314.

denying the Level 1 Appeal. (Exhibit 4). On January 26, 2022, (b)(6) submitted a Level II Appeal to the Florida Department of Management Services ("DMS"), which is the state agency responsible for procuring the health insurance plans and administering the state group insurance program. § 110.123(5), Fla. Stat. (2021). On February 4, 2022, (b)(6) (b)(6) received letter from DMS requesting additional documentation. After a clarifying phone call, DMS realized that they did in fact have the information necessary to make a determination. On February 24, 2022, (b)(6) received a letter from DMS denying the Level II Appeal. (Exhibit 5). In the Level II Appeal Denial, DMS cited to the discriminatory exclusion as the basis for the denial of (b)(6) medically necessary care. (Exhibit 5, at p. 2, "The following services and supplies are excluded from coverage under this Plan…: Gender reassignment or modification services and supplies"). As further support of the denial of the medically necessary prescription, the Level II Appeal Denial stated that it was not included in the CVS Caremark Specialty Guideline Management for Rx Drug Lupron Depot (Leuprolide acetate), and thus was considered "experimental/investigational and not medically necessary." The prescription would be covered under the CVS Caremark plan if the diagnosis was central precocious puberty rather than gender dysphoria. (Exhibit 5, at p. 2, "FDA-Approved Indication: Lupron Depot-PED is indicated for the treatment of children with central precocious puberty (CPP). All other indications are considered experimental/investigational and not medically necessary.")

(b)(6) appeal contained all of the required documentary evidence, including: (1) a copy of the initial denial notice, dated 11/03/2021; (2) a copy of (b)(6) Level I Appeal request to CVS Caremark; (3) a copy of the CVS Caremark Level I Appeal denial,

dated 12/18/2021; (4) a Level II Appeal to the Division of State Group Insurance (a subsection of DMS) appealing the Level I Appeal denial exactly as explained in the Level I denial letter; (5) a letter from (b)(6) treating physician and endocrinologist, Dr. Kristin Dayton, attesting to the medical necessity of the care being denied to (b)(6) (6) a letter from (b)(6) treating psychologist, Dr. Jennifer Evans, attesting to the medical necessity of the care being denied to (b)(6); and (7) a letter from (b)(6) treating psychiatrist, Dr. Michael Shapiro, attesting to the medical necessity of the care being denied to (b)(6)

The denials of coverage for (b)(6) were automatic, with no individualized inquiry into the medical necessity of the requested prescription; coverage was denied solely based on the discriminatory Exclusions for gender-affirming care with no medical necessity analysis or criteria applied. To obtain Depot Lupron outside their current insurance, the (b)(6) would need to either pay thousands in out-of-pocket costs.

The denial of coverage for this medically necessary care for (b)(6) contravenes the medical recommendations of the major American medical associations. *See* Ex. 1 *(Healthcare Amici Br. In Eknes-Tucker v. Ivey* (Doc. 91-1)). Amici curiae include, among others, the American Academy of Pediatrics ("AAP"), the Endocrine Society, the American Medical Association ("AMA"), the American Pediatric Society ("APS"), and the American Psychiatric Association "APA"). *Id.* at 11. Every major medical association, including those that submitted the amicus brief in *Eknes-Tucker v. Ivey*, have made clear that "[d]enying such evidence-based medical care [treatments for gender dysphoria] to adolescents who meet the requisite medical criteria puts them at risk of significant harm to their mental health." *Id.* at 12. The results of myriad studies indicate that adolescents suffering from gender dysphoria who receive medical interventions as part of their gender-

affirming care, interventions which include the puberty blocking medication that (b)(6) is being denied access to, experience improvements in their overall well-being. *Id.* at 24. Specifically, eight studies have been published that investigated the use of the puberty blocking medication that (b)(6) needs on adolescents suffering from gender dysphoria, and six studies have been published that investigated the use of hormone therapy to treat adolescents suffering from gender dysphoria. *Id.* at 24-25. These studies find positive mental health outcomes for those adolescents who received puberty blockers or hormone therapy, including "statistically significant reductions in anxiety, depression, and suicidal ideation." *Id.* at 25. One study from 2020 found that among transgender adults, those who did have access to puberty blocking hormone treatment while adolescents had lower odds of lifetime suicidal ideation than those who did not have access to this treatment (even after adjusting for demographic variables and level of family support). *Id.* The U.S. District Court for the Middle District of Alabama relied on binding 11th Circuit precedent and the medical expertise and authoritative evidence-based standards referenced above in finding in favor of the Plaintiffs on their Motion for Preliminary Injunction challenging an Alabama provision restricting transgender minors from utilizing puberty blockers and hormone therapies. *See Eknes-Tucker,* at 14-24.

Lack of access to gender-affirming care may directly contribute to poor mental health: individuals with gender dysphoria who have undergone no gender confirmation treatment are twice as likely to experience moderate to severe depression and four times more likely to experience anxiety than their surgically-affirmed peers.[4] Transgender youth

[4] Ashli Owen-Smith, et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals*, 15 J Sexual Med 4, 591-600 (Apr. 2018)

face rates of depression that are 5-7 times higher and rates of suicidality that are 50 times higher than that of the cisgender population.[5] Social gender transition and family support is linked to reduced rates of depression and suicidality in these youth.[6] Puberty blocking medications are not started prior to the onset of puberty, and have been linked to improvement in rates of depression and suicidality.[7]

DMS and CVS are Covered Entities Subject to Section 1557 of the ACA

DMS and CVS are both "covered health programs or activities" subject to the nondiscrimination provisions of Section 1557 of the Affordable Care Act. 42 U.S.C. 18116(a). DMS is the executive branch agency responsible for administering the State Group Insurance Program. §§20.22, 110.123(5), Fla. Stat. (2020). To implement the insurance program, DMS determines the benefits to be provided and the contributions to be required for the state group insurance program. §110.123(5)(a). DMS selects and contracts with Third Party Administrators to administer the State Plan, and CVS is the health plan administrator or all pharmacy benefits provided to state employees. (Exhibit 6, "CVS Nondiscrimination and Accessibility Notice (ACA § 1557)").

In the case *Claire v. Dep't of Mgmt. Servs.,* Case No. 4:20-cv-00020-MW-MAF (N.D. Fla., 2020) (J. Walker), which challenged the State Plan Exclusions as

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[5] Becerra-Culqui TA, Liu Y, Nash R, et al. Mental Health of Transgender and Gender Nonconforming Youth Compared With Their Peers. Pediatrics. 2018 May;141(5):e20173845. doi: 10.1542/peds.2017-3845.

[6] Olson KR, Durwood L, DeMeules M, McLaughlin KA. Mental Health of Transgender Children Who Are Supported in Their Identities. Pediatrics. 2016 Mar;137(3):e20153223. doi: 10.1542/peds.2015-3223. Erratum in: Pediatrics. 2018 Aug;142(2): PMID: 26921285; *see also* Bauer GR, Scheim AI, Pyne J, Travers R, Hammond R. Intervenable factors associated with suicide risk in transgender persons: a respondent driven sampling study in Ontario, Canada. BMC Public Health. 2015 Jun 2;15:525. doi: 10.1186/s12889-015-1867-2.

[7] Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. Pediatrics. 2020 Feb;145(2):e20191725. doi: 10.1542/peds.2019-1725. Erratum in: Pediatrics. 2021 Apr;147(4): PMID: 31974216.

discrimination on the basis of sex under Title VII and the Equal Protection Clause, discovery led to clear evidence that CVS Caremark was aware that the exclusions for gender-affirming care, including the exact care denied to (b)(6), could violate Section 1557 of the Affordable Care Act. (Exhibit 7). CVS made clear to DMS that Section 1557 prohibits sex discrimination, including the "exclusion or limitation of TGC coverage" (TGC means transgender care). *Id.* at 5. Similarly, DMS was made aware by multiple third-party administrators, including CVS, that maintaining the exclusion for medically necessary gender-affirming healthcare could violate Section 1557 of the ACA. DMS and CVS have continued to enforce the discriminatory exclusion, in violation of the nondiscrimination provisions applying to

DMS and CVS Discriminated on the Basis of Sex

Discrimination on the basis of "sex" has long been understood and interpreted by courts to bar discrimination against LGBTQ+ individuals, but on June 15, 2020, the landmark decision by the U.S. Supreme Court in *Bostock v. Clayton County, Georgia* made this explicit and unequivocal: sex-based discrimination includes discrimination because of sexual orientation or gender identity. 140 S. Ct. 1731, 1753-54 (2020).

On March 26, 2021, the Civil Rights Division of the U.S. Department of Justice issued a memorandum to Federal Agency Civil Rights Directors and General Counsel concluding that the Supreme Court's reasoning in *Bostock* applies to Title IX of the Education Amendments of 1972.[8] As made clear by the Affordable Care Act, Section 1557 prohibits discrimination "on the grounds prohibited under . . . Title IX." 42 U.S.C.

[8] U.S. Department of Justice Memorandum to Federal Agency Civil Rights Directors and General Counsel re: Application of Bostock v. Clayton County to Title IX of the Education Amendments of 1972. https://www.justice.gov/crt/page/file/1383026/download.

18116(a).

On May 25, 2021, the U.S. Department of Health and Human Services (HHS) issued a Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act,[9] which was published in the Federal Registrar. The Office for Civil Rights (OCR) at the U.S. Department of HHS is responsible for enforcing Section 1557 of the Affordable Care Act and regulations issued under Section 1557, protecting the civil rights of individuals who access or seek to access covered health programs or activities. Section 1557 prohibits discrimination on the bases of race, color, national origin, sex, age, and disability in covered health programs or activities. 42 U.S.C. 18116(a). The Notification of Interpretation by OCR stated: "Consistent with the Supreme Court's decision in *Bostock* and Title IX, beginning today, OCR will interpret and enforce Section 1557's prohibition on discrimination on the basis of sex to include: (1) Discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity."

Section 1557 of the ACA provides that "an individual shall not, on the ground prohibited under ... Title IX of the Education Amendments of 1972 ... be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program of activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments)." 42 U.S.C. § 18116(a).

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[9] *Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972,* Department of Health and Human Services, 42 U.S.C. § 18116(a) (effective May 10,2021). https://www.govinfo.gov/content/pkg/FR-2021-05-25/pdf/2021-10477.pdf

Under Title IX, "[n]o person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance." 20 U.S.C. § 1681. Title IX's prohibition on sex discrimination is construed consistently with Title VII's prohibition on sex discrimination. And in *Bostock*, the Supreme Court held that under Title VII, "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex." 140 S. Ct at 1741.

The State Plan exclusions, on their face and as applied to (b)(6) directly contradict existing guidelines by the American Academy of Pediatrics (AAP),[10] the Endocrine Society,[11] the American Academy of Child & Adolescent Psychiatry (AACAP),[12] and the World Professional Association for Transgender Health (WPATH).[13]

The American Medical Association opposes any discrimination based on an individual's sex, sexual orientation or gender identity, opposes the denial of health insurance on the basis of sexual orientation or gender identity, and supports public and private health insurance coverage for treatment of gender dysphoria as recommended by

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[10] Rafferty J; COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH; COMMITTEE ON ADOLESCENCE; SECTION ON LESBIAN, GAY, BISEXUAL, AND TRANSGENDER HEALTH AND WELLNESS. Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents. Pediatrics. 2018 Oct;142(4):e20182162. doi: 10.1542/peds.2018-2162.

[11] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017 Nov 1;102(11):3869-3903. doi: 10.1210/jc.2017-01658. Erratum in: J Clin Endocrinol Metab. 2018 Feb 1;103(2):699. Erratum in: J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-2759.

[12] AACAP Statement Responding to Efforts to ban Evidence-Based Care for Transgender and Gender Diverse Youth. November 8, 2019. https://www.aacap.org/AACAP/Latest_News/AACAP_Statement_Responding_to_Efforts-to_ban_Evidence-Based_Care_for_Transgender_and_Gender_Diverse.aspx.

[13] World Professional Association for Transgender Health. (2012). *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* [7th Version]. https://www.wpath.org/publications/soc.

the patient's physician.[14] GLMA: Health Professionals Advancing LGBTQ Equality recognizes that mental healthcare, hormone replacement therapy, and/or gender-affirming surgery are medically necessary for the treatment of transgender people who meet the criteria for gender dysphoria and advocates that these services not be excluded from any public or private insurance programs.[15] In addition, other medical associations, including the American Academy of Family Physicians, American College of Obstetricians and Gynecologists and American Psychiatric Association have stated that medically necessary transition-related care should be covered by insurance.[16]

In *Fain v. Crouch,* Case No. 3:20-cv-00740 (S.D. WV, August 02, 2022), the Court looked at an exclusion for specific treatments for gender dysphoria in the context of Section 1557 of the Affordable Care Act ("ACA"). While there are factual distinctions between the exclusion in West Virginia and the exclusion in the State Plans here, the analysis of the violation of the ACA is relevant and illustrative. In granting Summary Judgment in favor of Plaintiffs, the Court explained that the exclusion precluding

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[14] Removing Financial Barriers to Care for Transgender Patients H-185.950 (Our AMA supports public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician) (Res. 122 A-08; Modified: Res. 05, A-16); Sexual Orientation and/or Gender Identity as Health Insurance Criteria H-180.980 (The AMA opposes the denial of health insurance on the basis of sexual orientation or gender identity) (Res. 178, A-88; Reaffirmed: Sub. Res. 101, I-97; Reaffirmed: CMS Rep. 9, A-07; Modified: BOT Rep. 11, A-07; Reaffirmed: CMS Rep. 01, A-17); Reducing Suicide Risk Among Lesbian, Gay, Bisexual, Transgender, and Questioning Youth Through Collaboration with Allied Organizations H-60.927 (Our AMA will partner with public and private organizations dedicated to public health and public policy to reduce lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth suicide and improve health among LGBTQ youth) (Res. 402, A-12).

[15] GLMA 127-18-101: Transgender Healthcare (Therapeutic treatment, including hormone therapy, mental health therapy and gender affirming surgeries, are medically necessary for the treatment of gender dysphoria. These gender-affirming medical and surgical treatments should be covered by all public and private insurance plans.) (Approved 2018)

[16] See Am. Acad. Fam. Physicians, Coverage Equity for Drugs, Testing, Procedure, Preventive Services, and Reproductive Technologies (2017); Am. College Obstetricians & Gynecologists, Health Care for Transgender Individuals (2011); Am. Psychiatric Ass'n, Position Statement on Access to Care for Transgender and Gender Variant Individuals (2012).

individuals seeking treatment for gender dysphoria from coverage for their healthcare needs was discrimination on the basis of sex. *Id.* at 23. This is because "a transgender identity is inherent in an individual who duffers from gender dysphoria" and "transgender status, and thus, this exclusion, cannot be understood without a reference to sex." *Id. citing Bostock,* 140 S. Ct. at 1746. The Court also held that "the safety, effectiveness, and medical necessity have been clearly demonstrated by the expert evidence in the recrd and is confirmed by the many major health organizations supporting the safety and effectiveness of this treatment." *Id.* at 24. Thus, the Court held that because Defendants were a "health program or activity" under the ACA and because "Plaintiffs have been subjected to discrimination on the basis of sex," the Defendants in that case clearly violated Section 1557 of the ACA. *Id.*

In *Flack v. Wisconsin Department of Health Services*, 395 F.Supp.3d 1001, 1014-15 (2019), the United States District Court for the W.D. of Wisconsin found on summary judgment that the State Exclusion for gender-affirming care violated Section 1557 of the Affordable Care Act. ("Indeed, the court adopts the same analysis contained in the preliminary injunction opinion and order, finding that the Affordable Care Act's 1557 provides a private fight of action and the Challenged Exclusion discriminates on the basis of sex. [] Accordingly, plaintiff's motion for summary judgment on their 1557 claim is granted.")

In *Brandt v. Rutledge,* 551 F.Supp.3d 882 (E.D. Ark. 2021), where the United States District Court granted plaintiffs' motion for preliminary injunction enjoining another state provision restricting access to gender-affirming care for minors, the United States submitted a Statement of Interest. (Exhibit 8, *Statement of Interest of the United States*,

ECF 19). In the U.S.'s Statement of Interest, they explained:

> "This case implicates important federal interests. The United States is charged with protecting the civil rights of individuals seeking nondiscriminatory access to healthcare in a range of health programs and activities under Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116. The Department of Justice is further charged with the coordination and implementation of federal nondiscrimination laws that protect individuals against discrimination on the basis of sex in a wide range of federally-funded programs and activities, including, but not limited to, the provision of healthcare. Exec. Order No. 12250, § 1-201, 45 Fed. Reg. 72,995 (Nov. 4, 1980)."
>
> *Id.* at 2.

Please contact me if you have any questions or need any further information related to this complaint. My contact information can be found in my signature block below. Thank you for your time and attention to this matter.

Sincerely,

/s/ Simone Chriss

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(b)(6) **Complaint, Exhibit 1**

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

REV. PAUL A. EKNES-TUCKER et al.,

Plaintiffs,

v.

KAY IVEY, et al.

Defendants.

Case No. 2:22-cv-184-LCB-SRW

BRIEF OF *AMICI CURIAE* AMERICAN ACADEMY OF PEDIATRICS AND ADDITIONAL NATIONAL AND STATE MEDICAL AND MENTAL HEALTH ORGANIZATIONS IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Civil Procedure 7.1, the undersigned counsel for the American Academy of Pediatrics ("AAP"), the Alabama Chapter of the American Academy of Pediatrics ("AL-AAP"), the Academic Pediatric Association, the American Academy of Child and Adolescent Psychiatry ("AACAP"), the American Academy of Family Physicians ("AAFP"), the American Academy of Nursing ("AAN"), the American Association of Physicians for Human Rights, Inc. d/b/a GLMA: Health Professionals Advancing LGBTQ Equality ("GLMA"), the American College of Obstetricians and Gynecologists ("ACOG"), the American College of Osteopathic Pediatricians ("ACOP"), the American College of Physicians ("ACP"), the American Medical Association ("AMA"), the American Pediatric Society ("APS"), the American Psychiatric Association ("APA"), the Association of American Medical Colleges ("AAMC"), the Association of Medical School Pediatric Department Chairs ("AMSPDC"), the Endocrine Society, the National Association of Pediatric Nurse Practitioners ("NAPNAP"), the Pediatric Endocrine Society ("PES"), the Society for Adolescent Health and Medicine ("SAHM"), the Society for Pediatric Research ("SPR"), the Society of Pediatric Nurses ("SPN"), the Societies for Pediatric Urology, and the World Professional Association for Transgender Health ("WPATH") certify that:

1. AAP, AL-AAP, the Academic Pediatric Association, AACAP, AAFP, AAN, GLMA, ACOG, ACOP, ACP, AMA, APS, APA, AAMC, AMSPDC, the Endocrine Society, NAPNAP, PES, SAHM, SPR, SPN, SPU, and WPATH, respectively, have no parent corporation.

2. No corporations hold any stock in AAP, AL-AAP, the Academic Pediatric Association, AACAP, AAFP, AAN, GLMA, ACOG, ACOP, ACP, AMA, APS, APA, AAMC, AMSPDC, the Endocrine Society, NAPNAP, PES, SAHM, SPR, SPN, SPU or WPATH.

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STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici curiae are the American Academy of Pediatrics ("AAP"), the Alabama Chapter of the American Academy of Pediatrics ("AL-AAP"), the Academic Pediatric Association, the American Academy of Child and Adolescent Psychiatry ("AACAP"), the American Academy of Family Physicians ("AAFP"), the American Academy of Nursing ("AAN"), the American Association of Physicians for Human Rights, Inc. d/b/a GLMA: Health Professionals Advancing LGBTQ Equality ("GLMA"), the American College of Obstetricians and Gynecologists ("ACOG"), the American College of Osteopathic Pediatricians ("ACOP"), the American College of Physicians ("ACP"), the American Medical Association ("AMA"), the American Pediatric Society ("APS"), the American Psychiatric Association ("APA"), the Association of American Medical Colleges ("AAMC"), the Association of Medical School Pediatric Department Chairs ("AMSPDC"), the Endocrine Society, the National Association of Pediatric Nurse Practitioners ("NAPNAP"), the Pediatric Endocrine Society ("PES"), the Society for Adolescent Health and Medicine ("SAHM"), the Society for Pediatric Research ("SPR"), the Society of Pediatric Nurses ("SPN"), the Societies for Pediatric Urology, and the World Professional Association for Transgender Health ("WPATH").[1]

[1] Plaintiffs and Plaintiff-Intervenor have consented to the filing of this brief; Defendants have not consented to the filing of this brief. *Amici* affirm that no counsel for a party authored this brief in whole or in part and that no person other than *amici* or their counsel made any monetary contributions intended to fund the preparation or submission of this brief.

Amici are professional medical and mental health organizations seeking to ensure that all children and adolescents, including those with gender dysphoria, receive the optimal medical and mental healthcare they need and deserve. *Amici* represent thousands of healthcare providers who have specific expertise with the issues raised in this brief. The Court should consider *amici*'s brief because it provides important expertise and addresses misstatements about the treatment of transgender adolescents.

INTRODUCTION

Alabama Senate Bill 184 ("the Healthcare Ban") would prohibit healthcare providers from providing or even referring patients under the age of 19 for critical, evidence-based treatments for gender dysphoria. Denying such evidence-based medical care to adolescents who meet the requisite medical criteria puts them at risk of significant harm to their mental health. The legislative findings in the Healthcare Ban mischaracterize the well-accepted medical guidelines for treating gender dysphoria in adolescents and the guidelines' supporting evidence. Below, *amici* provide the Court with an accurate description of these well-accepted treatment guidelines and summarize the scientific evidence supporting the medical interventions prohibited by the Healthcare Ban.

Gender dysphoria is a clinical condition that is marked by distress due to an incongruence between the patient's gender identity (i.e., the innate sense of oneself

as being a particular gender) and sex assigned at birth. This incongruence can lead to clinically significant distress and impair functioning in many aspects of the patient's life.[2] If not treated, or treated improperly, gender dysphoria can result in debilitating anxiety, depression, and self-harm, and is associated with higher rates of suicide. As such, the effective treatment of gender dysphoria saves lives.

The widely accepted recommendation of the medical community, including that of the respected professional organizations participating here as *amici*, is that the standard of care for treating gender dysphoria is "gender-affirming care,"[3] which Plaintiffs refer to as "transition."[4] Gender-affirming care is care that supports a child or adolescent as they explore their gender identity—in contrast with efforts to change the individual's gender identity to match their sex assigned at birth, which are known to be ineffective and harmful. For adolescents with persistent gender dysphoria that worsens with the onset of puberty, gender-affirming care may include medical interventions to align their physiology with their gender identity. Empirical evidence indicates that gender-affirming care, including gender-affirming medical interventions, can alleviate clinically significant distress and lead to significant

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[2] *See* Jason Rafferty, *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142(4) *Pediatrics* e20182162, at 2 (tbl. 1), 3 (2018) (hereinafter, "AAP Policy Statement"), https://publications.aap.org/pediatrics/article/142/4/e20182162/37381/Ensuring-Comprehensive-Care-and-Support-for.

[3] *Id.* at 10.

[4] *See, e.g.*, Memorandum in Support of Preliminary Injunction at 12-16 (Dkt. # 8) (April 21, 2022).

improvements in the mental health and overall well-being of adolescents with gender dysphoria.

The Healthcare Ban disregards this medical evidence by threatening providers with a felony conviction simply for treating adolescent patients in accordance with the accepted standard of care. In addition, the Healthcare Ban prevents healthcare providers from utilizing their medical expertise in treating these adolescent patients and profoundly intrudes on the patient-provider relationship by banning referrals for gender-affirming medical treatments. Accordingly, *amici* urge this Court to grant Plaintiffs' motion for a temporary restraining order and preliminary injunction.

ARGUMENT

This brief first provides background on gender identity and gender dysphoria. It then describes the well-accepted medical guidelines for treating gender dysphoria as they apply to adolescents and the evidence that suggests the effectiveness of this care for adolescents with gender dysphoria. Finally, the brief explains how the Healthcare Ban would irreparably harm adolescents with gender dysphoria by denying care to those who need it.

I. Understanding Gender Identity and Gender Dysphoria.

A person's gender identity is a person's deep internal sense of belonging to a

particular gender.[5] Most people have a gender identity that aligns with their sex assigned at birth.[6] However, transgender people have a gender identity that does not align with their sex assigned at birth.[7] In the United States, it is estimated that approximately 1.4 million individuals are transgender.[8] Of these individuals, approximately 10% are teenagers aged 13 to 17.[9] Individuals often start to understand their gender identity during prepubertal childhood and adolescence.

While being transgender is a normal variation of human identity,[10] many transgender people suffer from gender dysphoria, a serious medical condition in which the patient experiences significant distress that can lead to "impairment in peer and/or family relationships, school performance, or other aspects of their life."[11] Gender dysphoria is a formal diagnosis under the American Psychiatric Association's Diagnostic and Statistical Manual (DSM-5).

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[5] AAP Policy Statement at 2 (tbl. 1).

[6] *See* Am. Psychological Ass'n, *Guidelines for psychological practice with transgender and gender nonconforming people*, 70(9) American Psychologist 832, 862 (2015) (hereinafter, "Am. Psychological Ass'n Guidelines"), https://www.apa.org/practice/guidelines/transgender.pdf.

[7] *See id.* at 863.

[8] *See* Jody L. Herman et al., *Ages of Individuals Who Identify as Transgender in the United States*, Williams Inst., at 2 (Jan. 2017), http://williamsinstitute.law.ucla.edu/wp-content/uploads/Age-Trans-Individuals-Jan-2017.pdf.

[9] *See id.* at 3.

[10] James L. Madara, *AMA to states: Stop interfering in healthcare of transgender children*, Am. Med. Ass'n (Apr. 26, 2021), https://www.ama-assn.org/press-center/press-releases/ama-states-stop-interfering-health-care-transgender-children; *see also* Am. Psychological Ass'n, *APA Resolution on Gender Identity Change Efforts*, 4 (2021), https://www.apa.org/about/policy/resolution-gender-identity-change-efforts.pdf.

[11] AAP Policy Statement at 3.

If untreated or inadequately treated, gender dysphoria can cause depression, anxiety, self-harm, and suicidality.[12] Indeed, over 60% of transgender adolescents and young adults reported having engaged in self-harm during the preceding 12 months, and over 75% reported symptoms of generalized anxiety disorder in the preceding two weeks.[13] Even more troubling, more than 50% of this population reported having seriously considered attempting suicide,[14] and more than one in three transgender adolescents reported having attempted suicide in the preceding 12 months.[15]

II. The Widely Accepted Guidelines for Treating Adolescents With Gender Dysphoria Provide for Medical Interventions When Indicated.

The widely accepted view of the professional medical community is that gender-affirming care is the appropriate treatment for gender dysphoria and that, for some adolescents, gender-affirming medical interventions are necessary.[16] This care

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[12] *See* Brayden N. Kameg & Donna G. Nativio, *Gender dysphoria in youth: An overview for primary care providers*. 30(9) J. Am. Assoc. Nurse Pract. 493 (2018), https://pubmed.ncbi.nlm.nih.gov/30095668.

[13] *See* Amit Paley, *The Trevor Project 2020 National Survey*, at 1, https://www.thetrevorproject.org/wp-content/uploads/2020/07/The-Trevor-Project-National-Survey-Results-2020.pdf.

[14] *See id.* at 2.

[15] *See* Michelle M. Johns et al., *Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students–19 States and Large Urban School Districts, 2017*, US Dep't of Health and Human Servs., Centers for Disease Control & Prevention, 68(3) MMWR 67, 70 (2019), https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6803a3-H.pdf.

[16] *See, e.g.*, Endocrine Soc'y, *Transgender Health: An Endocrine Society Position Statement* (2020) (hereinafter, "Endocrine Soc'y Position Statement"), https://www.endocrine.org/advocacy/position-statements/transgender-health.

greatly reduces the negative physical and mental health consequences that result when gender dysphoria is untreated.[17]

A. The Guidelines for Treating Gender Dysphoria Include Thorough Mental Health Assessments and, for Some Adolescents, Medical Interventions.

The treatment protocols for gender dysphoria are laid out in established, evidence-based clinical guidelines: (i) the Endocrine Society Clinical Practice Guideline for Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons, and (ii) the WPATH Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People (together, the "Guidelines").[18]

The Guidelines provide that youth with gender dysphoria should be evaluated, diagnosed, and treated by a qualified mental health professional ("MHP"). Further, the Guidelines provide that each patient who receives gender-affirming care receives only evidence-based, medically necessary, and appropriate interventions that are tailored to the patient's individual needs.

I. A Robust Mental Health Assessment Is Required Before Medical Interventions Are Provided.

According to the Guidelines, gender-affirming care begins with a thorough

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[17] *See id.*

[18] Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons*, 102(11) J. Clinical Endocrinology & Metabolism 3869 (Nov. 2017) (hereinafter, "Endocrine Society Guidelines"), https://academic.oup.com/jcem/article/102/11/3869/4157558; WPATH, *Standards of Care* (7th Version), https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English.pdf (hereinafter, "WPATH Guidelines").

evaluation by a qualified mental health professional, who: (1) is trained in childhood and adolescent developmental psychopathology, (2) is competent in diagnosing and treating the ordinary problems of children and adolescents, and (3) meets the competency requirements for MHPs working with adults.[19] These include: (1) a master's degree or equivalent in a clinical behavioral science field, (2) competence in using the *Diagnostic Statistical Manual of Mental Disorders* and/or the *International Classification of Diseases* for diagnostic purposes, (3) the ability to recognize and diagnose coexisting mental health concerns and distinguish them from gender dysphoria, (4) documented supervised training and competence in psychotherapy or counseling, (5) being knowledgeable about gender identities and expressions and the assessment and treatment of gender dysphoria, and (6) continuing education in the assessment and treatment of gender dysphoria.[20]

When evaluating a patient with gender dysphoria, the MHP must, among other things, assess the patient's "gender identity and gender dysphoria, history and development of gender dysphoric feelings, the impact of stigma attached to gender nonconformity on mental health, and the availability of support from family, friends,

[19] *See* WPATH Guidelines at 13.

[20] *See id.* at 22.

and peers."[21] The MHP also must screen for coexisting mental health concerns, [22] which "need to be optimally managed prior to, or concurrent with, treatment of gender dysphoria."[23] If gender dysphoria is diagnosed, the Guidelines provide that the MHP should discuss treatment for gender dysphoria and any coexisting concerns, including potential risks.[24]

2. The Guidelines Recommend Only Non-Physical Interventions for Prepubertal Children Suffering From Gender Dysphoria.

For prepubertal children suffering from gender dysphoria, the Guidelines provide for mental healthcare and support for the child and their family.[25] The Guidelines do *not* recommend that any physical interventions (such as medications or surgery) be provided to prepubertal children with gender dysphoria.[26]

3. In Certain Circumstances, the Guidelines Provide for the Use of Medical Interventions to Treat Adolescents Suffering From Gender Dysphoria.

For patients whose gender dysphoria continues into adolescence—after the onset of puberty—the Guidelines provide that, in addition to mental healthcare, medical interventions may also be indicated. Before an adolescent may receive any

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[21] *Id.* at 23-24.

[22] *Id.* at 24-25.

[23] *Id.* at 25.

[24] *Id.* at 24.

[25] *See id.* at 16-17; Endocrine Society Guidelines at 3877-78.

[26] *See* WPATH Guidelines at 17-18, Endocrine Society Guidelines at 3871.

medical interventions for gender dysphoria, a qualified MHP must determine that: (1) the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria, (2) the gender dysphoria emerged or worsened after the onset of puberty, (3) any coexisting psychological, medical, or social problems that could interfere with treatment have been addressed, and (4) the adolescent and the parents or guardians have given informed consent.[27] Further, a pediatric endocrinologist or other clinician experienced in pubertal assessment must (5) agree with the indication for treatment, (6) confirm the patient has started puberty, and (7) confirm that there are no medical contraindications.[28]

If all of the above criteria are met, the Guidelines instruct that gonadotropin-releasing hormone (GnRH) analogues, or "puberty blockers," may be offered beginning at the onset of puberty.[29] The purpose of puberty blockers is to delay pubertal development until adolescents are old enough and have had sufficient time to make more informed decisions about whether to pursue further treatments.[30] Puberty blockers also can make pursuing transition later in life easier, because they prevent irreversible changes such as protrusion of the Adam's apple or breast

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[27] WPATH Guidelines at 19.

[28] Endocrine Society Guidelines at 3878 (tbl. 5).

[29] WPATH Guidelines at 18; Simona Martin et al., *Criminalization of Gender-Affirming Care—Interfering with Essential Treatment for Transgender Children and Adolescents*, 385 New Eng. J. Med. 579 (2021), https://www.nejm.org/doi/full/10.1056/NEJMp2106314.

[30] WPATH Guidelines at 19.

growth.[31] Puberty blockers have well-known efficacy and side-effect profiles.[32] In addition, their effects are generally reversible.[33] In fact, puberty blockers have been used by pediatric endocrinologists for more than 30 years for the treatment of precocious puberty.[34] The risks of any serious adverse effects of these treatments are exceedingly rare when provided under clinical supervision.[35]

Later in adolescence—and if the criteria below are met—hormone therapy may be used to initiate puberty consistent with the patient's gender identity.[36] Hormone therapy is only prescribed when a qualified MHP has confirmed the persistence of the patient's gender dysphoria, the patient's mental capacity to assent to the treatment, and that any coexisting problems have been addressed.[37] A pediatric endocrinologist or other clinician experienced in pubertal induction must also agree with the indication, the patient and their parents or guardians must be informed of the potential effects and side effects, and the patient and the patient's

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[31] *See* AAP Policy Statement at 5.

[32] Martin, *supra* note 29 at 2.

[33] *See id.*

[34] *See id.*

[35] *See, e.g.*, Annemieke S. Staphorsius et al., *Puberty suppression and executive functioning: an fMRI-study in adolescents with gender dysphoria*, 6 Psychoneuroendocrinology 190 (2015), https://pubmed.ncbi.nlm.nih.gov/25837854 (no adverse impact on executive functioning); Ken C. Pang, et al., *Long-term Puberty Suppression for a Nonbinary Teenager*, 145(2) Pediatrics e20191606 (2019), https://watermark.silverchair.com/peds_20191606.pdf (exceedingly low risk of delayed bone mineralization from hormone treatment).

[36] Martin, *supra* note 29 at 2.

[37] Endocrine Society Guidelines at 3878 (tbl. 5).

parents or guardians must give their informed consent.[38] Hormone therapy involves using gender-affirming hormones to allow adolescents to develop secondary sex characteristics consistent with their gender identity.[39] Although some of these changes become irreversible after those secondary sex characteristics are fully developed, others are partially reversible if the patient discontinues use of the hormones.[40]

The Guidelines contemplate that the prescription of puberty blockers and/or hormone therapy be coupled with education on the safe use of such medications and close monitoring to mitigate any potential risks.[41] Decisions regarding the appropriate treatment for each patient with gender dysphoria are made in consultation with the patient, their parents or guardians, and the medical and mental healthcare team. There is "no one-size-fits-all approach to this kind of care."[42]

B. The Guidelines for Treating Gender Dysphoria Were Developed Through a Robust and Transparent Process, Employing the Same Scientific Rigor That Underpins Other Medical Guidelines.

The Guidelines are the product of careful and robust deliberation following the same types of processes—and subject to the same types of rigorous

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[38] *See id.*

[39] *See* AAP Policy Statement at 6.

[40] *See id.* at 5-6.

[41] *See* Endocrine Society Guidelines at 3871, 3876.

[42] Martin, *supra* note 29, at 1.

requirements—as other guidelines promulgated by *amici* and other medical organizations.

For example, the Endocrine Society's Guidelines were developed following a 26-step, 26-month drafting, comment, and review process.[43] The Endocrine Society imposes strict evidentiary requirements based on the internationally recognized Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.[44] That GRADE assessment is then reviewed, re-reviewed, and reviewed again by multiple, independent groups of professionals. [45] Further, the Endocrine Society continually reviews its own guidelines and recently determined the 2017 transgender care guidelines continue to reflect the best available evidence.

The WPATH standards are the result of a drafting, comment, and review process that took five years.[46] The draft guidelines went through journal peer-review and were publicly available for discussion and debate, including multiple rounds of feedback from experts in the field as well as from transgender individuals.[47] They

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[43] *See, e.g.*, Endocrine Society Guidelines at 3872-73 (high-level overview of methodology).

[44] *See* Gordon Guyatt et al., *GRADE guidelines: 1. Introduction - GRADE evidence profiles and summary of findings tables*, 64 J. Clinical Epidemiology 383 (2011), https://www.who.int/alliance-hpsr/resources/publications/HSR-synthesis-Guyatt-2011.pdf; Gordon H. Guyatt et al., *GRADE: an emerging consensus on rating quality of evidence and strength of recommendations*, 336 BMJ 924 (2008), https://www.who.int/hiv/topics/treatment/grade_guyatt_2008.pdf.

[45] Endocrine Society, *Methodology*, https://www.endocrine.org/clinical-practice-guidelines/methodology (last visited May 4, 2022).

[46] *See* WPATH Guidelines at 109-10.

[47] *See id.*

are periodically updated to account for new developments in the research and practice, and WPATH is in the process of its eighth revision.[48]

C. Scientific Evidence Indicates the Effectiveness of Treating Gender Dysphoria According to the Guidelines.

The results of multiple studies indicate that adolescents suffering from gender dysphoria who receive medical interventions as part of their gender-affirming care experience improvements in their overall well-being.[49] Eight studies have been published that investigated the use of puberty blockers on adolescents suffering from gender dysphoria,[50] and six studies have been published that investigated the use of hormone therapy to treat adolescents suffering from gender dysphoria.[51] These

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[48] WPATH, *Standards of Care 8: History and Purpose*, https://www.wpath.org/soc8/history.

[49] *See* Martin, *supra* note 29, at 2.

[50] *See, e.g.*, Christal Achille, et al., *Longitudinal impact of gender-affirming endocrine intervention on the mental health and wellbeing of transgender youths: preliminary results*, 8 Int'l J Pediatric Endocrinology 1-5 (2020), https://pubmed.ncbi.nlm.nih.gov/32368216; Polly Carmichael, et al., *Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK*, 16(2) PloS One e0243894 (2021), https://pubmed.ncbi.nlm.nih.gov/33529227; Rosalia Costa, et al., *Psychological support, puberty suppression, and psychosocial functioning in adolescents with gender dysphoria*, 12(11) J. Sexual Med. 2206–2214 (2015), https://pubmed.ncbi.nlm.nih.gov/26556015; Annelou L.C. de Vries, et al., *Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study*, 8(8) J. Sexual Med. 2276-2283 (2011), https://pubmed.ncbi.nlm.nih.gov/20646177; Annelou L.C. de Vries, et al., *Young adult psychological outcome after puberty suppression and gender reassignment*, 134(4) Pediatrics 696-704 (2014), https://pubmed.ncbi.nlm.nih.gov/25201798; Laura E. Kuper, et al., *Body dissatisfaction and mental health outcomes of youth on gender-affirming hormone therapy*, 145(4) Pediatrics e20193006 (2020), https://pubmed.ncbi.nlm.nih.gov/ 32220906; Jack L. Turban, et al., *Pubertal suppression for transgender youth and risk of suicidal ideation*, 145(2) Pediatrics e20191725 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7073269; Anna I.R. van der Miesen, *Psychological functioning in transgender adolescents before and after gender-affirmative care compared with cisgender general population peers*, 66(6) J. Adolescent Health 699-704 (2020).

[51] *See, e.g.*, Christal Achille, et al., *Longitudinal impact of gender-affirming endocrine intervention on the mental health and well-being of transgender youths: preliminary results*, 8 Int'l J. Pediatric Endocrinology 1-5 (2020), https://pubmed.ncbi.nlm.nih.gov/32368216; Luke R. Allen, et al.,

studies find positive mental health outcomes for those adolescents who received puberty blockers or hormone therapy, including statistically significant reductions in anxiety, depression, and suicidal ideation.

For example, a 2020 study analyzed survey data from 89 transgender adults who had access to puberty blockers while adolescents and from more than 3,400 transgender adults who did not.[52] The study found that those who received puberty blocking hormone treatment had lower odds of lifetime suicidal ideation than those who wanted puberty blocking treatment but did not receive it, even after adjusting for demographic variables and level of family support.[53] Approximately *nine in ten* transgender adults who wanted puberty blocking treatment but did not receive it

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Well-being and suicidality among transgender youth after gender-affirming hormones, 7(3) Clinical Prac. Pediatric Psych. 302 (2019), https://psycnet.apa.org/record/2019-52280-009; Diego Lopez de Lara, et al., *Psychosocial assessment in transgender adolescents*, 93(1) Anales de Pediatria 41-48 (English ed. 2020), https://www.researchgate.net/publication/342652073; Annelou L.C. De Vries, et al., *Young adult psychological outcome after puberty suppression and gender reassignment*, 134(4) Pediatrics 696-704 (2014); Rittakerttu Kaltiala, et al., *Adolescent development and psychosocial functioning after starting cross-sex hormones for gender dysphoria*, 74(3) Nordic J. Psychiatry 213 (2020); Laura E. Kuper, et al., *Body dissatisfaction and mental health outcomes of youth on gender-affirming hormone therapy*, 145(4) Pediatrics e20193006(2020), https://pubmed.ncbi.nlm.nih.gov/32220906; Amy E. Green, et al., *Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth*, J. Adolescent Health (2021), https://www.jahonline.org/article/S1054-139X(21)00568-1/fulltext; Jack L. Turban, et al., *Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults*, J. Plos One (2022), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0261039.

[52] *See* Jack L. Turban et al., *Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation*, 145(2) Pediatrics e20191725 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7073269.

[53] *See id.*

reported lifetime suicidal ideation.[54] Additionally, a longitudinal study of nearly 50 transgender adolescents found that suicidality was decreased by a statistically-significant degree after receiving gender-affirming hormone treatment.[55]

As another example, a prospective two-year follow-up study of adolescents with gender dysphoria published in 2011 found that treatment with puberty blockers was associated with decreased depression and improved overall functioning.[56] A six-year follow-up study of 55 individuals from the 2011 study found that subsequent treatment with hormone therapy followed by surgery in adulthood was associated with a statistically significant decrease in depression and anxiety.[57] "Remarkably, this study demonstrated that these transgender adolescents and young adults had a sense of well-being that was equivalent or superior to that seen in age-matched controls from the general population."[58]

As scientists and researchers, *amici* always welcome more research, including on this crucial topic. However, the available data indicate that the gender-affirming

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[54] *See id.*

[55] *See* Luke R. Allen et al., *Well-being and suicidality among transgender youth after gender-affirming hormones*, 7(3) Clinical Prac. Pediatric Psych. 302 (2019), https://psycnet.apa.org/record/2019-52280-009.

[56] *See* Annelou L.C. de Vries et al., *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, 8(8) J. Sexual Medicine 2276 (2011), https://pubmed.ncbi.nlm.nih.gov/20646177.

[57] Annelou L.C. de Vries et al., *Young adult psychological outcome after puberty suppression and gender reassignment*, 134(4) Pediatrics 696 (2014), https://pubmed.ncbi.nlm.nih.gov/25201798.

[58] Stephen M. Rosenthal, *Challenges in the care of transgender and gender-diverse youth: an endocrinologist's view*, 17(10) Nature Rev. Endocrinology 581, 586 (Oct. 2021), https://pubmed.ncbi.nlm.nih.gov/34376826.

treatments prohibited by the Healthcare Ban are effective for the treatment of gender dysphoria. For these reasons, and as at least one court has recognized, the use of the gender-affirming medical interventions specified in the Guidelines is supported by all mainstream pediatric organizations, representing thousands of physicians across multiple disciplines.[59]

D. The Legislative Findings Are Factually Inaccurate and Ignore the Recommendations of the Medical Community.

1. There Is No Accepted Protocol of "Watchful Waiting" for Adolescents With Gender Dysphoria.

The Healthcare Ban's legislative findings endorse a "wait-and-see approach," based on the assumption that "a large majority" of children with signs of gender nonconformity will ultimately "resolve[] to an identity congruent with their sex by late adolescence."[60] This assertion lacks scientific support.

While some prepubertal children who experience gender dysphoria may go on to identify with their sex assigned at birth by the time they reach puberty, there are *no* stndies to support the proposition that *adolescents* with gender dysphoria will come to identify with their sex assigned at birth, whether they receive treatment or

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[59] *See, e.g.*, *Brandt v. Rutledge*, 551 F. Supp. 3d 882, 890 (E.D. Ark. 2021) ("The consensus recommendation of medical organizations is that the only effective treatment for individuals at risk of or suffering from gender dysphoria is to provide gender-affirming care.")

[60] Ala. Vulnerable Child Compassion and Protection Act, S.B. 184, No. 2022-289, § 2(5) (Ala. 2022).

not.[61] On the contrary, "[l]ongitudinal studies have indicated that the emergence or worsening of gender dysphoria with pubertal onset is associated with a very high likelihood of being a transgender adult."[62] In this regard, while some practitioners use "watchful waiting"—i.e., waiting until puberty begins before considering social transition[63]—with prepubertal children, it is not recommended for *adolescents.* Using "watchful waiting" with gender-dysphoric adolescents can cause immense harm by denying them treatment that could alleviate their distress and forcing them to experience full endogenous puberty, resulting in physical changes that may be reversed—if at all—only through surgery.

2. Claims That the Medical Community Is "Aggressively Pnshing" for Medical Interventions Are False.

The Healthcare Ban's legislative findings assert that "[s]ome in the medical community are aggressively pushing for interventions on minors."[64] This is false—adolescents are only provided medical interventions if they meet the rigorous criteria under the Guidelines. While it is true that the number of referrals to gender clinics has increased in recent years, this increase has coincided with a decrease in the

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[61] *See, e.g.*, Stewart L. Adelson, *Practice parameter on gay, lesbian, or bisexual sexual orientation, gender non-conformity, and gender discordance in children and adolescents*, 51 J. Am. Acad. of Child & Adolescent Psychiatry 957, 964 (2020), https://pubmed.ncbi.nlm.nih.gov/22917211 ("In contrast, when gender variance with the desire to be the other sex is present in adolescence, this desire usually does persist through adulthood").

[62] Rosenthal, *supra* note 58 at 585.

[63] AAP Policy Statement at 4.

[64] S.B. 184 § 2(6).

stigma against transgender people, an increase in public awareness of the existence of gender dysphoria and the availability of gender-affirming care, and improvements in insurance coverage, all of which likely led more people with gender identity issues to seek help. In any event, not all patients who seek care at gender clinics receive medical interventions. In fact, a 2018 study showed that the percentage of patients who presented to a gender clinic for evaluation and received medical interventions has actually *decreased* over time.[65]

III. The Healthcare Ban Would Irreparably Harm Many Adolescents With Gender Dysphoria By Denying Them the Treatment They Need.

The Healthcare Ban denies adolescents with gender dysphoria access to medical interventions that alleviate suffering, are grounded in science, and are endorsed by the medical community. The medical treatments prohibited by the Healthcare Ban can be a crucial part of treatment for adolescents with gender dysphoria and necessary to preserve their health. As discussed above, research shows that adolescents with gender dysphoria who receive puberty blockers and/or hormone therapy experience less depression, anxiety, and suicidal ideation. Several studies have found that hormone therapy is associated with reductions in the rate of

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[65] *See* Chantal M. Wiepjes et al., *The Amsterdam cohort of gender dysphoria study (1972-2015): trends in prevalence, treatment, and regrets*. 15(4) J. Sexual Med. 582, 582 (Feb. 2018), https://pubmed.ncbi.nlm.nih.gov/29463477.

suicide attempts and significant improvement in quality of life.[66] In light of this evidence supporting the connection between lack of access to gender-affirming care and lifetime suicide risk, banning such care can put patients' lives at risk.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion for a temporary restraining order and preliminary injunction should be granted.

[66] *See* M. Hassan Murad et al., *Hormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes*, 72(2) Clinical Endocrinology 214 (Feb. 2010), https://onlinelibrary.wiley.com/doi/10.1111/j.1365-2265.2009.03625.x; *see also* Turban et al., *Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation*, *supra* note 50.

Dated: May 4, 2022

Respectfully submitted,

/s/ Barry A. Ragsdale

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CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2022, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to counsel of record.

/s/ Barry A. Ragsdale
Of Counsel

(b)(6) **Complaint, Exhibit 2**

(b)(6)

ID#:
Reference #:

To Whom It May Concern:

(b)(6) has been a patient at UF Pediatric Endocrinology since (b)(6) They are being treated for the diagnosis of "endocrine disorder in a transgender person" (ICD-10 E34.9). (b)(6) a chromosomal female, identifies as a non-binary, and is living as a non-binary person at home and at school. For this point forward, (b)(6) will be referred to as (b)(6) and (b)(6)

We are seeking authorization for Lupron Depot-Ped injections, a gonadotropin releasing hormone (GnRH) agonist, to suppress pubertal development and the progression of endogenous estrogen exposure.

According to the (2017) guidelines published by The Endocrine Society, entitled "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline" (J Clin Endocrinol Metab Vol 102, Issue 11, 1 Nov 2017:3869-3903), GnRH analogues are used to achieve suppression of pubertal hormones in children and adolescents with Gender Dysphoria (GD). According recommendation 1.1-2, the diagnosis of GD should be made by a mental health professional (MHP), and (b)(6) meets this eligibility criteria. (b)(6) has been evaluated by a psychologist, Dr. Jennifer Evans, who has provided documentation of their diagnosis of GD and readiness for transitioning to the desired gender beginning with puberty suppression.

According to recommendation 2.1, "adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment, and are requesting treatment should initially undergo treatment to suppress pubertal development." In addition, recommendation 2.3 states that "we recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones." As previously stated, Alex meets the eligibility and readiness requirements as evidenced by the diagnosis of GD and the letter of readiness.

In addition, recommendation 2.2 states that "clinicians [are suggested to] begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty" Again (b)(6) meets this criteria since they have Tanner 3 development as documented by physical exam by a UF Pediatric Endocrinologist. Furthermore, recommendations 2.1-2.2 state that "for many adolescents with GD/gender incongruence, the pubertal physical changes are unbearable" and that suffering from GD "the experience of full endogenous puberty is an undesirable condition for the GD/gender-incongruent individual and may seriously interfere with healthy psychological functioning and well-being. Treating GD/gender-incongruent adolescents entering puberty with GnRH analogs has been shown to improve psychological functioning in several domains."

Health care service plans have an obligation under the Insurance Gender Nondiscrimination Act (IGNA), codified in Health and Safety Code section 1365.5. IGNA prohibits health plans from discriminating against individuals based on the individual's gender, including gender identity or gender expression. This prohibition includes the

availability of health coverage and the provision of benefits. In fact, IGNA prohibits health plans from limiting benefits because of an individual's sex. IGNA defines "sex" to include gender, gender identity, and gender expression. IGNA requires health plans to provide transgender individuals with the same contracts and coverage benefits that are available to non-transgender individuals.

Exclusions or limitations that are non-compliant with IGNA may result in transgender individuals being denied medically necessary care. Hormone therapy with GnRH analogs and then cross-sex hormones is medically necessary for individuals who meet the criteria set by the Endocrine Society for children and adolescents with "Gender Dysphoria," previously "Gender Identity Disorder."

In addition, the Office of Civil Rights (OCR) enforces Section 1557 of the Affordable Care Act (42 U.S.C. 18116), which provides that an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to discrimination on the grounds prohibited under Title VI of the Civil Rights Act of 1964,42 U.S.C. 2000d et seq. (race, color, national origin), Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 et seq. (sex), the Age Discrimination Act of 1975, 42 U.S.C. 6101 etseq. (age), or Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794 (disability), under any health program or activity, any part of which is receiving Federal financial assistance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the Affordable Care Act or its amendments. OCR has enforcement authority with respect to health programs and activities that receive Federal financial assistance from HHS or are administered by HHS or any entity established under Title I of the Affordable Care Act or its amendments.

Section 1557's sex discrimination prohibition extends to claims of discrimination based on gender identity or failure to conform to stereotypical notions of masculinity or femininity. Therefore, failure to provide medically necessary services for gender transition would be discriminatory and in violation of Section 1557.

I request that you approve Lupron Depot-Ped for (b)(6) thereby allowing us to continue to treat them according to current practice guidelines so that they will develop in a normal and healthy manner.

Sincerely,

Kristin Dayton

Kristin A. Dayton, MD
Clinical Assistant Professor
UF Health Pediatric Endocrinology

(b)(6) **Complaint, Exhibit 3**

Letter by Evans, Jennifer L., PsyD on 1/13/2022

Last edited by Knott, Christopher today at 11:13 AM

UF Health Pediatric Psychology - Medical Plaza
352-265-7337

UFHealth
PHYSICIANS

(b)(6)

January 13, 2022

Patient Name (b)(6)
Date of Birth

To Whom It May Concern,

My name is Jennifer Evans and I am a licensed psychologist. I work with patients who identify as transgender, non-binary, and gender diverse and I provide mental health evaluations, diagnostic support, and therapeutic treatment for these clients. This letter is informed by my mental health evaluation of (b)(6) and reflects my support of (b)(6) decision to begin taking puberty blockers. (b)(6) presents as a 12 y.o. patient who was assigned female at birth and currently identifies as nonbinary. (b)(6) uses He/Him/His or They/Them/Their pronouns.

I first met with (b)(6) on 3/19/21, and have met with them for individual psychotherapy, for a total of thirteen sessions as of the date of this letter. (b)(6) parent has also been included in these discussions and has been offered an opportunity to ask questions. My evaluation of (b)(6) has included a comprehensive mental status examination and psychosocial history, with particular emphasis upon gender identity issues. (b)(6) has demonstrated no impaired judgment during these sessions. (b)(6) has indicated intense discomfort with being identified or perceived as female, and a preference and increased comfort when identifying as a nonbinary for the past 2 years. (b)(6) clearly experiences discomfort or distress caused by a discrepancy between their gender identity and sex assigned at birth, associated gender role, and/or primary and secondary sex characteristics. (b)(6) has also been meeting with a pediatric endocrinologist since March of 2021.

It has been recommended both by myself, and (b)(6) pediatric endocrinologist, that (b)(6) begin taking Lurpon as soon as possible. (b)(6) has been prescribed Lupron Depot-PED 3-month

1125mg IM KIT by his physician (Dr. Kristin Dayton). This medication is medically necessary help treat (b)(6) Gender Identity Disorder of Childhood (F64.2).

My clinical impression is that (b)(6) sense of self has been enhanced by gender transition, and that this patient is likely to be helped and not harmed by beginning puberty blockers at this time. Patient demonstrates readiness to begin puberty blockers and has provided assent. (b)(6) parents have provided consent for (b)(6) to begin puberty blockers. (b)(6) and their family demonstrates understanding of the options and reports a well documented history of gender dysphoria. I am open to consultation and collaboration; please contact me if you have further questions regarding this patient.

Sincerely,
Jennifer Evans
Clinical Psychologist

Patient Care Research Education

UF Health is a collaboration of the University of Florida Health Science Center, Shands Hospital, and other health care entities

Revision History

Revised by Knott, Christopher today at 11:13 AM (current version)
Created by Evans, Jennifer L., PsyD on 1/13/2022 at 10:57 AM

(b)(6) Complaint, Exhibit 4

CVS caremark®

Fax Transmittal

From: CVS Caremark® Prior Authorization

You are receiving this fax because you or a member of your practice's staff recently contacted CVS Caremark to request a Prior Authorization related to a CVS Caremark plan member.

You should know, members are filling prescriptions up to 2 days faster when their prescribers consistently use electronic Prior Authorization (ePA). To get started or to learn more about how you can expedite the Prior Authorization process and receive near real-time decisions* by using ePA, visit Caremark.com/epa.

Method of submission	Median turnaround time
ePA	< 1 hour
Fax	12 hours

*May not result in near real-time decisions for all prior authorization types and reasons.

If this fax is in response to an inquiry about clinical coverage of a prescription drug for your patient the criteria for the specific drug is attached.

Please note that your inquiry does not constitute a request for coverage. CVS Caremark cannot process a request for coverage until we receive a completed criteria form or appropriate clinical information.

Utilization management decision making is based only on appropriateness of care and service and existence of coverage. CVS Caremark does not reward practitioners or other individuals conducting utilization management for issuing denials of coverage. Financial incentives for utilization management decision makers are not designed to encourage decisions that result in underutilization.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call 1-877-265-2711 at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within 30 days of receipt. The information contained in this message may be privileged and confidential and protected from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by replying to the message and deleting it from your computer. Thank you, CVS Caremark.

91-41319A 101320

CVS caremark™

Notice of Action
LEVEL I (Clinical) Appeal Denial

KRISTIN DAYTON
1699 SW 16th Ave
Gainesville, FL 32608

Date: 12/18/2021

Member Name: (b)(6)
Plan Member ID
Plan Name: State of Florida
PA#: (b)(6)
Plan-approved Criteria: Lupron Hormonal SGM
Claim Amount (if available):
Service Date: 12/18/2021 10:38:34 AM

Prescriber Name: KRISTIN DAYTON
Prescriber Phone: 1-3523340206
Prescriber Fax: 1-3522948097

Dear (b)(6)

CVS Caremark®, the Pharmacy Benefit Manager for the State Employees' Prescription Drug Plan (Rx Plan), has completed its review of your Level I (Clinical) Appeal. After review of the pertinent facts, information, clinical criteria, and provisions of the Rx Plan, CVS Caremark denied your Level I (clinical) Appeal for the following reason(s):

Your appeal for Lupron Depot-PED 3-month 11.25mg has been determined as not medically necessary. Per physician review, current plan approved criteria only allow coverage of Lupron Depot-PED 3-month 11.25mg for those who have a diagnosis of central precocious puberty. Your request was reviewed by an MD Board Certified in Family Medicine. 12/18/2021

If your prescribing physician provided diagnosis or treatment codes for this prescription/claim for Lupron Depot-Ped (3-Month) 11.25MG (Ped) IM KIT to CVS Caremark, that information is listed here:

ICD diagnosis code: F64.2
Associated diagnosis: Gender identity disorder of childhood
CPT treatment code:
Associated treatment:

You may contact your prescribing physician for more specific information about these codes. Additionally, you are entitled to receive, upon written request and free of charge, copies of all relevant documents used in making this decision.

This completes the Level I Appeal review by CVS Caremark. Pursuant to the terms of your health plan Benefit Document or Certificate of Coverage, you have the right to a Level II Appeal IF you believe that we have made an error in either considering the facts, applying the law or applying the provisions of the State Employees' Prescription Drug Plan in the denial of this Level I Appeal.

If you wish to appeal this decision, you may submit a Level II Appeal as follows:

Appealing to Division of State Group Insurance (DSGI) – A Level II Appeal

If you are not satisfied with the Level I Appeal decision, you may file a Level II Appeal to DSGI. You may request a Level II urgent appeal if the timeframe to complete the pre-service Level II Appeal would seriously jeopardize your life or health or your ability to regain maximum function or if in the opinion of a physician with knowledge of your medical condition, would subject you to severe pain that cannot be adequately managed without the care or treatment that is the subject of the urgent appeal.

This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.
Your privacy is important to us. Our employees are trained regarding the appropriate way to handle your private health information.

If your Level II Appeal is for the denial of a pre-service or concurrent care decision and meets the criteria in the paragraph immediately above, you may verbally request an urgent Level II Appeal by submitting your urgent Level II Appeal request and any necessary documentation to support your urgent Level II Appeal to DSGI electronically at DSGIAppeals@dms.myflorida.com or calling DSGI at **(850) 921-4600** and stating that you are requesting an urgent Level II Appeal.

If your appeal is for a pre-service (non-urgent) or post-service claim, you must submit your Level II Appeal in writing and explain your reason for the appeal. Your appeal should include all relevant medical records, as well as, any additional documentation, information, evidence, or testimony that you would like reviewed and considered during the appeal process.

Your Level II Appeal must be in writing or filed verbally (for urgent appeals only) and must be submitted electronically at DSGIAppeals@dms.myflorida.com or postmarked within 60 days of the written notice of CVS Caremark's denial of your Level I Appeal. Your Level II Appeal must include:

1. A copy of the denial notice (EOB, MHS, or other notice of denial);
2. A copy of your letter to CVS Caremark requesting a Level I Appeal;
3. A copy of CVS Caremark Level I Appeal denial;
4. A Level II Appeal letter to DSGI appealing the Level I Appeal decision; and
5. All relevant medical records, as well as, any other information or documentation that could assist in the review of your appeal.

Mail your written Level II Appeal to DSGI at:

Divison of State Group Insurance
Attention: Appeals Coordinator
PO Box 5450
Tallahassee, FL 32314-5450

Any Level II Appeal received without, at a minimum, the above information, will be returned to you or the representative who submitted your Level II Appeal. Prior to the notification of the Level II Appeal decision, you will be provided, free of charge, copies of any new or additional evidence or rationale considered in connection with your claim and you will be provided an opportunity to respond to such new evidence or rationale.

DSGI will review the Level II Appeal and provide a written notice of the review decision. If the Level II Appeal is for a pre-service (non-urgent) denial, DSGI will respond within 15 days from receipt of your appeal; if the Level II Appeal is for a post-service denial, DSGI will respond within 30 days from receipt of your appeal; and, if your appeal is urgent, DSGI will respond within 72 hours from receipt of your appeal. DSGI will notify you within the 72-hour period if your urgent Level II Appeal does not contain sufficient information and/or documentation for a review and decision; the 72-hour period will be suspended when the notice is sent to you. The notice will include a specific due date that DSGI must receive any additional information and/or documentation to review in consideration of your urgent Level II Appeal; the 72-hour period will restart on the noted due date. If DSGI's review is unfavorable (Level II Appeal is denied), the notice from DSGI will include information of any additional appeal or review rights available to you.

For requests that received (1) a Level I denial from CVS Caremark and (2) a Level II denial from DSGI, two review options are available to contest the Level II Appeal denial; an Administrative Hearing and an external review from an Independent Review Organization. You may request a review through either or both of these options. However, please note that each option has a specific timeframe for requesting a review as described below.

Requesting an Administrative Hearing

If you want to contest the Level II Appeal decision of DSGI through the Administrative Hearing process, you must submit a petition for an administrative proceeding that complies with Rule 28-106.201 or 28-106.301, Florida Administrative Code. Your petition must be received within 21 days after you received the written adverse decision on your Level II Appeal.

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Your privacy is important to us. Our employees are trained regarding the appropriate way to handle your private health information.

Requesting an External Review from an Independent Review Organization

For requests that received (1) a Level I denial from CVS Caremark and (2) a Level II denial from DSGI, you have the right to request an external review from an Independent Review Organization (IRO) **after the finalization of both the Level I and Level II Appeal processes only if:**

1. the decision involved a:
   a. denial of your request for payment of a claim and the decision involved a medical judgment including, but not limited to a decision based on medical necessity, appropriateness, health care setting, level of care or effectiveness of the health care service or treatment you requested or a determination that the treatment is experimental or investigational; or
   b. rescission (cancellation) of coverage; and
2. An external review is requested by you within four months of the Level II Appeal denial date.

You may call Customer Service toll-free at **1-888-766-5490** for additional information about requesting or to request an external review. External review is not available for claim denials based on an individual's eligibility under a plan. You may request an external review in writing within four months after receipt of the Level II Appeal decision.

Standard External Review

For requests that received (1) a Level I denial from CVS Caremark and (2) a Level II denial from DSGI, you may request a standard external review of your Level II Appeal denial if:

1. the decision involved a:
   a. denial of your request for payment of a claim and the decision involved a medical judgment including, but not limited to a decision based on medical necessity, appropriateness, health care setting, level of care or effectiveness of the health care service or treatment you requested or a determination that the treatment is experimental or investigational; or
   b. rescission (cancellation) of coverage; and
2. An external review is requested by you within four months of the Level II Appeal denial date.

The IRO will review your request for a standard external review and provide a written notice of the review decision within 45 days from the date of receipt of the request by the IRO.

Expedited or Urgent External Review

For requests that received (1) a Level I denial from CVS Caremark and (2) a Level II denial from DSGI, you may request an expedited or urgent external review if the timeframe to complete a standard external review would seriously jeopardize your life or health or your ability to regain maximum function or if in the opinion of a physician with knowledge of your medical condition, would subject you to severe pain that cannot be adequately managed without the care or treatment that is the subject of the urgent external review and if:

1. the decision involved a:
   a. denial of your request for payment of a claim and the decision involved a medical judgment including, but not limited to a decision based on medical necessity, appropriateness, health care setting, level of care or effectiveness of the health care service or treatment you requested or a determination that the treatment is experimental or investigational; or
   b. rescission (cancellation) of coverage; and
2. An external review is requested by you within four months of the Level II Appeal denial date.

The IRO will review your request for an urgent external review and provide a response within 72 hours from the date of receipt by the IRO.

IMPORTANT NOTES:

1. Throughout the appeal and review process, you have the right to present evidence and testimony as

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Your privacy is important to us. Our employees are trained regarding the appropriate way to handle your private health information.

well as request and receive, free of charge, copies of all documents and other information relevant to your claim and/or appeal, including, but not limited to, the following information about the processing of your claim:

- the specific rule, guideline, protocol or other similar criterion used, if any, in making the benefit or payment decision, and/or
- an explanation of the scientific or clinical factors relied upon if the claim was denied in whole or in part based on the lack of medical necessity or the experimental or investigational nature of a service or medication.

2. A favorable decision by the IRO is binding on the Plan and is cause to interrupt and stop any administrative hearing proceedings. An unfavorable decision by the IRO is binding on the Plan if you did not previously timely pursue action through the administrative hearing process.
3. If, after commencement of any administrative proceeding, you decide to request an external review by the IRO, the administrative proceeding will be held in abeyance pending the IRO decision.

If you need additional assistance regarding this Level I Appeal denial or have questions about your prescription drug plan, please feel free to call Customer Care toll-free at **1-888-766-5490**. Customer Care representatives are available 24/7 to assist you.

Sincerely,

CVS Caremark

cc: Dr. DAYTON

If you have questions about your rights, this notice, or for assistance, you can contact the Employee Benefits Security Administration toll-free at **1-866-444-EBSA (3272)**.

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Your privacy is important to us. Our employees are trained regarding the appropriate way to handle your private health information.

Questions? Do you need help in a different language or format? If you do not speak English or have special needs, oral interpretation and alternate formats of this notice are available, as is other assistance, by contacting us at the number on your benefit ID card.

Spanish:
Si usted necesita asistencia o necesita hablar con alguien en Español, por favor llame al número gratuito de Servicio al Cliente ubicado en su tarjeta de identificación de beneficios.

Chinese (simplified):
如果您需要帮助，或需要同中国人讲话，请拨打您的福利卡上面的客户服务免费电话号码。

Tagalog:
Kung kailangan ninyo ng tulong o kailangan ninyong makipag-usap sa isang tao sa Tagalog, mangyari lamang na tumawag nang walang-bayad sa Serbisyo sa Kostumer sa numero na nakasulat sa inyong ID kard ng benepisyo.

Navajo:
Shíka at'ohwol ei doodaii' dinék'ehgo łą bi'chį haadeedziih nínźiińgo. t'áá shǫǫdí, t'áá jíík'e ya ndaalníshí, ni naaltsoos bikáa'gi bi'chį hodiilniih.

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Your privacy is important to us. Our employees are trained regarding the appropriate way to handle your private health information.

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Department of MANAGEMENT SERVICES
We serve those who serve Florida

Tallahassee, FL 32399-
Phone: 850-921-4600 | Fax: 850-488-

(b)(6) **Complaint, Exhibit 5**

Ron DeSantis, Gover
J. Todd Inman, Secret

CERTIFIED MAIL RETURN RECEIPT REQUESTED
ARTICLE NUMBER: 7017 3450 0000 5906 9482

February 24, 2022

(b)(6)

RE: ***Level II Appeal Determination***
Member: (b)(6)
Member ID#:
Patient:
DOB:
Group: State of Florida – Capital Health Plan HMO / CVS Caremark
Provider: Kristin Dayton, MD
DOS: *Pre-service*

(b)(6)

We have reviewed and made a determination regarding the Level II Appeal that (b)(6) *submitted to the Division of State Group Insurance (DSGI) on behalf of your dependent,* (b)(6) *a minor child. The issue is CVS Caremark's denial of coverage for Rx Drug Lupron Depot (Leuprolide). After carefully reviewing all the appeal documents and the facts below, we must deny the Level II Appeal because gender reassignment or modification services and supplies are a specific exclusion under your Plan.*

The State Employees' HMO Plan Group Health Insurance Booklet and Benefits Document (Plan Document), effective January 1, 2022, states on page 68-75 under Section VIII. Prescription Drug Program:

> *"The Plan's general Limitation and Exclusion apply to the prescription drug program. See "Limitations and Exclusions" section within this document.*
>
> ***Important Information about the Prescription Drug Program***
>
> *13. CVS Specialty administers the Specialty Management Program for this Plan. This program is intended to optimize outcomes and promote the safe, clinically appropriate and cost-effective use of specialty medications supported by evidence based medical guidelines. Failure to meet the criteria for this program during the coverage review will result in denial of medication coverage for the Health Plan Member and discontinuation of medication coverage for the Health Plan Member."*

The Plan Document also states the following on pages 57-58 under Section VI. Limitations and Exclusions:

> ***"VI. LIMITATIONS AND EXCLUSIONS***

Services Not Covered by the Plan The following services and supplies are excluded from coverage under this Plan unless a specific exception is noted. Exceptions may be subject to certain coverage Limitations.	
Gender reassignment or modification services and supplies	

Additionally, the CVS Caremark Specialty Guideline Management for Rx Drug Lupron Depot (Leuprolide acetate) states:

"2. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Lupron Depot-PED is indicated for the treatment of children with central precocious puberty (CPP).

All other indications are considered experimental/investigational and not medically necessary.

Therefore, after carefully reviewing all the appeal documents and the facts above, we must deny the Level II Appeal because gender reassignment or modification services and supplies are a specific plan exclusion, not a covered benefit. If you believe that we have made an error in either considering the facts or applying the Plan document in this appeal, you may do one of the following within 21 days of receiving this letter:

- File a request (petition) for a formal hearing. Your request must state the facts you dispute and must comply with the requirements of Rule 28-106.201, Florida Administrative Code (enclosed), or
- File a request for an informal hearing. Your request must state why you disagree with the decision and must comply with the requirements of Rule 28-106.301, Florida Administrative Code (enclosed). If you do not state the disputed facts in your letter, we will automatically treat it as an informal hearing request.

r request for a formal or informal hearing must be in writing and received by the Agency Clerk of the artment of Management Services within 21 days of your receipt of this letter. The enclosed informational explains the hearings process. If you choose to request a hearing, send your written request to:

Agency Clerk and Hearings Coordinator
Office of the General Counsel
Department of Management Services
4050 Esplanade Way, Suite 160
Tallahassee, FL 32399-0950

to petition for a hearing within the time allowed, you will have waived your right to a hearing and the et forth in this letter will become final on the 22nd day after your receipt of this letter. Please note that should in no way influence your decision to proceed with Dayton's recommendation to purchase the

prescription drug, Rx Drug Lupron Depot [Leuprolide] for your dependent. The intent of this letter is to inform you of the outcome of our benefit review.

You also have the right to request an external review from an Independent Review Organization (IRO) concerning a benefit claim for medical services, supplies or prescription drugs. You must file your request for the external review within 120 days of the date of the receipt of this Level II Appeal decision. To request an external review or for more information, please call CVS Caremark at the number on the back of your membership card.

You may request a standard external review of your Level II Appeal if the decision denies your request for payment of a claim and involves a medical judgment that is based on, but not limited to, the following:

- Medical necessity, appropriateness, health care setting, level of care or effectiveness of the health care service or treatment you requested, or
- Treatment that is experimental or investigational.

You may request an urgent external review if the timeframe to complete a standard external review would seriously jeopardize (b)(6) life, health, or ability to regain maximum function or, if in the opinion of a physician with knowledge of (b)(6) medical condition, would subject him to severe pain that cannot be adequately managed without the care or treatment that is the subject of the urgent external review.

A favorable decision by the IRO is binding on the Plan.

Sincerely,

Ryan Stokes
Director

RS/dtb

Enclosures: Level II Appeal Hearings Informational Page
Rule 28-106.201, Florida Administrative Code
Rule 28-106.301, Florida Administrative Code

Kristin Dayton, MD

Nondiscrimination and Accessibility Notice (ACA § 1557)

CVS Pharmacy, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. CVS Pharmacy, Inc. does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

CVS Pharmacy, Inc.:

- Provides certain aids and services, free of charge, when necessary so that people with disabilities have an equal opportunity to communicate effectively with us, such as:
  - Auxiliary aids and services
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides language services, free of charge, when necessary to provide meaningful access to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact Customer Care toll-free at 1-800-746-7287, Monday through Friday 8:00 a.m. to 9 p.m. (EST) and Saturday through Sunday 10:00 a.m. to 6:30 p.m. (EST). TTY users should call 711.

If you believe that CVS Pharmacy, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

CVS Pharmacy, Inc.
Grievance Department
Attn: Civil Rights Coordinator
P.O. Box MC 1234
Woonsocket, Rhode Island, 02895

Fax: 1-401-652-9935

You can file a grievance by mail, or by fax. If you need help filing a grievance, the CVS Pharmacy, Inc. Grievance Department's Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD).

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Get Help in Other Languages
If you need help or speak a non-English language, call 1-800-746-7287 (TTY: 711) and you will be connected to an interpreter who will assist you at no cost.

ENGLISH
ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call 1-800-746-7287 (TTY: 711).

SPANISH
ATENCIÓN: Si usted habla español, tenemos servicios de asistencia lingüística disponibles para usted sin costo alguno. Llame al 1-800-746-7287 (TTY: 711).

CHINESE
小贴士：如果您说普通话，欢迎使用免费语言协助服务。请拨 1-800-746-7287 (TTY: 711)。

VIETNAMESE
CHÚ Ý: Nếu quý vị nói tiếng Việt, thì có sẵn các dịch vụ trợ giúp ngôn ngữ miễn phí dành cho quý vị. Hãy gọi số 1-800-746-7287 (TTY: 711).

KOREAN
알림: 한국어를 하시는 경우 무료 통역 서비스가 준비되어 있습니다. 1-800-746-7287 (TTY: 711)로 연락주시기 바랍니다.

TAGALOG
Pansinin: Kung nagsasalita ka ng Tagalog, mga serbisyo ng tulong sa wika, nang walang bayad, ay magagamit sa iyo. Tawagan ang 1-800-746-7287 (TTY: 711).

RUSSIAN
ВНИМАНИЕ: Если вы говорите на русском языке, вам будут бесплатно предоставлены услуги переводчика. Звоните по телефону: 1-800-746-7287 (телетайп: 711).

ARABIC
ةظحلام: اذإ تنك ثدحتتة ،ةيبرعلا رفوتتة تامدخ ةدعاسملا ةيوغللا ناجم كلذلجأ. لصتا مقرلاب 1-800-746-7287 (نم فتاهلا يصنلا: 711).

FRENCH CREOLE
ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 1-800-746-7287 (TTY: 711).

FRENCH
ATTENTION : Si vous parlez français, des services gratuits d'interprétation sont à votre disposition. Veuillez appeler le 1-800-746-7287 (TTY: 711).

POLISH UWAGA: Dla osób mówiących po polsku dostępna jest bezpłatna pomoc językowa. Zadzwoń pod numer 1-800-746-7287 (TTY: 711).

PORTUGUESE ATENÇÃO: Se fala português, estão disponíveis serviços gratuitos de assistência linguística na sua língua. Telefone para 1-800-746-7287 (TTY: 711).

ITALIAN
ATTENZIONE: Se lei parla italiano, sono disponibili servizi gratuiti di assistenza linguistica nella sua lingua. Chiami 1-800-746-7287 (TTY: 711).

JAPANESE お知らせ: 日本語での対応を望まれる方には、無料で通訳サービスをご利用になれます。電話番号1-800-746-7287 (TTY: 711)までお問い合わせ下さい。

GERMAN

BITTE BEACHTEN: Wenn Sie Deutsch sprechen, stehen Ihnen unsere Dolmetscher unter der Nummer 1-800-746-7287 (TTY: 711) kostenlos zur Verfügung.

FARSI

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(b)(6) **Complaint, Exhibit 7**

From: [redacted]
Sent: Wednesday, June 22, 2016 5:18 PM
To: [redacted]
Subject: FW: Benefit Coverage - Transgender Care Drugs-Important update on coverage for drugs used. **response needed by June 30th 2016 **
Attachments: State of Florida 38527B FNL Transgender Care Client Letter.pdf

Heads up on this issue!

From: [redacted]
Sent: Wednesday, June 22, 2016 2:47 PM
To: [redacted]@dms.myflorida.com>
Subject: FW: Benefit Coverage - Transgender Care Drugs-Important update on coverage for drugs used. **response needed by June 30th 2016 **

Thanks,
[redacted]

From: [redacted]
Sent: Wednesday, June 22, 2016 2:44 PM
To: [redacted]@CVSCaremark.com>
Cc: [redacted]@CVSHealth.com>; [redacted]@CVSCaremark.com>; [redacted]@dms.myflorida.com>
Subject: Benefit Coverage - Transgender Care Drugs-Important update on coverage for drugs used. **response needed by June 30th 2016 **

As of this date and until further notified by the State of Florida, the State Employees' Prescription Drug Plan does NOT cover services, drugs, and supplies provided in connection with intersex surgery, sexual reassignment and/or sexual modification.

It is our understanding that though the federal guidance provides for an effective, it also provided for a Jan 1, 2017 effective date for plans renewing on or after the implied effective date. The SOF move will provide CMK notice should it decide to move forward with coverage for service, supplies, and drugs provided in connection with sexual reassignment. This issue is currently under review by the Office of the General Counsel, Department of Management Services for any impact to medical and prescription drug coverage offered by the Division of State Group Insurance.

With this said as it pertains to sexual "reassignment surgery" please note that "covered" drugs should be allowed for members based on medical necessity and the gender on the enrollment file passed from the SOF to CMK. It is possible that a person's gender could change from one enrollment file to another and in such a case it is possible that the covered person may fill prescription for covered drugs that may have previously denied.

Please let me know if you have any questions or if I did not completely understand the total ask of CMK's email below.

[redacted]
PPO Plan & PBM Contract Manager

PLAINTIFF'S EXHIBIT
[redacted]

[redacted]

Bureau of Policy & Development
Division of State Group Insurance
DMS Customer Satisfaction Survey
Florida Department of Management Services
4050 Esplanade Way, Ste. 215, Tallahassee, Florida 32399
Direct: (850) 921-4631
Main Office: (850) 921-4600
[redacted]
@FloridaDMS
facebook.com/FLDMS

"We Serve Those Who Serve Florida"
Maintain Process-Oriented Mindset
Challenge the Status Quo
Create Efficiencies
Respect State Employees

From: [redacted]@CVSCaremark.com]
Sent: Thursday, June 16, 2016 5:32 PM
To: [redacted]@dms.myflorida.com>
Cc: [redacted]@CVSCaremark.com>; [redacted]@CVSCaremark.com>; [redacted]@CVSCaremark.com>
Subject: Transgender Care Drugs-Important update on coverage for drugs used. **response needed by June 30th 2016 **

Greetings [redacted]

I want to make you aware of an important change CVS Caremark® is making to our standard utilization management criteria in three drug classes. The changes are being made to make certain drug classes approvable for plan members seeking transgender care (TGC). This will help to ensure compliance with emerging federal and state laws and regulations.

Criteria are being updated in these classes, effective September 1, 2016.

- Gonadotropin Releasing Hormone (GnRH) agonists (i.e., Lupron products, Supprelin LA®, Zoladex®) ***(Specialty guideline management (SGM) currently in place)***
- Testosterones ***(no utilization management currently in place)***
- Depo-Provera® (medroxyprogesterone) ***(no utilization management currently in place)***

Please review the attached letter from Dr. William Fulcher, CVS Health Medical Director, for more information on the legal and clinical aspects of this decision.

- If you decide to **move forward** with the standard criteria for the SGM drugs that allow for approval of TGC diagnoses, no action is required.
- If you decide to **not allow** for approval of TGC diagnoses, please contact me as soon as possible, so we can ensure you are transitioned to criteria that do not allow for coverage of TGC diagnoses. **The deadline to do so is June 30th 2016.**

Should you have any questions, please contact me.

Thank you!

[redacted] Clinical Advisor
p 813-814-9193 | c 813-504-0853 | f 480-862-1264

[redacted]

[redacted]

CVS Health | Tampa, FI 33626

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CVSHealth

One CVS Drive
Woonsocket, RI 02895

June 2016

Dear Client:

CVS Caremark® is committed to supporting your plan in providing clinically-appropriate prescription drug coverage and complying with applicable laws and regulations. Hormone therapies and medications for transgender care (TGC) have been a topic of interest to clients recently.

In order to remain consistent with emerging laws and regulations, CVS Caremark is updating our standard utilization management (UM) criteria to allow approval for TGC, where supported by the clinical literature and experts in the field.

UM criteria – Prior Authorization (PA) and Specialty Guideline Management (SGM) – for the following drug classes routinely used for TGC will be updated effective September 1, 2016 for clients with standard commercial criteria and UM auto update.

- Gonadotropin-releasing hormone (GnRH) agonists (i.e., Lupron products, Supprelin® LA, Zoladex®)
- Testosterones
- Depo-Provera® (medroxyprogesterone)

Please note that estrogens and spironolactone are also used in TGC and do not typically have benefit restrictions.

It is important to understand that not all transgender persons seek complete or even partial gender transitions. Some never ultimately choose to utilize hormone therapy and/or surgery to transition to their desired gender. In fact, the prevalence of transgender persons seeking specific therapy for their gender identity is estimated to be low. In 2011, the Williams Institute concluded that there were ~700,000 transgender persons in the U.S., or approximately 0.3% of the population.[1] This study estimated utilization rates for transgender services to be:

- ~1/10,000 employees (employers with < 10,000 employees) and
- ~1/20,000 employees (employers with 10,000-50,000 employees)[2].

Every individual's clinical needs are unique and the size and scope of services vary. In a 2015 study by the Johns Hopkins School of Public Health, researchers estimated the incremental cost of care for transgender persons to be ~$0.016 PMPM, deemed cost effective by the researchers as compared to negative endpoints, including HIV, suicide, depression and drug abuse.[3]

Should you have questions about these changes or choose not to provide coverage for TGC at this time, please contact your Clinical Advisor or Strategic Account Executive to opt out no later than July 15, 2016.

Sincerely,

[redacted]
Medical Director
CVS Health

This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Health
106-385278 061016

CVSHealth

Emerging Laws and Regulations in the Area of Transgender Care

Section 1557 of the Affordable Care Act (ACA) prohibits exclusion from participation, denial of benefits or discrimination on the basis of race, color, national origin, sex, age or disability, in health programs or activities any part of which receive federal financial assistance.[iv] The Department of Health and Human Services (HHS), through the Office of Civil Rights (OCR), recently issued final regulations broadly interpreting the scope of Section 1557 and expressly prohibiting exclusion or limitation of TGC coverage.[v] The final regulations apply to any "entity that operates a health program or activity, any part of which receives federal financial assistance," including, at a minimum, Marketplace exchange plans, Medicare Part D plans, EGWPs, managed Medicaid plans and certain employee health benefit programs.[vi]

An increasing number of states have enacted laws or established policies prohibiting exclusion or limitation of TGC coverage. Currently, California, Colorado, Connecticut, District of Columbia, Illinois, Massachusetts, Nevada, New York, Oregon, Vermont, and Washington have laws or policies providing that exclusion or limitation of TGC coverage is discriminatory or is likely to be discriminatory under some circumstances. The Office of Personnel Management has a similar policy for the Federal Employees Health Benefits Program.[vii]

[i] Gates GJ. How many people are lesbian, gay, bisexual, or transgender? Williams Institute, UCLA School of Law. 2011. http://williamsinstitute.law.ucla.edu/wp-content/uploads/Gates-How-Many-People-LGBT-Apr-2011.pdf. Accessed June 10, 2016.

[ii] http://williamsinstitute.law.ucla.edu/research/transgender-issues/costs-barrier-is-providing-transition-related-health-care-coverage-herman-2013/. Accessed June 10, 2016.

[iii] Padula WV, Heru S2, Campbell JD3. Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis. J Gen Intern Med. 2016 Apr 31(4): 394-401.

[iv] (42 U.S.C. 18116).

[v] 81 Fed. Reg. 31375, 31428-37, 45 C.F.R. § 92.207.

[vi] 81 Fed. Reg. 31375, 31428-38; 45 C.F.R. §§ 92.4, 92.207, 92.208.

[vii] U.S. Office of Personnel Management. FEHB Program Carrier Letter. Letter No. 2015–12 (Jun. 23, 2015), *available at* https://www.opm.gov/healthcare-insurance/healthcare/carriers/2015/2015-12.pdf. Accessed June 10, 2016.

This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Health.
106-38527B 061016

(b)(6) **Complaint, Exhibit 8**

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS

FILED
U.S. DISTRICT COURT
EASTERN DISTRICT ARKANSAS
JUN 17 2021
JAMES W. McCORMACK, CLERK
By: _____ DEP CLERK

DYLAN BRANDT, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	Case No. 4:21-cv-450-JM
	)	
LESLIE RUTLEDGE, *et al.*,	)	
	)	
Defendants.	)	

STATEMENT OF INTEREST OF THE UNITED STATES

The United States respectfully submits this Statement of Interest, under 28 U.S.C. § 517,[1] to advise the Court of its view that the Equal Protection Clause of the Fourteenth Amendment bars the State of Arkansas from discriminating against transgender[2] minors by enacting legislation that wholesale prohibits healthcare providers from providing them with certain categories of medically necessary care, or referring them to another provider for such care. House Bill 1570 (H.B. 1570), passed into law on April 6, 2021 and enacted as Act 626, prohibits the provision of or referral for "gender transition procedures" for any individual under eighteen (18) years of age. Act 626 § 3, 93rd Gen. Assemb., Reg. Sess. (Ark. 2021) (to be codified at Ark. Code Ann. § 20-9-1502(a)-(b)). Plaintiffs have filed a private action challenging the law on

[1] Under 28 U.S.C. § 517, "[t]he Solicitor General, or any officer of the Department of Justice, may be sent by the Attorney General to any State or district in the United States to attend to the interests of the United States in a suit pending in a court of the United States, or in a court of a State, or to attend to any other interest of the United States." *Id.*; *see also Jones Truck Lines, Inc. v. AFCO Steel, Inc.*, 849 F. Supp. 1296, 1305 n.4 (E.D. Ark. 1994) (recognizing that the United States may "assert to a court its position . . . in matters of significant interest").

[2] The term "transgender" refers to a person whose gender identity differs from the person's assigned sex at birth, whereas the term "cisgender" refers to a person whose gender identity is the same as the person's assigned sex at birth. For example, a transgender girl is a person who identifies as a girl but whose sex assigned at birth was male.

multiple grounds, including the Equal Protection Clause. The United States files this Statement of Interest in support of Plaintiffs' Motion for Preliminary Injunction, as Act 626 cannot survive the heightened scrutiny to which it must be subjected and therefore would violate the Equal Protection Clause if allowed to go into effect.

This case implicates important federal interests. The United States is charged with protecting the civil rights of individuals seeking nondiscriminatory access to healthcare in a range of health programs and activities under Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116. The Department of Justice is further charged with the coordination and implementation of federal nondiscrimination laws that protect individuals against discrimination on the basis of sex in a wide range of federally-funded programs and activities, including, but not limited to, the provision of healthcare. Exec. Order No. 12250, § 1-201, 45 Fed. Reg. 72,995 (Nov. 4, 1980).

The United States has a strong interest in protecting the rights of lesbian, gay, bisexual, and transgender individuals. To that end, the President has issued an Executive Order that recognizes the right of all persons to "be treated with respect and dignity," "to access healthcare . . . without being subjected to sex discrimination," and to "receive equal treatment under the law, no matter their gender identity or sexual orientation." Exec. Order No. 13,988, 86 Fed. Reg. 7,023 (Jan. 25, 2021). The United States also recently filed a Statement of Interest in *Diamond v. Ward*, No. 5:20-cv-00453-MTT (M.D. Ga., Apr. 22, 2021), regarding the inadequacy, under the Eighth Amendment to the U.S. Constitution, of medical treatment for gender dysphoria that was provided to a transgender woman while in the custody of the Georgia Department of Corrections.

Act 626 specifically and discriminatorily denies transgender minors, and only transgender minors, the ability to receive medically necessary care based solely on their sex

assigned at birth. Discriminating against transgender minors in this manner violates the Equal Protection Clause. Such discrimination would be justified only if Arkansas could show that it is substantially related to achieving an important governmental interest. Arkansas cannot make that showing. For this reason, the United States believes that Plaintiffs' Equal Protection challenge to Act 626 is likely to succeed on the merits.

BACKGROUND

Act 626 was passed into law on April 6, 2021 by a simple majority of the General Assembly, overcoming a Governor's veto less than 24 hours prior. The Act states that "a physician or other healthcare professional shall not provide gender transition procedures to any individual under eighteen (18) years of age," nor refer any individual to another healthcare professional for the same. Act 626 § 3 (to be codified at Ark. Code Ann. 20-9-1502(a)-(b)). The legislature's proffered justification for this Act is that "the risks of gender transition procedures far outweigh the benefits at this stage of clinical study on these procedures." *Id.* § 2(15). For purposes of Act 626, "gender transition procedures" include any:

> medical or surgical service, including without limitation physician's services, inpatient and outpatient hospital services, or prescribed drugs related to gender transition that seeks to: (i) Alter or remove physical or anatomical characteristics or features that are typical for the individual's biological sex; or (ii) Instill or create physiological or anatomical characteristics that resemble a sex different from the individual's biological sex . . .

Id. § 3 (to be codified at Ark. Code Ann. 20-9-1501(6)). Act 626 defines "biological sex" to mean:

> the biological indication of male and female in the context of reproductive potential or capacity, such as sex chromosomes, naturally occurring sex hormones, gonads, and nonambiguous internal and external genitalia present at birth, without regard to an individual's psychological, chosen, or subjective experience of gender.

Id. (to be codified at Ark. Code Ann. 20-9-1501(1)).[3] Act 626's definition of "gender transition" surgeries does not include procedures provided to individuals under eighteen years of age who have a medically verified or diagnosed "disorder of sex development."[4] *Id.* (to be codified at Ark. Code Ann. 20-9-1502(c)(1), (2)). Under the law, any healthcare professional who provides a gender transition procedure to a minor, or makes a referral for such a procedure, is subject to discipline by a licensing entity or disciplinary review board. *Id.* (to be codified at Ark. Code Ann. 20-9-1504(a)). Further, they face legal liability in a judicial or administrative proceeding for any "actual or threatened violation" of the Act. *Id.* (to be codified at Ark. Code Ann. 20-9-1504(b)).

On May 25, 2021, Plaintiffs filed this action against Leslie Rutledge, Arkansas Attorney General; Amy Embry, Executive Director of the Arkansas State Medical Board; and fourteen

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[3] The United States does not concede the accuracy of this definition. The binary of "male" or "female" (here "the biological indication of male and female") does not account for full scientific understanding of biological sex. And scientific literature suggests that the concept of "biological sex" is more complicated than "biological indication[s]" of "reproductive potential or capacity." For example, there is significant evidence of variations in brain development and brain anatomy that are not accounted for in defendant's definition. *See generally, e.g.*, Sarah S. Richardson, SEX ITSELF: THE SEARCH FOR MALE & FEMALE IN THE HUMAN GENOME (2013); Ivanka Savic & Stefan Arver, *Sex Dimorphism of the Brain in Male-to-Female Transsexuals*, 21 CEREBRAL CORTEX 2525 (2011); Bonnie Auyeung, et al., *Fetal Testosterone Predicts Sexually Differentiated Childhood Behavior in Girls and in Boys*, 20 PSYCHOL. SCI. 144 (2009); Eileen Luders, et al., *Regional Gray Matter Variation In Male-To-Female Transsexualism*, 46 NEUROIMAGE 904 (2009); Dick F. Swaab, *Sexual Differentiation Of The Brain And Behavior*, 21 BEST PRAC. & RCHS.: CLINICAL ENDOCRIN. & METABOLISM 431 (2007); Han Berglund, et al., *Brain Response to Putative Pheromones In Lesbian Women*, 103 PROC. NAT'L. ACAD. SCI. 8269 (Jan-Åke Gustafsson, et al. eds., 2006); Stephanie H.M. Van Goozen, et al., *Organizing and Activating Effects of Sex Hormones in Homosexual Transsexuals*, 116 BEHAV. NEUROSCI. 982 (2002); Richard Green & E.B. Keverne, *The Disparate Maternal Aunt–Uncle Ratio in Male Transsexuals: An Explanation Invoking Genomic Imprinting*, 202 J. THEO. BIOLOGY 55 (2000); Frank P.M. Kruijver, et al., *Male-to-Female Transsexuals Have Female Neuron Numbers in a Limbic Nucleus*, 85 J. CLINICAL ENDOCRIN. & METABOLISM 2034 (2000); Jay N. Giedd, et al., *Sexual Dimorphism Of The Developing Human Brain*, 21 PROGRESS NEURO-PSYCHOPHARMACOLOGY & BIOL. PSYCHIATRY 1185 (1997).

[4] The law's reference to "disorders of sex development" is a carve-out for the approximately 1.7% of people who are born intersex. *See* Anne Fausto-Sterling, THE FIVE SEXES, REVISITED, SCIS., July-Aug. 2000, at 18, 20. "Intersex" is an umbrella term for the many possible differences in sex traits or reproductive anatomy compared to the usual two ways that human bodies develop. These can include differences in genitalia, hormones, internal anatomy, brain anatomy, brain development, or chromosomes. Because there are multiple factors that influence sex, those factors may provide different outcomes for different people.

members of the Arkansas State Medical Board, all in their official capacities. Compl. For Declaratory and Injunctive Relief 1, ECF No. 1. Plaintiffs include transgender minors and their families, as well as two medical doctors who bring their claims in their individual capacities on behalf of themselves and their patients. *Id.* at 1, 4-8. The complaint seeks declaratory and injunctive relief, alleging the law violates the Equal Protection Clause of the Fourteenth Amendment (minor and doctor plaintiffs), the Due Process Clause of the Fourteenth Amendment (parent plaintiffs), and the First Amendment (all plaintiffs). *Id.* at 46. Plaintiffs filed a motion for preliminary injunction and a memorandum in support of that motion on June 15, 2021.

ARGUMENT

In determining whether to grant a motion for a preliminary injunction, the court reviews: "(1) the threat of irreparable harm to the movant; (2) the state of the balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that movant will succeed on the merits; and (4) the public interest." *Home Instead, Inc. v. Florance*, 721 F.3d 494, 497 (8th Cir. 2013) (quoting *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981) (en banc)). In this Statement of Interest, the United States argues that the plaintiffs are likely to succeed on the merits on their Equal Protection claim. This Statement does not address the other preliminary injunction factors, or plaintiffs' claims under the Due Process Clause or the First Amendment.[1]

A state law that specifically denies a limited class of people the ability to receive medically necessary care from their healthcare providers solely on the basis of their sex assigned at birth violates the Equal Protection Clause. And yet, this is exactly what Arkansas's Act 626 would do. Act 626 makes physicians and other healthcare professionals liable legally and for

professional misconduct if they provide or refer a transgender minor for gender-affirming care – i.e., procedures that affirm the gender with which one identifies. For transgender individuals, gender-affirming care includes procedures that support the process by which a person transitions from living as a gender that corresponds to their sex assigned at birth to living as a different gender. Act 626 limits only transgender minors from receiving gender-affirming care as prescribed by a healthcare provider, and no one else. Indeed, cisgender minors are able to receive gender-affirming care that involves the exact same treatment denied to transgender minors, simply because for one minor the care affirms their "biological sex" as defined in Act 626 and for the other it does not. These restrictions explicitly target transgender people.

That the law references treatments for "gender transition" instead of explicitly referencing "transgender minors" is of no legal consequence: by limiting the treatments available based on adherence to the law's definition of "biological sex," transgender minors are the only group denied care because of their "biological sex" as it relates to their gender identity. *See Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993) ("Some activities may be such an irrational object of disfavor that, if they are targeted, and if they also happen to be engaged in exclusively or predominantly by a particular class of people, an intent to disfavor that class can readily be presumed."); *see also Bostock v. Clayton Cnty., Ga.*, 140 S. Ct. 1731, 1742 (2020) (when an employer discriminates against an employee based on the employee's sexual orientation or gender identity, the employer "inescapably *intends* to rely on sex in its decisionmaking") (emphasis added).

As discussed below, Act 626 discriminates against transgender people and violates the Equal Protection Clause under the requisite heightened scrutiny analysis. Discriminatory treatment against transgender people should be evaluated under a heightened scrutiny analysis,

as it constitutes both sex discrimination and discrimination against transgender people as an independently protected class. Under this analysis, Act 626 fails. Arkansas cannot demonstrate that prohibiting certain medically necessary healthcare only for transgender people is substantially related to achieving a legitimate government interest.

I. Act 626 is subject to heightened scrutiny under the Equal Protection Clause.

The threshold inquiry in evaluating any Equal Protection claim is whether the classification at issue warrants heightened review because it jeopardizes a fundamental right or categorizes on the basis of an inherently suspect characteristic. *Nordlinger v. Hahn*, 505 U.S. 1, 10 (1992) (citations omitted). As discussed below, Act 626 is subject to heightened scrutiny because it discriminates based on sex and transgender status.

A. Act 626 is subject to heightened scrutiny under the Equal Protection Clause because it discriminates on the basis of sex.

Prohibiting medically necessary care in the manner proscribed by Act 626 amounts to intentional discrimination against transgender minors on the basis of sex.

Recently, the Supreme Court has explained that one cannot "discriminate against a person for being . . . transgender without discriminating against that individual based on sex." *Bostock*, 140 S. Ct. at 1741. The Supreme Court has long held that the Equal Protection Clause prevents states from discriminating against individuals on the basis of sex, absent "an exceedingly persuasive" justification. *See United States v. Virginia*, 518 U.S. 515, 532-33 (1996) ("VMI"). Three courts of appeals – the Fourth, the Seventh, and the Eleventh Circuits—have held that classifications based on gender identity or transgender status warrant heightened scrutiny as a constitutional matter because they are classifications "on the basis of sex." *See Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 610-13 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *reh'g en banc denied*, 976 F.3d 399 (4th Cir. 2020), *petition for cert. filed*, No. 20-

1163 (Feb. 19, 2021); *Adams ex. rel. Kasper v. Sch. Bd. of St. Johns Cnty.*, 968 F.3d 1286, 1296 (11th Cir. 2020) ("discrimination against a transgender individual because of [his or] her gender-nonconformity is sex discrimination, whether it's described as being on the basis of sex or gender.") (quoting *Glenn v. Brumby*, 663 F.3d 1312, 1317 (11th Cir. 2011)), *petition for reh'g en banc pending*, No. 18-13592 (11th Cir. Aug. 28, 2020); *Whitaker By Whitaker ex rel. v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1051 (7th Cir. 2017).

Act 626 on its face discriminates on the basis of sex. Under the Act, transgender minors are singled out for different treatment based on the law's definition of sex, which is limited to what the State terms "biological sex." This classification alone, which "draw[s] distinctions using sex or gender . . . for differential treatment" triggers heightened scrutiny. *See Adams*, 968 F.3d at 1295 (citing *Cleburne*, 473 U.S. at 440). The Act uses the sex a person is assigned at birth to prohibit certain medical procedures. This is, by definition, sex discrimination. *See Bostock*, 140 S Ct. at 1741 (explaining that "if changing the employee's sex would have yielded a different choice by the employer . . . a statutory violation has occurred").

Act 626 forbids providing certain forms of care to minors based on sex alone when it permits a minor who was assigned the female sex at birth and identifies as female to receive care that would be denied to a minor who was assigned the male sex at birth but identifies as female (that is, who is transgender). A minor may not directly receive or be referred for care that includes any "gender transition procedure," that would "alter or remove physical characteristics or features" associated with the individual's "biological sex," as defined by the law, or those that "seek to . . . instill or create physiological or anatomical characteristics that resemble a sex different from the individual's biological sex." Act 626 § 3 (to be codified at Ark. Code Ann. 20-9-1501(6)(A)). This restriction applies only to minors who have a gender identity different than

their sex assigned at birth, i.e., transgender minors. However, minors can receive those same medical treatments if the treatments do not "alter . . . characteristics or features" associated with their "biological sex" as defined by the law. *Id.* For example, a minor whose assigned sex at birth was *male* can receive puberty-blocking medication to treat precocious puberty so that the minor can live as a boy, rather than prematurely experiencing sexual development. But a minor whose assigned sex at birth was *female* cannot receive puberty-blocking medication so that the minor can live as a boy, rather than developing the secondary sex characteristics of a woman. This difference in outcome is based solely on a difference in their sex assigned at birth.

When Arkansas differentiates in this way, it necessarily classifies these minors on the basis of sex. *See Flack v. Wis. Dep't of Health Servs.*, 328 F. Supp. 3d 931, 948 (W.D. Wis. 2018) (holding that insurer's denial of coverage for medically necessary care based on plaintiffs' sex assigned at birth was a "straightforward case of sex discrimination"); *see also Bostock*, 140 S. Ct. at 1746 ("By discriminating against transgender persons, the employer unavoidably discriminates against persons with one sex identified at birth and another today."); *Whitaker*, 858 F.3d at 1051 (school district's policy requiring students to use bathroom in accordance with the sex on the student's birth certificate "cannot be stated without referencing sex" and, therefore, "is inherently based upon a sex-classification and heightened review applies").

The State also discriminates against transgender minors for failing to conform to the sex- and gender-based stereotypes associated with the sex they were assigned at birth. As the Eleventh Circuit has explained, "discrimination against a transgender individual because of her gender-nonconformity is sex discrimination, whether it's described as being on the basis of sex or gender." *Glenn*, 663 F.3d at 1317. The law permits gender-affirming care when such care

reinforces the gender-based stereotypes associated with the individual's sex assigned at birth, but prohibits it when the gender-affirming care does not reinforce those gender-based stereotypes.

For example, the law would permit a minor whose sex assigned at birth was female to undergo a voluntary cosmetic breast augmentation procedure, but not allow a minor whose sex assigned at birth was male to undergo the same procedure – even when recommended as medically appropriate by a physician – simply because on the first minor, the procedure aligns with stereotypical notions of the minor's sex assigned at birth, while on the second minor, the same procedure does not. Similarly, the law would permit a doctor to prescribe testosterone to a minor whose sex assigned at birth was male for male hypogonadism, where the body produces insufficient testosterone, because that prescription aligns with gender-based stereotypes about what is considered "masculine." But a doctor would face professional reprimand and legal action for prescribing medically necessary testosterone to a minor whose sex assigned at birth was female because that prescription would undermine the gender-based stereotypes associated with his sex assigned at birth (or "femininity"). By deciding who receives medically prescribed care based on the State's definition of "biological sex," Arkansas's lawmakers are supplanting the medical judgment and expertise of the minors' treating healthcare providers with stereotypical beliefs about appropriate gender expression.

Relatedly, Act 626's carve-out for intersex[5] minors further confirms the law's reliance on gender-based stereotypes related to a minor's sex assigned at birth, and in fact undermines the law's underinclusive definition of "biological sex." Specifically, the law excludes from its prohibition any "services" to intersex minors, presumably when those procedures are intended to conform the minor's physical appearance to stereotypical expectations associated with the sex

[5] *See supra* n.4.

the minor was assigned at birth. Act 626 § 3 (to be codified at Ark. Code Ann. 20-9-1502(c)). There is no explanation or justification why these "services," explicitly deemed "not gender transition procedures," are permissible when considered to be medically necessary for intersex minors, but grounds for professional misconduct and civil litigation when provided to transgender minors. *See id.* Allowing these procedures for an intersex minor, but disallowing the same procedures prescribed by a medical professional to affirm a transgender minor's gender identity, constitutes a distinction based on impermissible gender and sex-based stereotypes.

B. Act 626 is subject to heightened scrutiny under the Equal Protection Clause because it discriminates on the basis of transgender status.

Prohibiting medically necessary care in the manner proscribed by Act 626 also discriminates against transgender minors on the basis of transgender status.

The text of Act 626 explicitly classifies transgender people for different treatment. The law's legislative findings make clear that the law specifically addresses "children who are gender-nonconforming" and who "experience distress at identifying with their biological sex." *Id.* § 2(3). It prohibits any healthcare professional from "provid[ing] gender transition procedures," or making a referral for the same, to any individual under eighteen years of age. *Id.* § 3 (to be codified at Ark. Code Ann. 20-9-1502(a), (b)). These "procedures" are defined as medical or surgical services that support a "gender transition," defined by the act as "the process in which a person goes from identifying with and living as a gender that corresponds to his or her biological sex to identifying with and living as a gender different from his or her biological sex." *Id.* (to be codified at Ark. Code Ann. 20-9-1501(5)). By definition, a transgender person is someone whose gender identity is inconsistent with their sex assigned at birth, and thus transgender people are the only class of people who would seek "gender transition" services. Act

626 requires that transgender minors, as a group, be treated differently from cisgender minors – and imposes significant penalties for violations of its provisions.

For example, similar to the example provided prior, *supra* Section I.A., if a medical doctor determines that two young people with the same sex assigned at birth should each be prescribed the same puberty-blocking medication, the doctor is permitted to prescribe such medication to the cisgender minor to suppress precocious puberty, but faces professional reprimand and legal liability for prescribing the *exact same* medication to a transgender minor even when the medication is necessary as a gender-affirming treatment.

The Supreme Court has analyzed four factors to determine whether a classification warrants heightened scrutiny: (1) whether the class has historically been subjected to discrimination, *see Lyng v. Castillo*, 477 U.S. 635, 638 (1986); (2) whether the class has a defining characteristic that "frequently bears no relation to ability to perform or contribute to society," *Cleburne*, 473 U.S. at 440-41 (quoting *Frontiero v. Richardson*, 411 U.S. 677, 686 (1973) (plurality opinion)); (3) whether the class has "obvious, immutable, or distinguishing characteristics that define them as a discrete group," *Lyng*, 477 U.S. at 638; and (4) whether the class is a minority lacking political power, *Bowen v. Gilliard*, 483 U.S. 587, 602 (1987). After evaluating the four factors as they relate to transgender people, both the Fourth and Ninth Circuits – the only circuits to have addressed this question to date – recognized transgender people as a quasi-suspect class under the Equal Protection Clause. *See Grimm*, 972 F.3d at 611 (finding "[e]ach factor readily satisfied" with regards to transgender people); *Karnoski v. Trump*, 926 F.3d 1180, 1200 (9th Cir. 2019) (upholding the district court's application of strict scrutiny after applying the factors to determine transgender people are a quasi-suspect class); *but cf. Brown v. Zavaras*, 63 F.3d 967, 971 (10th Cir. 1995) (recognizing that "sexual identity" may be

immutable but unable to evaluate the factors because of pro se plaintiff's conclusory allegations and following the since overruled holding in *Holloway v. Arthur Andersen & Co.*, 566 F.2d 659 (9th Cir. 1977), that transgender plaintiff not entitled to heightened scrutiny). Several district courts have concluded the same. *See, e.g.*, *F.V. v. Barron*, 286 F. Supp. 3d 1131, 1145 (D. Idaho 2018), decision clarified sub nom. *F.V. v. Jeppesen*, 466 F. Supp. 3d 1110 (D. Idaho 2020), and decision clarified sub nom. *F.V. v. Jeppesen*, 477 F. Supp. 3d 1144 (D. Idaho 2020); *Flack*, 328 F. Supp. 3d at 951–53; *M.A.B. v. Bd. of Educ. of Talbot Cnty.*, 286 F. Supp. 3d 704, 719-21 (D. Md. 2018); *Evancho v. Pine–Richland Sch. Dist.*, 237 F. Supp. 3d 267, 288 (W.D. Pa. 2017); *Bd. of Educ. of the Highland Loc. Sch. Dist. v. United States Dep't of Educ.*, 208 F. Supp. 3d 850, 873-74 (S.D. Ohio 2016); *Adkins v. City of New York*, 143 F. Supp. 3d 134, 139-140 (S.D.N.Y. 2015); *Norsworthy v. Beard*, 87 F. Supp. 3d 1104, 1119 (N.D. Cal. 2015). Although no Court within the Eighth Circuit has yet examined this question, each of the four factors supports a finding that transgender status warrants heightened scrutiny.

1. The class has been subjected to historical discrimination.

Even the most cursory study of the treatment of transgender individuals in the United States reveals that such individuals, as a class, have historically been subject to discrimination. *See Grimm*, 972 F.3d at 611-12; *Flack*, 328 F. Supp. 3d at 952-53; *M.A.B.*, 286 F. Supp. 3d at 720; *Evancho*, 237 F. Supp. 3d at 288; *Highland*, 208 F. Supp. 3d at 874; *Adkins*, 143 F. Supp. 3d at 139. As the court in *Whitaker* observed, "[t]here is no denying that transgender individuals face discrimination, harassment, and violence because of their gender identity." 858 F.3d at 1051. Transgender people experience higher levels of physical and sexual violence, harassment, and discrimination in the workplace, housing, healthcare, and school than their non-transgender counterparts. *See Karnoski v. Trump*, No. C-17-1297-MJP, 2018 WL 1784464 at *10 (W.D.

Wash. Apr. 13, 2018) (citing Sandy E. James et al., Nat'l Ctr. for Transgender Equal., *The Report of the 2015 U.S. Transgender Survey*, 132-34 (Dec. 2016), *available at* https://perma.cc/FC9M-4QZJ (hereinafter USTS Report)), *vacated on other grounds and remanded*, 926 F.3d 1180 (9th Cir. 2019). For example, nearly half (47%) of respondents to the 2015 USTS Report disclosed being sexually assaulted in their lifetime. USTS Report at 205. Rates of sexual assault of transgender people of color is even more pronounced, as this number increases to 65% for American Indian and Alaskan Native respondents, 59% for multiracial respondents, 58% for Middle Eastern respondents, and 53% for Black respondents. *Id.* In the healthcare setting, nearly one in four (23%) respondents reported delaying healthcare in the past year for fear of being mistreated, and one in three (33%) respondents who had seen a healthcare provider in the previous year reported at least one negative experience because of their real or perceived gender identity, including being verbally harassed, physically attacked, or sexually assaulted. *Id.* at 96-98.

Transgender people are not spared experiences of discrimination, harassment, and violence during childhood and adolescence. Seventy-seven percent (77%) of respondents to the USTS Report who had come out as transgender or were perceived as transgender in kindergarten through twelfth grade (K-12) reported at least one experience of "being verbally harassed, prohibited from dressing according to their gender identity, or physically or sexually assaulted" because of their real or perceived gender identity. USTS Report at 131; *see also Grimm*, 972 F.3d at 597. Nearly one in four (24%) of these respondents reported being physically attacked in K-12 because people thought they were transgender. USTS Report at 132. Experiences of discrimination among transgender minors are not limited to the education setting, as a recent study found 61% of transgender respondents ages thirteen to twenty-four who were employed

had experienced discrimination in the workplace. The Trevor Project, *Research Brief: LGBTQ Youth in the Workplace* 1 (Mar. 30, 2021), *available at* https://perma.cc/P73U-HSUB. Further, Arkansas is not the only state seeking to restrict the rights of transgender youth. Twenty states have introduced bills limiting the ability of transgender minors to access gender-affirming medical care; thirty-one states have introduced bills restricting the ability of transgender student athletes to compete on sports teams in accordance with their gender identity. *See* Priya Krishnakumar, *This Record-Breaking Year for Anti-Transgender Legislation Would Affect Minors the Most*, CNN (Apr. 15, 2021), *available at* https://perma.cc/AN6W-DF6F.

2. The class's defining characteristic has no relation to ability to contribute to society.

The second factor in assessing whether a classification warrants heightened scrutiny is whether the class has a defining characteristic that "bears [a] relation to ability to perform or contribute to society." *Cleburne*, 473 U.S. at 440-41 (internal quotation omitted). Transgender status bears no such relation. As the court in *Adkins* noted, there is no "data or argument suggesting that a transgender person, simply by virtue of transgender status, is any less productive than any other member of society." 143 F. Supp. 3d at 139. *Accord Grimm*, 972 F.3d at 612; *M.A.B.*, 286 F. Supp. 3d at 720; *Evancho*, 237 F. Supp. 3d at 288; *Highland*, 208 F. Supp. 3d at 874; *Norsworthy*, 87 F. Supp. 3d at 1119 n.8. The American Psychiatric Association (APA) has stated that "[b]eing transgender or gender diverse implies no impairment in judgment, stability, reliability, or general social or vocational capabilities." APA Assembly and Board of Trustees, *Position Statement on Discrimination Against Transgender and Gender Diverse Individuals* (2012, 2018). Indeed, the court in *M.A.B.* was unaware of any "argument suggesting that a transgender person or person experiencing gender dysphoria is any less productive than any other member of society." 286 F. Supp. 3d at 720. To the contrary, any impairment is likely

"the product of a long history of persecution forcing transgender people to live as those who they are not." *Adkins*, 143 F. Supp. 3d at 139.

3. The class shares characteristics that define them as a discrete group.

The third factor to consider is whether the class in question shares "obvious, immutable, or distinguishing characteristics that define them as a discrete group." *Bowen,* 483 U.S. at 602 (quoting *Lyng*, 477 U.S. at 638). Multiple courts have held that transgender status is immutable, and "being transgender is not a choice[,] [r]ather, it is as natural and immutable as being cisgender." *Grimm*, 972 F.3d at 612-13; *see also*, *M.A.B.*, 286 F. Supp. 3d at 720 ("transgender status is immutable"); *Evancho*, 237 F. Supp. 3d at 288 (plaintiffs' "transgender characteristics are inherent in who they are as people"); *Norsworthy*, 87 F. Supp. 3d at 1119 n.8 (finding transgender identity "equally immutable" as sexual orientation). Further, transgender people share a distinguishing characteristic – that their sex assigned at birth does not align with their gender identity. *M.A.B.*, 286 F. Supp. 3d at 721; *see also Highland*, 208 F. Supp. 3d at 874 ("transgender people have 'immutable [and] distinguishing characteristics that define them as a discrete group,' or as the Second Circuit put it in *Windsor*, 'the characteristic of the class calls down discrimination when it is manifest'") (quoting *Lyng*, 477 U.S. at 638; *Windsor v. United States*, 699 F.3d 169, 183 (2d Cir. 2012) (internal citations omitted), *aff'd*, 570 U.S. 744 (2013)); *Adkins*, 143 F. Supp. 3d at 139-140 ("mismatch between the gender indicated on the document and the gender of the holder calls down discrimination, among other problems").

4. The class is a minority lacking political power.

The final consideration is whether transgender people are a minority or lack political power. *Bowen*, 483 U.S. at 602 (quoting *Lyng*, 477 U.S. at 638). Transgender people meet both these criteria. *See Grimm*, 972 F.3d at 613 ("transgender people constitute a minority lacking

political power"). There is no question that transgender people comprise a small percentage of the United States population, with recent estimates that transgender individuals make up at 0.6% of the U.S. adult population. *Id.* This percentage is the same for Arkansas where an estimated 0.6% (13,400) of the population identify as transgender. Andrew R. Flores et al., *How Many Adults Identify as Transgender in the United States?* UCLA, Williams Inst., June 2016, at 3, *available at* https://perma.cc/ATR5-DKG5. In addition, while the number of openly transgender elected officials is growing, they still represent a fraction of public office holders. *Grimm*, 972 F.3d at 613 ("Even considering the low percentage of the population that is transgender, transgender persons are underrepresented in every branch of government."). There are over 500,000 elected positions at the federal, state, and local level. Jennifer Lawless, *Becoming a Candidate: Political Ambition and the Decision to Run for Office* 2 (2012). Openly transgender people hold thirty-nine (<0.008%) of these offices. Victory Institute, *Out for America*, *available at* https://perma.cc/E5H3-FJP6 (last visited June 16, 2021). Across the country, states are introducing and passing legislation aimed at restricting the rights of transgender individuals, particularly transgender minors. *See* discussion *supra* Part I.B.1. The limited political power and the resulting political vulnerability of the transgender community is undeniable.

Upon consideration of these factors, the court should conclude that transgender people are a quasi-suspect class entitled to heightened scrutiny.

II. Act 626 cannot survive heightened scrutiny because it is not substantially related to achieving Arkansas's articulated governmental interests.

Act 626 cannot survive heightened scrutiny. To survive a heightened scrutiny analysis, the government actor must show that the action in question "serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives." *See VMI*, 518 U.S. at 533 (quoting *Miss. Univ. for Women v.*

Hogan, 458 U.S. 718, 724 (1982)) (internal quotation marks omitted). "The burden of justification is demanding and it rests entirely on the State." *VMI*, 518 at 533 (citing *Miss. Univ. for Women*, 458 U.S. at 724). Heightened scrutiny requires that the justification proffered be "exceedingly persuasive." *Id.* at 531. The required inquiry provides an enhanced measure of protection in circumstances where there is a greater danger that the legal classification results from impermissible prejudice or stereotypes, *see, e.g.*, *City of Richmond v. J.A. Croson Co.*, 488 U.S. 469, 493 (1989) (plurality opinion), or those that reflect "a bare . . . desire to harm a politically unpopular group," *United States Dep't of Agric. v. Moreno*, 413 U.S. 528, 534 (1973). Act 626 cannot survive the rigorous analysis that heightened scrutiny demands.

Arkansas proffers the protection of the "health and safety of its citizens, especially vulnerable children" as its important governmental interest. Act 626 § 2(1). This justification is mere pretext for animus against transgender minors. When evaluating an articulated governmental interest, the "justification must be genuine, not hypothesized," and "must not rely on overbroad generalizations." *VMI*, 518 U.S. at 533; *see also Grimm*, 972 F.3d at 615 (holding that policy restricting access to restroom by "biological sex" is "marked by misconception and prejudice" against transgender plaintiff) (citation omitted); *Adams*, 968 F.3d at 1297 (holding that no substantial relationship existed between defendants' articulated justification and its policy because the concerns articulated by defendants were merely hypothesized, and because the policy treated transgender plaintiff differently "simply because he defies gender stereotypes"); *SmithKline Beecham Corp. v. Abbott Lab'ys*, 740 F.3d 471, 483 (9th Cir. 2014) (noting that the court must examine the law's "actual purposes and carefully consider the resulting inequality to ensure that our most fundamental institutions neither send nor reinforce messages of stigma or second-class status.") (citing *Windsor*, 570 U.S. 744)). A classification does not withstand

heightened scrutiny when "the alleged objective" of the classification differs from the "actual purpose." *Miss. Univ. for Women,* 458 U.S. at 730.

The State argues that this law is necessary to protect vulnerable children because the "risks of gender transition procedures far outweigh any benefit at this stage of clinical study." Act 626 § 2(15). This contention is both pretextual and factually incorrect, contradicted by the text of the law itself, by the lawmakers' statements, by the medical consensus around such care, and by the demonstrated negative impacts of denying gender-affirming, medically necessary care to vulnerable transgender minors.

First, this stated justification is pretextual. If the State's purported health-driven concerns regarding the medical risks of the procedures undertaken as part of gender-affirming care were genuine, the State would prohibit these procedures for all minors, whether they are transgender, cisgender, or intersex. But instead of adopting an across-the-board standard, the State has prohibited those treatments only when provided to a specific class of people – transgender minors. As discussed in the example above, testosterone may be prescribed to a cisgender boy for male hypogonadism, even though studies indicate that such treatment could also have a negative effect on fertility, yet a transgender boy may not be prescribed the same. *See* Jordan Cohen et al., *Low Testosterone in Adolescents & Young Adults*, 10 Frontiers in Endocrinology, Jan. 10, 2020, *available at* https://perma.cc/J7DD-AR3R. This singling out of transgender minors reveals that the purported neutral health-related justification is pretextual. *See Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 547 (1993) (observing that a state undermines its stated interest "when it leaves appreciable damage to that supposedly vital interest unprohibited") (internal quotation marks and citation omitted).

Further, legislative hearings on H.B. 1570 (now Act 626) demonstrate the legislature's bias. Across multiple days, the Arkansas House and Senate heard testimony from opponents of the bill – limited to two minutes per witness – ranging from medical professionals to transgender people themselves, discussing the detailed treatment protocols in place for transgender minors as well as the life-threatening effects of making gender-affirming care inaccessible. *See*, *e.g.*, *Hearing on H.B. 1570 Before the H. Pub. Health, Welfare, & Lab. Comm.*, 2021 Leg. 93rd Sess., March 9, 2021 at 4:54:55- 5:37:48 (Ark. 2021) (hereinafter Mar. 9 Hearing) (statements of Courtney Friarson, Gary Wheeler, Kristen Sowell, Lance Lavar, MD Hunter, Dr. Michele Hutchinson, Willow Bashirs, Chris Attig, Carmen Angelica), *available at* https://perma.cc/9MMK-B8QQ; *Hearing on H.B. 1570 Before the S. Pub. Health, Welfare, & Lab. Comm.*, 2021 Leg. 93rd Sess., Mar. 22, 2021 at 4:20:51-5:07:35 (Ark. 2021) (hereinafter Mar. 22 Hearing) (statements of Lance Lavar, Cash Ashley, Chris Attig, Courtney Friarson, Dr. Natalie Burr, Jennifer Steel, Joanna Brandt, Dr. Kathryn Stambough, Kristen Sowell, Genevieve Bergman, Stacy O'Brien, Willow Bashirs, MD Hunter, Elizabeth Barger, Dr. Michele Hutchinson), *available at* https://perma.cc/84UQ-MV5N. The two-minute time restriction reportedly resulted in multiple people with first-hand experience on the topic being cut-off mid-testimony. Yet, according to reports, such restrictions did not appear to apply to those witnesses presenting in favor of the bill. *See*, *e.g.*, Mar. 22 Hearing at 4:15:03 (Chair Sen. Cecile Bledsoe informing a witness speaking in favor of the bill that the two-minute restriction did not apply to him and that she would "love for [him] to go on."); Katie Eyer, *Why the Arkansas Ban on Medical Care for Transgender Kids Is Unconstitutional*, The Regulatory Review, May 4, 2021, *available at* https://perma.cc/UL94-ZW7V.

Statements of H.B. 1570 (now Act 626) co-sponsors also reveal that the true motivation driving this law is anti-transgender bias. For example, Representative Jim Wooten, when addressing concerns of transgender people, stated "what if your child comes to you and says I want to be a cow?" Andrew DeMillo, *Arkansas Lawmakers OK Transgender Sports, Treatment Limits*, Associated Press (Mar. 10, 2021), *available at* https://perma.cc/5CD8-MTWV. Representative Marcus Richmond has shared anti-transgender social media posts. *See* "Richmond 4 State Rep District 21," *Is that lunch he is holding?*, Facebook (Jan. 31, 2021), https://perma.cc/9FAX-WL6R (reposting image and comment regarding Dr. Rachel Levine, the current Assistant Secretary for Health at the U.S. Department of Health and Human Services, and a transgender woman, in which Dr. Levine is referred to by her previous name and male pronouns); Facebook (March 2, 2021), https://perma.cc/9G67-BELW (reposting cartoon denigrating gender-affirming care for minors, originally posted by Representative Alan Clark). The biases and moral disapproval articulated by the law and its sponsors are not justifiable reasons to legislate.[6] *See Lawrence v. Texas*, 539 U.S. 558, 577-78 (2003) (holding moral disapproval of same-sex sexual conduct and identity was impermissible basis for legislation); *see also Palmore v. Sidoti,* 466 U.S. 429, 433 (1984) (noting in the race context that "[t]he Constitution cannot control such prejudices but neither can it tolerate them. Private biases may be outside the reach of the law, but the law cannot, directly or indirectly, give them effect.").

Second, this justification lacks a scientific or other factual basis. Gender-affirming treatment is supported by medical evidence that has been subject to rigorous study. Indeed, every major expert medical association recognizes that gender-affirming care for transgender minors,

[6] Intermediate scrutiny is the appropriate level of review in this case. But even under rationality review, this statute would fail because bare dislike of an unpopular social group is never a legitimate legislative motive. *See Cleburne*, 473 U.S. at 446-47; *Moreno*, 413 U.S. at 534.

including forms of care prohibited by Act 626, may be medically appropriate and necessary to improve the physical and mental health of transgender people. Kellan E. Baker, *The Future of Transgender Coverage*, 376 New Eng. J. Med., 1801 (2017), *available at* https://perma.cc/DLU7-DA6V. The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (2013),[7] has also formally recognized that transgender people may experience gender dysphoria, a medical condition defined by "a marked incongruence between one's experienced/expressed gender and their assigned gender" that is "associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning." Gender-affirming health services for minors, such as puberty blockers and hormone therapies with testosterone or estrogen, can reduce dysphoria and improve other markers of well-being, such as quality of life, interpersonal and psychological functioning, and self-esteem. *See* National Academies of Sciences, Engineering, and Medicine, *Understanding the Well-Being of LGBTQI+ Populations* 363-64 (2020), *available at* https://perma.cc/77TP-L6DU. Additionally, studies show that suppressing development of secondary sex characteristics reduces the need for future surgery by preventing physical changes that are otherwise irreversible and allowing youth more time to explore their gender identity. *Id.*; Jason Raftery, et al., *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 Pediatrics No. 4 (Oct. 2018), *available at* https://perma.cc/L9X6-ALEP. By contrast, transgender minors who do not receive gender-affirming care face increased rates of victimization, suicide, substance abuse, and other potentially risky behavior. *See, e.g.*, U.S. Dep't Health & Human Servs. Weekly Morbidity and

[7] The Diagnostic and Statistical Manual of Mental Disorders is issued by the American Psychiatric Association and is a widely utilized and recognized resource for clinical practice used by mental health clinicians and researchers.

Mortality Rep. Vol. 68, *Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students — 19 States and Large Urban School Districts*, 2017, 67-71 (Jan. 25, 2019), *available at* https://perma.cc/N7TR-X6Q9. In short, the medical community is in overwhelming accord that gender-affirming care is clinically indicated.

Further, rather than being experimental, the care prohibited by Act 626 has been recognized as part of the standards of care by major medical associations. For example, the American Medical Association (AMA) recognizes that "standards of care and accepted medically necessary services that affirm gender or treat gender dysphoria may include mental health counseling, non-medical social transition, gender-affirming hormone therapy, and/or gender-affirming surgeries," and that "[e]very major medical association in the United States recognizes the medical necessity of transition-related care for improving the physical and mental health of transgender people." Letter from J. Madara, CEO, Am. Med. Ass'n to Bill McBride, Exec. Dir., Nat'l Governors Ass'n, Apr. 26, 2021 (hereinafter AMA Letter), *available at* https://perma.cc/3DG8-KXCE.[8]

Focusing on surgical treatments for minors like "genital or nongenital gender reassignment surgery" that are prohibited by Act 626 is a red herring. Act 626 § 3 (to be codified at Ark. Code Ann. 20-9-1501(6)(A)(ii)). In reality, those treatments are very rarely prescribed for transgender minors. In fact, treatment guidelines for children and adolescents require a

[8] *See also* "Frontline Physicians Call on Politicians to End Political Interference in the Delivery of Evidence Based Medicine," May 15, 2019 (statement issued on behalf of American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American College of Physicians, American Osteopathic Association, and American Psychiatric Association regarding state laws that "inappropriately interfere with the patient-physician relationship, unnecessarily regulate the evidence-based practice of medicine and, in some cases, even criminalize physicians who deliver safe, legal, and necessary medical care"), *available at* https://perma.cc/TR52-77XB (last visited June 16, 2021).

methodical, step-by-step treatment regimen that infrequently leads to surgery for minors. For example, the Endocrine Society sets specific, evidence-based clinical practice guidelines for gender dysphoric/gender-incongruent people, including specific recommendations for treatment of adolescents. Generally recommended treatment begins with hormone-suppression when a minor starts puberty. And the addition of gender-affirming hormones is only recommended "after a multidisciplinary team has confirmed the persistence of gender dysphoria/gender incongruence and [the transgender individual has] sufficient mental capacity to give informed consent" (which is estimated to be present by age 16). *See Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. of Clinical Endocrinology & Metabolism, 3869 (2017), as amended. Additionally, the current treatment guidelines, as found in the Standards of Care issued by the World Professional Association for Transgender Health (WPATH),[9] recommend against gender-affirming genital surgery until someone has reached the legal age of majority to give consent for medical procedures. *See* World Pro. Ass'n for Transgender Health, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Conforming People*, 7th ed. (2012). Indeed, Arkansas' officials' own words undermine the "grave concern" apparently prompting this law, instead showing Act 626 is a "solution" in search of a problem. Representative Robin Lundstrum, originator of the law, admitted she in fact does not know of a single genital reassignment surgery having been performed on a minor in the State. March 9 Hearing; 4:51:22 (statement of Rep. Lundstrum); *see also* Asa Hutchinson, Governor, State of Arkansas, Press Conf. Vetoing House

[9] WPATH is a professional association that develops "best practices and supportive policies" related to the health and treatment of transsexual, transgender, and gender nonconforming people.

Bill 1570 (Apr. 5, 2021) (hereinafter Hutchinson Press Conf.) ("In Arkansas, gender reassignment surgery is not performed on anyone under 18.").

Rather than rely on the judgment of medical professionals and evidence-based treatment guidelines, Arkansas has inserted itself within one of the most confidential and personal of relationships: the physician-patient relationship. The AMA calls state laws such as this one "a dangerous governmental intrusion into the practice of medicine." AMA Letter. In his statement vetoing the bill, Governor Hutchinson stated that should H.B. 1570 become law, it would create "new standards of legislative interference with physicians and parents . . . put[ting] the state as the definitive oracle of medical care, overriding parents, patients, and healthcare experts." Hutchinson Press Conf. Indeed, multiple healthcare professionals testified against H.B. 1570 when it was under consideration, highlighting the existing treatment guidelines and the potential of increased suicide rates among transgender minors should they be denied access to medically necessary care as a result of the bill's passage. Mar. 9 Hearing at 5:11:12 – 5:13:24 (statement of Dr. Michele Hutchinson); Mar. 22 Hearing at 4:30:19 – 4:32:36, 4:41:35 – 4:43:57, 5:01:25 – 5:05:53 (statements of Dr. Natalie Burr, Dr. Kathryn Stambough, Dr. Michele Hutchinson). The Arkansas chapter of the Academy of Pediatrics even organized a rally against passage of H.B. 1570. *See* Tristan Hill, *Arkansas Pediatricians Rally Against HB 1570*, KNWA FOX 24 (Apr. 3, 2021), *available at* https://perma.cc/3P9L-RDPY. Indeed, in response to a question from Representative Tippi McCullough, Representative Lundstrum admitted that she did not produce even one "Arkansas health care professional with experience and expertise in this issue" to speak in support of H.B. 1570. *H. Floor Sess. on H.B. 1570*, 2021 Leg. 93rd Sess., March 10, 2021 at 2:09:56, *available at* https://perma.cc/8XDL-X4PF.

Act 626 cannot survive heightened scrutiny because the State's articulated objectives are merely pretextual justifications lacking any scientific or factual basis. The law, which prohibits widely-accepted treatment protocols, would deny transgender minors medically necessary care solely based on their sex assigned at birth and their transgender status. If the State truly intended to protect "vulnerable" minors, it would not insert itself into the physician-patient relationship for purposes of depriving these minors' necessary and appropriate treatment.

CONCLUSION

Federal law bars the State of Arkansas from singling out transgender minors for specifically and discriminatorily denying their access to medically necessary care based solely on their sex assigned at birth. Such action would violate the Equal Protection Clause. By denying only transgender minors' access to medically necessary care, and penalizing the healthcare providers who would provide it, the State does not further its purported goal of protecting the "health and safety" of Arkansan minors but rather thwarts it by denying the most vulnerable among them life-saving care.

Respectfully submitted, this Seventeenth day of June, 2021.

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS

DYLAN BRANDT, *et al.*,	)
	)
Plaintiffs,	)
	)
vs.	) Case No. 4:21-cv-450-JM
	)
LESLIE RUTLEDGE, *et al.*,	)
	)
Defendants.	)

CERTIFICATE OF SERVICE

I hereby certify that on June 17, 2021, I submitted a paper copy of the attached Statement of Interest on behalf of the United States of America to the Clerk of the Court, and when it is entered into the CM/ECF system it will be served to all parties.

Respectfully submitted,

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Memorandum from the Centers for Medicare & Medicaid Services Regarding Suspension of Certain Provisions of the Patient Protection and Affordable Care Act	Centers for Medicare & Medicaid Services	CMS	June 20, 2020					
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The Impact of COVID-19 on the LGBTQ+ Community: A Comparison of Health-Centered, Harm-Reduction, Genetic, Cigarette, Social, and Minority Stress, and Global Mortality Trends	Natalie Pennington et al.	Elsevier Preprints & Research	2020	https://www.sciencedirect.com/science/article/pii/S2666560320300109	Public Citation			
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Venous blood gases found to perform equally for front-door screen for heart attack	Chris Hayes	Medscape Inc.	Jan. 11, 2017	https://www.medscape.com/viewarticle/874815?src=wnl_edit_tpal_mscape_cardio_170111_mscape_cardio_ACS_Venous_blood_gases_found_to_perform_equally_for_front_door_screen_for_heart_attack&uac=262552BZ&impID=1405104&faf=1	Check if immediate.			
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Audit Draft Lawsuit Cites Hospital Computer Model	Nanyra Gadgette	HealthLaw Civil Inst.	December 11, 2019					
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Transgender Airmen Can Undergo Medical Treatment for Surgery, Pentagon	Abigail Abrams	Time	Jun. 5, 2017	https://time.com/4810988/transgender-airmen-medical-treatment-surgery/	Check Cite Completed
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
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Health Conditions, Disparities, and Stressful Events Among Lesbian, Gay, Bisexual, Transgender, and Queer Adults in Colorado	Abigail A. Matthews et al.	Am. J. Public Health	[illegible]	[illegible]	Passed
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[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Absentee Ballot Fact Sheet	Wesley	N/A	[illegible]	https://www.wesleyhealthcare.com/documents/pdf/Absentee_Ballot_Fact_Sheet.pdf	Webpage
"Press 1 for English / Vaccination Sign-Up Phone Greeting in Spanish or Other Language"	Richard Pollack	Kaiser Health News	Mar. 23, 2021	https://khn.org/news/press-1-for-english-a-vaccination-sign-up-greeting-in-spanish-or-other-language/	
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Gender Dysphoria Treatment

Policy Number: CS145.M
Effective Date: March 1, 2023

➲ Instructions for Use

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Related Community Plan Policies

- Brow Ptosis and Eyelid Repair
- Botulinum Toxins A and B
- Cosmetic and Reconstructive Procedures
- Gonadotropin Releasing Hormone Analogs
- Panniculectomy and Body Contouring Procedures
- Rhinoplasty and Other Nasal Surgeries
- Speech Language Pathology Services

Commercial Policy

- Gender Dysphoria Treatment

Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Indiana	Gender Dysphoria Treatment (for Indiana Only)
Kentucky	None
Louisiana	Gender Dysphoria Treatment (for Louisiana Only)
Nebraska	None
New Jersey	Gender Dysphoria Treatment (for New Jersey Only)
North Carolina	None
Ohio	Gender Dysphoria Treatment (for Ohio Only)
Pennsylvania	Gender Dysphoria Treatment (for Pennsylvania Only)
Tennessee	None
Virginia	Virginia Medicaid Department of Medical Assistance Services: Bulletin > Coverage of Gender Dysphoria Services

Coverage Rationale

➲ See Benefit Considerations

Note: This Medical Policy does not apply to individuals with ambiguous genitalia or disorders of sexual development.

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Surgical treatment for Gender Dysphoria may be indicated for individuals who provide the following documentation:

- For breast surgery, a written psychological assessment from at least one Qualified Behavioral Health Provider experienced in treating Gender Dysphoria* is required. The assessment must document that an individual meets all of the following criteria:
  - Persistent, well-documented Gender Dysphoria
  - Capacity to make a fully informed decision and to consent for treatment
  - Must be at least 18 years of age (age of majority)
  - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
- For genital surgery, a written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender Dysphoria*, who have independently assessed the individual, is required. The assessment must document that an individual meets all of the following criteria:
  - Persistent, well-documented Gender Dysphoria
  - Capacity to make a fully informed decision and to consent for treatment
  - Must be at least 18 years of age (age of majority)
  - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
  - Complete at least 12 months of successful continuous full-time real-life involvement in the experienced gender
  - Complete 12 months of continuous hormone therapy appropriate for the experienced gender (unless medically contraindicated)
- Treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Provider experienced in treating Gender Dysphoria*

When the above criteria are met, the following surgical procedures to treat Gender Dysphoria are medically necessary and covered as a proven benefit:

- Bilateral mastectomy or breast reduction*
- Clitoroplasty (creation of clitoris)
- Hysterectomy (removal of uterus)
- Labiaplasty (creation of labia)
- Laser or electrolysis hair removal in advance of genital reconstruction prescribed by a physician for the treatment of Gender Dysphoria
- Metoidioplasty (creation of penis, using clitoris)
- Orchiectomy (removal of testicles)
- Penectomy (removal of penis)
- Penile prosthesis
- Phalloplasty (creation of penis)
- Salpingo-oophorectomy (removal of fallopian tubes and ovaries)
- Scrotoplasty (creation of scrotum)
- Testicular prostheses
- Urethroplasty (reconstruction of female urethra)
- Urethroplasty (reconstruction of male urethra)
- Vaginectomy (removal of vagina)
- Vaginoplasty (creation of vagina)
- Vulvectomy (removal of vulva)

*When bilateral mastectomy or breast reduction is performed as a stand-alone procedure, without genital reconstruction procedures, completion of hormone therapy prior to the breast procedure is not required.

Certain ancillary procedures, including but not limited to the following, are considered cosmetic and not medically necessary, when performed as part of surgical treatment for Gender Dysphoria (check the federal, state or contractual requirements for benefit coverage**):

Refer to the Benefit Considerations section as member specific benefit plan language may vary.

- Abdominoplasty (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures)

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- Blepharoplasty (also refer to the Medical Policy titled Brow Ptosis and Eyelid Repair)
- Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures)
- Breast enlargement, including augmentation mammaplasty and breast implants
- Brow lift
- Calf implants
- Cheek, chin and nose implants
- Face/forehead lift and/or neck tightening
- Facial bone remodeling for facial feminization
- Hair transplantation
- Injection of fillers or neurotoxins (also refer to the Medical Benefit Drug Policy titled Botulinum Toxins A and B)
- Laser or electrolysis hair removal not related to genital reconstruction
- Lip augmentation
- Lip reduction
- Liposuction (suction-assisted lipectomy) (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures)
- Mastopexy
- Pectoral implants for chest masculinization
- Rhinoplasty (also refer to the Medical Policy titled Rhinoplasty and Other Nasal Surgeries)
- Skin resurfacing (e.g., dermabrasion, chemical peels, laser)
- Thyroid cartilage reduction/reduction thyroid chondroplasty/trachea shave (removal or reduction of the Adam's apple)
- Voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords)
- Voice lessons and voice therapy

**Note: For New York plans, refer to the Benefit Considerations section for more information.

Definitions

Gender Dysphoria in Adolescents and Adults: A disorder characterized by the following diagnostic criteria [Diagnostic and Statistical Manual of Mental Disorders, 5th edition, Text Revison (DSM-5-TR™)]:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:
   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
   3. A strong desire for the primary and/or secondary sex characteristics of the other gender
   4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).
B. The condition is associated with clinically significant distress or impairment in social, occupational or other important areas of functioning.

Gender Dysphoria in Children: A disorder characterized by the following diagnostic criteria [Diagnostic and Statistical Manual of Mental Disorders, 5th edition, Text Revision (DSM-5-TR™)]:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be criterion A1):
   1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
   2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.

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3. A strong preference for cross-gender roles in make-believe play or fantasy play.
4. A strong preference for the toys, games or activities stereotypically used or engaged in by the other gender.
5. A strong preference for playmates of the other gender.
6. In boys (assigned gender), a strong rejection of typically masculine toys, games and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games and activities.
7. A strong dislike of ones' sexual anatomy.
8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.

B. The condition is associated with clinically significant distress or impairment in social, school or other important areas of functioning.

Qualified Behavioral Health Provider:

- Recommended minimum credentials for behavioral health providers working with adults presenting with gender dysphoria [World Professional Association for Transgender Health (WPATH) Guidelines, version 7, 2012]:
  - A minimum of a master's degree or its equivalent in a clinical behavioral science field. This degree should be granted by an institution accredited by the appropriate national or regional accrediting board. The behavioral health provider should have documented credentials from a relevant licensing board;
  - Competence in using the current version of the Diagnostic Statistical Manual of Mental Disorders (DSM) and/or the International Classification of Diseases (ICD) for assessment and diagnostic purposes;
  - Ability to recognize and diagnose coexisting mental health concerns and to distinguish these from gender dysphoria;
  - Documented supervised training and competence in psychotherapy or counseling;
  - Knowledgeable about gender nonconforming identities and expressions, and the evaluation and treatment of gender dysphoria;
  - Continuing education in the assessment and treatment of gender dysphoria;
  - Develop and maintain cultural competence to facilitate their work with transsexual, transgender, and gender nonconforming clients.
- Recommended minimum credentials for behavioral health providers working with children or adolescents presenting with gender dysphoria (WPATH Guidelines, version 7, 2012):
  - Meet the competency requirements for behavioral health providers working with adults, as outlined above;
  - Trained in childhood and adolescent developmental psychopathology;
  - Competent in diagnosing and treating the ordinary problems of children and adolescents.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
11950	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (e.g., collagen); over 10.0 cc
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
15734	Muscle, myocutaneous, or fasciocutaneous flap; trunk
15738	Muscle, myocutaneous, or fasciocutaneous flap; lower extremity
15750	Flap; neurovascular pedicle

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CPT Code	Description
15757	Free skin flap with microvascular anastomosis
15758	Free fascial flap with microvascular anastomosis
15769	Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
15780	Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (e.g., tattoo removal)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal
15793	Chemical peel, nonfacial; dermal
15819	Cervicoplasty
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
15824	Rhytidectomy; forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area

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CPT Code	Description
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
17380	Electrolysis epilation, each 30 minutes
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19303	Mastectomy, simple, complete
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (e.g., wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft (includes obtaining autograft)
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (e.g., plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
21899	Unlisted procedure, neck or thorax
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip

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CPT Code	Description
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
31599	Unlisted procedure, larynx
31899	Unlisted procedure, trachea, bronchi
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
53430	Urethroplasty, reconstruction of female urethra
54125	Amputation of penis; complete
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54406	Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis
54408	Repair of component(s) of a multi-component, inflatable penile prosthesis
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54660	Insertion of testicular prosthesis (separate procedure)
54690	Laparoscopy, surgical; orchiectomy
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
55970	Intersex surgery; male to female
55980	Intersex surgery; female to male
56625	Vulvectomy simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57110	Vaginectomy, complete removal of vaginal wall
57335	Vaginoplasty for intersex state
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)

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CPT Code	Description
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250 g or less;
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58290	Vaginal hysterectomy, for uterus greater than 250 g
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral
64856	Suture of major peripheral nerve, arm or leg, except sciatic; including transposition
64892	Nerve graft (includes obtaining graft), single strand, arm or leg; up to 4 cm length
64896	Nerve graft (includes obtaining graft), multiple strands (cable), hand or foot; more than 4 cm length
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals

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Diagnosis Code	Description
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
Z87.890	Personal history of sex reassignment

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Description of Services

Gender Dysphoria is a condition in which there is a marked incongruence between an individual's experienced/expressed/alternative gender and assigned gender (DSM-5-TR). Treatment options include behavioral therapy, psychotherapy, hormone therapy, and surgery for gender transformation. Surgical treatments for gender dysphoria may include the following: clitoroplasty, hysterectomy, labiaplasty, mastectomy, orchiectomy, penectomy, phalloplasty or metoidioplasty (alternative to phalloplasty), placement of testicular and/or penile prostheses, salpingo-oophorectomy, scrotoplasty, urethroplasty, urethroplasty, vaginectomy, vaginoplasty and vulvectomy.

Other terms used to describe surgery for gender dysphoria include gender affirming surgery, sex transformation surgery, sex change, sex reversal, gender change, transsexual surgery, transgender surgery, and sex reassignment.

Benefit Considerations

Coverage Information

Benefit coverage for health services is determined by the federal, state or contractual requirements that may require coverage for a specific service.

Unless otherwise specified, if a plan covers treatment for Gender Dysphoria, coverage includes psychotherapy, hormone therapy, puberty suppressing medications and laboratory testing to monitor the safety of hormone therapy. This benefit also includes certain surgical treatments listed in the Coverage Rationale section. Refer to the Medical Benefit Drug Policy titled Gonadotropin Releasing Hormone Analogs.

Limitations and Exclusions

Certain treatments and services are not covered. Examples include, but are not limited to:

- Treatment received outside of the United States
- Reproduction services, including, but not limited to, sperm preservation in advance of hormone treatment or Gender Dysphoria surgery, cryopreservation of fertilized embryos, oocyte preservation, surrogate parenting, donor eggs, donor sperm and host uterus (refer to the federal, state or contractual requirements for benefit coverage)
- Transportation, meals, lodging or similar expenses
- Cosmetic procedures (refer to the Medical Policy titled Cosmetic and Reconstructive Procedures and the Coverage Rationale section). Refer to the section below for additional information on New York plans
- Reversal of genital surgery or reversal of surgery to revise secondary sex characteristics

Coverage does not apply to members who do not meet the indications listed in the Coverage Rationale section above.

For New York Plans Only

Certain ancillary procedures may be considered cosmetic and not medically necessary when performed as part of surgical treatment for Gender Dysphoria. Clinical review for medical necessity of ancillary procedures is conducted on a case-by-case basis.

Clinical Evidence

Almazan et al. (2021) conducted a secondary analysis of the 2015 United States Transgender Survey (USTS) that included 27,715 transgender and gender diverse (TGD) people to evaluate whether gender-affirming surgeries were associated with better mental health outcomes including psychological distress, substance use and suicide risk when compared to TGD people who do not undergo gender-affirming surgeries. The survey was conducted across all 50 states, Washington, DC, U.S. territories and U.S. military bases abroad. The exposure group included respondents who indicated they had undergone 1 or more gender-affirming surgeries at least 2 years prior to submitting survey responses. This group was compared to respondents who indicated a desire to undergo 1 or more types of gender-affirming surgeries but denied having had any gender-affirming surgeries. Of the 27,715 respondents, 3,559 (12.8%) indicated they had undergone 1 or more gender-affirming surgeries at least 2 years prior to the survey while 59.2% (n = 16,401) indicated a desire to undergo a gender-affirming surgery but had not done so as of the time they responded to the survey. Demographics of the respondents to the survey showed that

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81.1% (n = 16,182) were between the ages of 18 and 44 years, 82.1% (n = 16,386) identified as white, 38.8% (n = 7,751) identified as transgender women, 32.5% (n = 6,489) identified as transgender men and 26.6% (n = 5,300) identified as nonbinary. After adjusting for sociodemographic factors, the authors concluded that the analysis showed TGD people with a history of gender-affirming surgery had significantly lower odds of past-month psychological distress, past-year tobacco smoking, and past-year suicidal ideation compared with TGD people who did not have any gender-affirming surgery. Limitations noted by the authors included the nonprobability sampling of the database, the self-reporting structure of the measures, and the risk of confounding. The authors concluded that the study showed a positive association between gender-affirming surgery and improved mental health outcomes for TGD people who seek gender affirming surgical interventions.

Scandurra et al. (2019) performed a systematic review assessing the health of nonbinary and genderqueer (NBGQ) individuals compared to binary transgender (BT) and cisgender individuals. Eleven studies were included in the review. Results related to the difference in health between NBGQ and BT were mixed, with some finding a better health status while others a worse one. Results related to the differences in health between NBGQ and cisgender individuals highlighted higher health needs in NBGQ individuals compared with cisgender counterparts. The authors noted the need for research expansion in terms of both methodology and research contents.

Wernick et al. (2019) conducted a systematic review of the psychological benefits of gender-affirming surgery. Thirty-three studies were included in the analysis. Overall, most of the studies comparing pre- and post-operative data on quality of life, body image/satisfaction, and overall psychological functioning among individuals with gender dysphoria suggested that gender-affirming surgery leads to multiple, significant psychological benefits. Of the studies comparing psychological well-being between individuals who did or did not undergo surgery, most demonstrated a trend of better mental health among individuals who underwent surgery compared with those who did not. The authors encouraged future research to focus on standardizing the assessment of psychological functioning pre- and post-gender-affirming surgery to gather longitudinal data that will allow for more definitive conclusions to be made about factors that contribute to the psychological benefits of surgery.

Cohen et al. (2019) conducted a systematic review of surgical options and associated outcomes for transmasculine top surgery. Twenty-two studies were included (n = 2,447). The authors reported that future research is needed to improve patient selection, surgical decision making, and patient-reported outcomes for different chest contouring techniques.

Mahfouda et al. (2019) conducted a systematic review of the available published evidence on gender-affirming hormone and surgical interventions in transgender children and adolescents, amalgamating findings on mental health outcomes, cognitive and physical effects, side-effects, and safety variables. The small amount of available data suggest that when clearly indicated in accordance with international guidelines, gender-affirming hormone therapy and chest wall masculinization in transgender males are associated with improvements in mental health and quality of life. Evidence regarding surgical vaginoplasty in transgender females younger than age 18 years remains extremely scarce and conclusions cannot yet be drawn regarding its risks and benefits in this age group. Further research on an international scale is urgently warranted to clarify long-term outcomes on psychological functioning and safety.

A Hayes report on sex reassignment surgery (2018; updated 2021) for the treatment of gender dysphoria made the following conclusions:

- Studies suggest that following sex reassignment surgery, patients reported decreased gender dysphoria and improved body image satisfaction. However, results were mixed regarding effects of sex reassignment surgery on quality of life and psychological symptoms.
- Few studies compare outcomes in patients who received sex reassignment surgery with stand-alone hormone therapy. The results of these studies suggest that sex reassignment surgery may improve gender dysphoria, quality of life, body image and psychological symptoms to a greater extent than hormone therapy alone. However, the results were conflicting.
- Few studies compared outcomes in patients who received different components of sex reassignment surgery. For most outcome measures, there was only a single study available. This evidence is therefore insufficient to support definitive conclusions regarding the comparative effectiveness of different components of sex reassignment surgery for treating gender dysphoria.
- Not all studies reported all outcomes; the following findings therefore do not inform overall incidence of complications. Following sex reassignment surgery, there were very low rates of regret of surgery (0% to 6% per study) and suicide (2% to 3% per study). Complications following sex reassignment surgery were common, and some were serious.

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Dreher et al. (2018) conducted a systematic review and meta-analysis to evaluate the epidemiology, presentation, management, and outcomes of neovaginal complications in the MtF transgender reassignment surgery patients. Selected studies reported on 1,684 patients with an overall complication rate of 32.5% and a reoperation rate of 21.7% for non-esthetic reasons. The most common complication was stenosis of the neo-meatus (14.4%). Wound infection was associated with an increased risk of all tissue-healing complications. Use of sacrospinous ligament fixation (SSL) was associated with a significantly decreased risk of prolapse of the neovagina. The authors concluded that gender-affirmation surgery is important in the treatment of gender dysphoric patients, but there is a high complication rate in the reported literature. Variability in technique and complication reporting standards makes it difficult to assess the accurately the current state of MtF gender reassignment surgery. Further research and implementation of standards is necessary to improve patient outcomes.

Manrique et al (2018) conducted a systematic review of retrospective studies on the outcomes of MtF vaginoplasty to minimize surgical complications and improve patient outcomes for transgender patients. Forty-six studies met the authors eligibility criteria. A total of 3,716 cases were analyzed. The results showed the overall incidence of complications as follows: 2% fistula, 14% stenosis and strictures, 1% tissue necrosis, and 4% prolapse. Patient-reported outcomes included a satisfaction rate of 93% with overall results, 87% with functional outcomes, and 90% with esthetic outcomes. Ability to have orgasm was reported in 70% of patients. The regret rate was 1%. The authors concluded that multiple surgical techniques have demonstrated safe and reliable means of MtF vaginoplasty with low overall complication rates and with a significant improvement in the patient's quality of life. Studies using different techniques in a similar population and standardized patient-reported outcomes are required to further analyze outcomes among the different procedures and to establish best-practice guidelines.

Van Damme et al. (2017) conducted a systematic review of the effectiveness of pitch-raising surgery performed in MtF transsexuals. Twenty studies were included: eight using cricothyroid approximation, six using anterior glottal web formation and six using other surgery types or a combination of surgical techniques. A substantial rise in postoperative frequency was identified. The majority of patients seemed satisfied with the outcome. However, none of the studies used a control group and randomization process. Further investigation regarding long-term results using a stronger study design is necessary.

Gaither et al. (2017) retrospectively reviewed the records of 330 MtF patients from 2011 to 2015, to assess surgical complications related to primary penile inversion vaginoplasty. Complications included granulation tissue, vaginal pain, wound separation, labial asymmetry, vaginal stenosis, fistula formation, urinary symptoms including spraying stream or dribbling, infection, vaginal fissure or vaginal bleeding. Median age at surgery was 35 years, and median follow-up in all patients was 3 months. The results showed that 95 of the patients presented with a postoperative complication with the median time to a complication being 4.4 months. Rectoneovaginal fistulas developed in 3 patients, and 30 patients required a second operation. Age, body mass index and hormone replacement therapy were not associated with complications. The authors concluded that penile inversion vaginoplasty is a relatively safe procedure. Most complications due to this surgery develop within the first 4 months postoperatively. Age, body mass index and hormone replacement therapy are not associated with complications and, thus, they should not dictate the timing of surgery.

An ECRI special report systematically reviewed the clinical literature to assess the efficacy of treatments for gender dysphoria. The authors identified limited evidence from mostly low-quality retrospective studies. Evidence on gender reassignment surgery was mostly limited to evaluations of MtF individuals undergoing vaginoplasty, facial feminization surgery and breast augmentation. Outcomes included mortality, patient satisfaction, physical well-being, psychological-related outcomes, quality of life, sexual-related outcomes, suicide and adverse events. Concluding remarks included the need for standardized protocols and prospective studies using standardized measures for correct interpretation and comparability of data (ECRI, 2016).

Morrison et al. (2016) conducted a systematic review of the facial feminization surgery literature. Fifteen studies were included, all of which were either retrospective or case series/reports. The studies covered a variety of facial feminization procedures. A total of 1,121 patients underwent facial feminization surgery, with seven complications reported, although many studies did not explicitly comment on complications. Satisfaction was high, although most studies did not use validated or quantified approaches to address satisfaction. The authors noted that further studies are needed to better compare different techniques to more robustly establish best practices. Prospective studies and patient-reported outcomes are needed to establish quality of life outcomes for patients.

Frey et al. (2016) conducted a systematic review of metoidioplasty and radial forearm flap phalloplasty (RFFP) in FtM transgender genital reconstruction. Eighteen studies were included: 7 for metoidioplasty and 11 for RFFP. The quality of evidence was low to very low for all included studies. In studies examining metoidioplasty, the average study size and length of

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follow-up were 54 patients and 4.6 years, respectively [1 study did not report (NR)]. Eighty-eight percent underwent a single-stage reconstruction, 87% reported an aesthetic neophallus (3 NR) and 100% reported erogenous sensation (2 NR). Fifty-one percent of patients reported successful intercourse (3 NR) and 89% of patients achieved standing micturition (3 NR). In studies examining RFFP, the average study size and follow-up were 60.4 patients and 6.23 years, respectively (6 NR). No patients underwent single-stage reconstructions (8 NR). Seventy percent of patients reported a satisfactorily aesthetic neophallus (4 NR) and 69% reported erogenous sensation (6 NR). Forty-three percent reported successful penetration of partner during intercourse (6 NR) and 89% achieved standing micturition (6 NR). Compared with RFFP, metoidioplasty was significantly more likely to be completed in a single stage, have an aesthetic result, maintain erogenous sensation, achieve standing micturition and have a lower overall complication rate. The authors reported that, although the current literature suggests that metoidioplasty is more likely to yield an "ideal" neophallus compared with RFFP, any conclusion is severely limited by the low quality of available evidence.

Using a retrospective chart review, Buncamper et al. (2016) assessed surgical outcome after penile inversion vaginoplasty. Outcome measures were intraoperative and postoperative complications, reoperations, secondary surgical procedures and possible risk factors. Of 475 patients who underwent the procedure, 405 did not have additional full-thickness skin grafts while 70 did have grafts. Median follow-up was 7.8 years. The most frequently observed intraoperative complication was rectal injury (2.3 percent). Short-term postoperative bleeding that required transfusion (4.8 percent), reoperation (1.5 percent) or both (0.4 percent) occurred in some cases. Major complications were three (0.6 percent) rectoneovaginal fistulas, which were successfully treated. Revision vaginoplasty was performed in 14 patients (2.9 percent). Comorbid diabetes was associated with a higher risk of local infection, and use of psychotropic medication predisposed to postoperative urinary retention. Successful vaginal construction without the need for secondary functional reoperations was achieved in the majority of patients.

Bouman et al. (2016) prospectively assessed surgical outcomes of primary total laparoscopic sigmoid vaginoplasty in 42 transgender women with penoscrotal hypoplasia. Mean follow-up time was 3.2 ±2.1 years. The mean operative duration was 210 ±44 minutes. There were no conversions to laparotomy. One rectal perforation was recognized during surgery and immediately oversewn without long-term consequences. The mean length of hospitalization was 5.7 ±1.1 days. One patient died as a result of an extended-spectrum beta-lactamase-positive necrotizing fasciitis leading to septic shock, with multiorgan failure. Direct postoperative complications that needed laparoscopic reoperation occurred in three cases (7.1 percent). In seven cases (17.1 percent), long-term complications needed a secondary correction. After 1 year, all patients had a functional neovagina with a mean depth of 16.3 ±1.5 cm.

Despite the significant increase in genital gender affirming surgery (GAS) within the past 50 years, there is limited data regarding hair removal practices in preparation for genital GAS. Genital GAS involves reconstruction of the genitals to match a patient's identified sex. The use of hair-bearing flaps in this procedure may result in postoperative intra-vaginal and intra-urethral hair growth and associated complications, including lower satisfaction with genital GAS. In 2016, Zhang et al. conducted a literature review, recommendations from experience, and a practical laser hair removal (LHR) approach to hair removal prior to genital GAS.

Horbach et al. (2015) conducted a systematic review of vaginoplasty techniques in MtF individuals with gender dysphoria. Twenty-six studies were included (mostly retrospective case series of low to intermediate quality). Outcome of the penile skin inversion technique was reported in 1,461 patients and bowel vaginoplasty in 102 patients. Neovaginal stenosis was the most frequent complication in both techniques. Sexual function and patient satisfaction were overall acceptable, but many different outcome measures were used. Ouality of life was only reported in one study. Comparison between techniques was difficult due to the lack of standardization. The authors concluded that the penile skin inversion technique is the most researched surgical procedure. Outcome of bowel vaginoplasty has been reported less frequently but does not seem to be inferior. The available literature is heterogeneous in patient groups, surgical procedure, outcome measurement tools and follow-up. There is a need for prospective studies with standardized surgical procedures, larger patient groups and longer follow-up periods. Uniformity in outcome measurement tools such as validated questionnaires and scores for sexual function and quality of life is mandatory for correct interpretation and comparability of data.

Bouman et al. (2014) conducted a systematic review of surgical techniques and clinical outcomes of intestinal vaginoplasty. Twenty-one studies were included (n = 894). All studies had a retrospective design and were of low quality. Prevalence and severity of procedure-related complications were low. The main postoperative complication was introital stenosis, necessitating surgical correction in 4.1% of sigmoid-derived and 1.2% of ileum-derived vaginoplasties. Neither diversion colitis nor cancer was reported. Sexual satisfaction rate was high, but standardized questionnaires were rarely used. Quality of life was not reported.

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The authors concluded that prospective studies, using standardized measures and questionnaires, are warranted to assess functional outcomes and quality of life.

Djordjevic et al. (2013) evaluated 207 patients who underwent single-stage metoidioplasty, comparing two different surgical techniques of urethral lengthening. The procedure included lengthening and straightening of the clitoris, urethral reconstruction and scrotoplasty with implantation of testicular prostheses. Buccal mucosa graft was used in all cases for dorsal urethral plate formation and joined with one of the two different flaps: longitudinal dorsal clitoral skin flap (n = 49) (group 1) and labia minora flap (n = 158) (group 2). The median follow-up was 39 months. The total length of reconstructed urethra ranged from 9.1 to 12.3 cm in group 1 and from 9.4 to 14.2 cm in group 2. Voiding while standing was significantly better in group 2 (93%) than in group 1 (87.82%). Urethral fistula occurred in 16 patients in both groups. Overall satisfaction was noted in 193 patients. The authors concluded that combined buccal mucosa graft and labia minora flap was the method of choice for urethroplasty in metoidioplasty, minimizing postoperative complications.

In a non-randomized study, Dhejne et al. (2011) evaluated mortality, morbidity and criminal rates after gender reassignment surgery in 324 individuals (MtF n = 191; FtM n = 133). Random population controls (10:1) were matched by birth year and birth sex or reassigned final sex. The authors reported substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts and psychiatric hospitalizations in sex-reassigned individuals (both MtF/FtM) compared to a healthy control population. FtMs had a higher risk for criminal convictions.

Murad et al. (2010) conducted a systematic review to evaluate the effects of hormone therapy on patients undergoing gender reassignment surgery. The authors identified 28 eligible studies, all of which were observational and most lacked controls. These studies enrolled 1,833 participants with gender dysphoria (1,093 MtF; 801 FtM). After gender reassignment surgery, individuals reported improvement in gender dysphoria (80%), psychological symptoms (78%), sexual function (72%) and quality of life (80%). The authors concluded that very low quality evidence suggests that gender reassignment, that includes hormonal interventions, is likely to improve gender dysphoria, psychological functioning and comorbidities, sexual function and overall quality of life.

Sutcliffe et al. (2009) systematically reviewed five individual procedures for MtF gender reassignment surgery: clitoroplasty, labiaplasty, orchiectomy, penectomy and vaginoplasty. Further evaluations were made of eight surgical procedures for FtM gender reassignment surgery: hysterectomy, mastectomy, metoidioplasty, phalloplasty, salpingo-oophorectomy, scrotoplasty/placement of testicular prostheses, urethroplasty and vaginectomy. Eighty-two published studies (38 MtF; 44 FtM) were included in the review. For MtF procedures, the authors found no evidence that met the inclusion criteria concerning labiaplasty, penectomy or orchiectomy. A large amount of evidence was available concerning vaginoplasty and clitoroplasty procedures. The authors reported that the evidence concerning gender reassignment surgery in both MtF and FtM individuals with gender dysphoria has several limitations including lack of controlled studies, lack of prospective data, high loss to follow-up and lack of validated assessment measures. Some satisfactory outcomes were reported, but the magnitude of benefit and harm for individual surgical procedures cannot be estimated accurately using the current available evidence.

World Professional Association for Transgender Health (WPATH)

WPATH, formerly known as the Harry Benjamin International Gender Dysphoria Association, is an advocacy group devoted to transgender health. WPATH guidelines (2012) present eligibility and readiness criteria for transition-related treatment, as well as competencies of health care providers. WPATH is currently reviewing their Standards of Care with an anticipated release date for their update of 2022.

WPATH describes the transition from one gender to another in the following three stages:

- Living in the gender role consistent with gender identity
- The use of hormone therapy after living in the new gender role for a least three months
- Gender-affirmation surgery after living in the new gender role and using hormonal therapy for at least 12 months

Clinical Practice Guidelines

American Academy of Pediatrics (AAP)

In a 2018 policy statement entitled Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents, the AAP states the following regarding surgery: Surgical approaches may be used to feminize or masculinize features, such as hair distribution, chest, or genitalia, and may include removal of internal organs, such as ovaries or the uterus

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(affecting fertility). These changes are irreversible. Although current protocols typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family (Rafferty et al, 2018).

American College of Obstetrics and Gynecology (ACOG)

An ACOG committee opinion (2021) provides guidance on health care for transgender and gender diverse individuals. The document does not make specific recommendations regarding surgery but does provide an overview of surgical procedures and education for clinicians who care for transgender patients before and after surgery.

Endocrine Society

Endocrine Society practice guidelines (Hembree et al., 2017) addressing endocrine treatment of gender-dysphoric/ gender-incongruent persons makes the following recommendations regarding surgery for sex reassignment and gender confirmation:

- Suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country (Recommendation based on low quality evidence).
- A patient pursue genital gender-affirming surgery only after the mental health practitioner (MHP) and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being (Strong recommendation based on low quality evidence).
- Surgery is recommended only after completion of at least one year of consistent and compliant hormone treatment unless hormone therapy is not desired or medically contraindicated (Ungraded Good Practice Statement).
- The physician responsible for endocrine treatment medically clears individual for surgery and collaborates with the surgeon regarding hormone use during and after surgery (Ungraded Good Practice Statement).
- Recommend that clinicians refer hormone treated transgender individuals for genital surgery when (Strong recommendation based on very low quality evidence):
  - The individual has had a satisfactory social role change
  - The individual is satisfied about the hormonal effects
  - The individual desires definitive surgical changes
- Suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement (Recommendation based on very low quality evidence)

University of California, San Francisco (UCSF) Center of Excellence for Transgender Health

The UCSF Center of Excellence evidence-based guidelines for the primary and gender-affirming care of transgender and gender nonbinary people address various surgical procedures, including risks, complications, approaches and perioperative and postoperative care (Deutsch, 2016).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Gender transformation surgeries are procedures, and therefore, not subject to FDA regulation. However, medical devices, drugs, biologics or tests used as a part of these procedures may be subject to FDA regulation. Refer to the following website to search by product name. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 12, 2022)

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Policy History/Revision Information

Date	Summary of Changes

03/01/2023	Coverage Rationale
	• Revised coverage criteria for genital surgery for Gender Dysphoria; replaced criterion requiring an individual must:
	  ○ "Complete at least 12 months of successful continuous full-time real-life *experience* in the *desired* gender" with "complete at least 12 months of successful continuous full-time real-life *involvement* in the *experienced* gender"
	  ○ "Complete 12 months of continuous *cross-sex* hormone therapy appropriate for the *desired* gender (unless medically contraindicated)" with "complete 12 months of continuous hormone therapy appropriate for the *experienced* gender (unless medically contraindicated)"
	• Added instruction to refer to the *Benefit Considerations* section [of the policy] as member specific benefit plan language may vary
	Supporting Information
	• Updated *Benefit Considerations*, *Clinical Evidence*, and *References* sections to reflect the most current information at the time of review
	• Archived previous policy version CS145.L

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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Gender Dysphoria Treatment

Policy Number: 2021T0580L
Effective Date: November 1, 2021

➲ Instructions for Use

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Related Commercial Policies

- Blepharoplasty, Blepharoptosis and Brow Ptosis Repair
- Botulinum Toxins A and B
- Cosmetic and Reconstructive Procedures
- Gonadotropin Releasing Hormone Analogs
- Habilitative Services and Outpatient Rehabilitation Therapy
- Panniculectomy and Body Contouring Procedures
- Rhinoplasty and Other Nasal Surgeries

Community Plan Policy

- Gender Dysphoria Treatment

Coverage Rationale

➲ See Benefit Considerations

Notes:

- This Medical Policy does not apply to individuals with ambiguous genitalia or disorders of sexual development.
- This Medical Policy does not apply to fully-insured group plans in California. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: CA.
- This Medical Policy does not apply to fully-insured group plans in the state of Washington. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: WA.

Surgical treatment for Gender Dysphoria may be indicated for individuals who provide the following documentation:

- For breast surgery, a written psychological assessment from at least one Qualified Behavioral Health Provider experienced in treating Gender Dysphoria* is required. The assessment must document that an individual meets all of the following criteria:
  - Persistent, well-documented Gender Dysphoria
  - Capacity to make a fully informed decision and to consent for treatment
  - Must be at least 18 years of age (age of majority)
  - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
- For genital surgery, a written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender Dysphoria*, who have independently assessed the individual, is required. The assessment must document that an individual meets all of the following criteria:
  - Persistent, well-documented Gender Dysphoria
  - Capacity to make a fully informed decision and to consent for treatment
  - Must be at least 18 years of age (age of majority)

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- Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
- Complete at least 12 months of successful continuous full-time real-life experience in the desired gender
- Complete 12 months of continuous cross-sex hormone therapy appropriate for the desired gender (unless medically contraindicated)

- Treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Provider experienced in treating Gender Dysphoria*

When the above criteria are met, the following surgical procedures to treat Gender Dysphoria are medically necessary and covered as a proven benefit:

- Bilateral mastectomy or breast reduction*
- Clitoroplasty (creation of clitoris)
- Hysterectomy (removal of uterus)
- Labiaplasty (creation of labia)
- Laser or electrolysis hair removal in advance of genital reconstruction prescribed by a physician for the treatment of Gender Dysphoria
- Metoidioplasty (creation of penis, using clitoris)
- Orchiectomy (removal of testicles)
- Penectomy (removal of penis)
- Penile prosthesis
- Phalloplasty (creation of penis)
- Salpingo-oophorectomy (removal of fallopian tubes and ovaries)
- Scrotoplasty (creation of scrotum)
- Testicular prostheses
- Urethroplasty (reconstruction of female urethra)
- Urethroplasty (reconstruction of male urethra)
- Vaginectomy (removal of vagina)
- Vaginoplasty (creation of vagina)
- Vulvectomy (removal of vulva)

*When bilateral mastectomy or breast reduction is performed as a stand-alone procedure, without genital reconstruction procedures, completion of hormone therapy prior to the breast procedure is not required.

Certain ancillary procedures, including but not limited to the following, are considered cosmetic and not medically necessary, when performed as part of surgical treatment for Gender Dysphoria:

Refer to the Benefit Considerations section as member specific benefit plan language may vary.

Note: For fully insured group policies in New York, refer to the Benefit Considerations section for more information.

- Abdominoplasty (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures)
- Blepharoplasty (also refer to the Coverage Determination Guideline titled Blepharoplasty, Blepharoptosis and Brow Ptosis Repair)
- Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures)
- Breast enlargement, including augmentation mammaplasty and breast implants
- Brow lift
- Calf implants
- Cheek, chin and nose implants
- Injection of fillers or neurotoxins (also refer to the Medical Benefit Drug Policy titled Botulinum Toxins A and B)
- Face/forehead lift and/or neck tightening
- Facial bone remodeling for facial feminization
- Laser or electrolysis hair removal not related to genital reconstruction
- Hair transplantation

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- Lip augmentation
- Lip reduction
- Liposuction (suction-assisted lipectomy) (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures)
- Mastopexy
- Pectoral implants for chest masculinization
- Rhinoplasty (also refer to the Coverage Determination Guideline titled Rhinoplasty and Other Nasal Surgeries)
- Skin resurfacing (e.g., dermabrasion, chemical peels, laser)
- Thyroid cartilage reduction/reduction thyroid chondroplasty/trachea shave (removal or reduction of the Adam's apple)
- Voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords)
- Voice lessons and voice therapy

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information
Gender Dysphoria Treatment	
14000, 14000, 14001, 14041, 15734, 15738, 15750, 15757, 15758, 15820, 15821, 15822, 15823, 15830, 15847, 15877, 15878, 15879, 17999, 19303, 19316, 19318, 19325, 19340, 19342, 19350, 21121, 21123, 21125, 21127, 21137, 21138, 21139, 21172, 21175, 21179, 21180, 21208, 21209, 21210, 30400, 30410, 30420, 30430, 30435, 30450, 53410, 53430, 54125, 54400, 54401, 54405, 54520, 54660, 54690, 55175, 55180, 55970, 55980, 56625, 56800, 56805, 57110, 57335, 58150, 58180, 58260, 58262, 58290, 58291, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58661, 58720, 58940, 64856, 64892, 64896, 67900	Medical notes documenting the following: • The history of medical conditions requiring treatment or surgical intervention • A well-defined physical/physiologic abnormality resulting in a medical condition that requires treatment • Recurrent or persistent functional deficit caused by the abnormality • Clinical studies/tests addressing the physical/physiologic abnormality confirming its presence and degree to which it causes impairment • Color photos, where applicable, of the physical and/or physiological abnormality • Physician plan of care with proposed procedures and whether this request is part of a staged procedure; indicate how the procedure will improve and/or restore function • For CPT codes 58260, 58262, 58290 and 58291, provide the additional information: o The history of medical conditions requiring treatment or surgical intervention o Physician plan of care with proposed procedures and whether this request is part of a staged procedure o A written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender Dysphoria, who have independently assessed the individual. The assessment should include all of the following: ▪ The member is capable to make a fully informed decision and to consent for treatment ▪ The member must be at least 18 years of age (age of majority) ▪ If significant medical or mental health concerns are present, they must be reasonably well controlled ▪ The member has completed at least 12 months of successful continuous full-time real-life experience in the desired gender ▪ The member has completed 12 months of continuous cross-sex hormone therapy appropriate for the desired gender (unless medically contraindicated) o A treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Provider experienced in treating Gender Dysphoria

**For code descriptions, see the Applicable Codes section.*

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Definitions

Gender Dysphoria in Adolescents and Adults: A disorder characterized by the following diagnostic criteria (Diagnostic and Statistical Manual of Mental Disorders, 5th edition [DSM-5]):

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:
   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics [(or in young adolescents, the anticipated secondary sex characteristics)].
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender [or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)].
   3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
   4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).
B. The condition is associated with clinically significant distress or impairment in social, occupational or other important areas of functioning.

Gender Dysphoria in Children: A disorder characterized by the following diagnostic criteria (Diagnostic and Statistical Manual of Mental Disorders, 5th edition [DSM-5]):

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be criterion A1):
   1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
   2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
   3. A strong preference for cross-gender roles in make-believe play or fantasy play.
   4. A strong preference for the toys, games or activities stereotypically used or engaged in by the other gender.
   5. A strong preference for playmates of the other gender.
   6. In boys (assigned gender), a strong rejection of typically masculine toys, games and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games and activities.
   7. A strong dislike of ones' sexual anatomy.
   8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.
B. The condition is associated with clinically significant distress or impairment in social, school or other important areas of functioning.

Qualified Behavioral Health Provider:

- Recommended minimum credentials for behavioral health providers working with adults presenting with gender dysphoria (World Professional Association for Transgender Health [WPATH] Guidelines, version 7, 2012):
  - A minimum of a master's degree or its equivalent in a clinical behavioral science field. This degree should be granted by an institution accredited by the appropriate national or regional accrediting board. The behavioral health provider should have documented credentials from a relevant licensing board;
  - Competence in using the current version of the Diagnostic Statistical Manual of Mental Disorders (DSM) and/or the International Classification of Diseases (ICD) for assessment and diagnostic purposes;
  - Ability to recognize and diagnose coexisting mental health concerns and to distinguish these from gender dysphoria;
  - Documented supervised training and competence in psychotherapy or counseling;
  - Knowledgeable about gender nonconforming identities and expressions, and the evaluation and treatment of gender dysphoria;
  - Continuing education in the assessment and treatment of gender dysphoria;
  - Develop and maintain cultural competence to facilitate their work with transsexual, transgender, and gender nonconforming clients.

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- Recommended minimum credentials for behavioral health providers working with children or adolescents presenting with gender dysphoria (WPATH Guidelines, version 7, 2012):
  - Meet the competency requirements for behavioral health providers working with adults, as outlined above;
  - Trained in childhood and adolescent developmental psychopathology;
  - Competent in diagnosing and treating the ordinary problems of children and adolescents.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
11950	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (e.g., collagen); over 10.0 cc
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
15734	Muscle, myocutaneous, or fasciocutaneous flap; trunk
15738	Muscle, myocutaneous, or fasciocutaneous flap; lower extremity
15750	Flap; neurovascular pedicle
15757	Free skin flap with microvascular anastomosis
15758	Free fascial flap with microvascular anastomosis
15769	Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
15780	Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (e.g., tattoo removal)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal

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CPT Code	Description
15793	Chemical peel, nonfacial; dermal
15819	Cervicoplasty
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
15824	Rhytidectomy; forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
17380	Electrolysis epilation, each 30 minutes
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19303	Mastectomy, simple, complete
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (e.g., wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21125	Augmentation, mandibular body or angle; prosthetic material

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CPT Code	Description
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft (includes obtaining autograft)
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (e.g., plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
21899	Unlisted procedure, neck or thorax
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
31599	Unlisted procedure, larynx
31899	Unlisted procedure, trachea, bronchi
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
53430	Urethroplasty, reconstruction of female urethra
54125	Amputation of penis; complete
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54406	Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis
54408	Repair of component(s) of a multi-component, inflatable penile prosthesis
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis

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CPT Code	Description
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54660	Insertion of testicular prosthesis (separate procedure)
54690	Laparoscopy, surgical; orchiectomy
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
55970	Intersex surgery; male to female
55980	Intersex surgery; female to male
56625	Vulvectomy simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57110	Vaginectomy, complete removal of vaginal wall;
57335	Vaginoplasty for intersex state
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250 g or less
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58290	Vaginal hysterectomy, for uterus greater than 250 g
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)

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CPT Code	Description
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral
64856	Suture of major peripheral nerve, arm or leg, except sciatic; including transposition
64892	Nerve graft (includes obtaining graft), single strand, arm or leg; up to 4 cm length
64896	Nerve graft (includes obtaining graft), multiple strands (cable), hand or foot; more than 4 cm length
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals

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Diagnosis Code	Description
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
Z87.890	Personal history of sex reassignment

Description of Services

Gender Dysphoria is a condition in which there is a marked incongruence between an individual's experienced/expressed/alternative gender and assigned gender (DSM-5). Treatment options include behavioral therapy, psychotherapy, hormone therapy, and surgery for gender transformation. Surgical treatments for Gender Dysphoria may include the following: clitoroplasty, hysterectomy, labiaplasty, mastectomy, orchiectomy, penectomy, phalloplasty or metoidioplasty (alternative to phalloplasty), placement of testicular and/or penile prostheses, salpingo-oophorectomy, scrotoplasty, urethroplasty, urethroplasty, vaginectomy, vaginoplasty and vulvectomy.

Other terms used to describe surgery for Gender Dysphoria include gender affirming surgery, sex transformation surgery, sex change, sex reversal, gender change, transsexual surgery, transgender surgery, and sex reassignment.

Benefit Considerations

Coverage Information

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service.

This medical policy does not apply to fully-insured group plans in California. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: CA.

This Medical Policy does not apply to fully-insured group plans in the state of Washington. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: WA.

Unless otherwise specified, if a plan covers treatment for Gender Dysphoria, coverage includes psychotherapy, cross-sex hormone therapy, puberty suppressing medications and laboratory testing to monitor the safety of hormone therapy. This

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benefit also includes certain surgical treatments listed in the Coverage Rationale section. Refer to the Drug Policy titled Gonadotropin Releasing Hormone Analogs.

Limitations and Exclusions

Certain treatments and services are not covered. Examples include, but are not limited to:

- Treatment received outside of the United States
- Reproduction services, including, but not limited to, sperm preservation in advance of hormone treatment or Gender Dysphoria surgery, cryopreservation of fertilized embryos, oocyte preservation, surrogate parenting, donor eggs, donor sperm and host uterus (see the Reproduction exclusion in the member specific benefit plan document)
- Transportation, meals, lodging or similar expenses
- Cosmetic procedures (refer to the Coverage Determination Guideline titled Cosmetic and Reconstructive Procedures and the Coverage Rationale section). See below for additional information on New York fully insured group policies.
- Reversal of genital surgery or reversal of surgery to revise secondary sex characteristics

Coverage does not apply to members who do not meet the indications listed in the Coverage Rationale section above.

For Fully Insured Group Policies in New York Only

Certain ancillary procedures may be considered cosmetic and not medically necessary when performed as part of surgical treatment for Gender Dysphoria. Clinical review for medical necessity of ancillary procedures is conducted on a case-by-case basis.

Clinical Evidence

Scandurra et al. (2019) performed a systematic review assessing the health of nonbinary and genderqueer (NBGQ) individuals compared to binary transgender (BT) and cisgender individuals. Eleven studies were included in the review. Results related to the difference in health between NBGQ and BT were mixed, with some finding a better health status while others a worse one. Results related to the differences in health between NBGQ and cisgender individuals highlighted higher health needs in NBGQ individuals compared with cisgender counterparts. The authors noted the need for research expansion in terms of both methodology and research contents.

Wernick et al. (2019) conducted a systematic review of the psychological benefits of gender-affirming surgery. Thirty-three studies were included in the analysis. Overall, most of the studies comparing pre- and post-operative data on quality of life, body image/satisfaction, and overall psychological functioning among individuals with gender dysphoria suggested that gender-affirming surgery leads to multiple, significant psychological benefits. Of the studies comparing psychological well-being between individuals who did or did not undergo surgery, most demonstrated a trend of better mental health among individuals who underwent surgery compared with those who did not. The authors encouraged future research to focus on standardizing the assessment of psychological functioning pre- and post-gender-affirming surgery to gather longitudinal data that will allow for more definitive conclusions to be made about factors that contribute to the psychological benefits of surgery.

Cohen et al. (2019) conducted a systematic review of surgical options and associated outcomes for transmasculine top surgery. Twenty-two studies were included (n=2447). The authors reported that future research is needed to improve patient selection, surgical decision making, and patient-reported outcomes for different chest contouring techniques.

Mahfouda et al. (2019) conducted a systematic review of the available published evidence on gender-affirming cross-sex hormone (CSH) and surgical interventions in transgender children and adolescents, amalgamating findings on mental health outcomes, cognitive and physical effects, side-effects, and safety variables. The small amount of available data suggest that when clearly indicated in accordance with international guidelines, gender-affirming CSHs and chest wall masculinization in transgender males are associated with improvements in mental health and quality of life. Evidence regarding surgical vaginoplasty in transgender females younger than age 18 years remains extremely scarce and conclusions cannot yet be drawn regarding its risks and benefits in this age group. Further research on an international scale is urgently warranted to clarify long-term outcomes on psychological functioning and safety.

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A Hayes report on sex reassignment surgery (2018; updated 2021) for the treatment of gender dysphoria made the following conclusions:

- Studies suggest that following sex reassignment surgery, patients reported decreased gender dysphoria and improved body image satisfaction. However, results were mixed regarding effects of sex reassignment surgery on quality of life and psychological symptoms.

- Few studies compare outcomes in patients who received sex reassignment surgery with stand-alone hormone therapy. The results of these studies suggest that sex reassignment surgery may improve gender dysphoria, quality of life, body image and psychological symptoms to a greater extent than hormone therapy alone. However, the results were conflicting.

- Few studies compared outcomes in patients who received different components of sex reassignment surgery. For most outcome measures, there was only a single study available. This evidence is therefore insufficient to support definitive conclusions regarding the comparative effectiveness of different components of sex reassignment surgery for treating gender dysphoria.

- Not all studies reported all outcomes; the following findings therefore do not inform overall incidence of complications. Following sex reassignment surgery, there were very low rates of regret of surgery (0% to 6% per study) and suicide (2% to 3% per study). Complications following sex reassignment surgery were common, and some were serious.

Dreher et al. (2018) conducted a systematic review and meta-analysis to evaluate the epidemiology, presentation, management, and outcomes of neovaginal complications in the MtF transgender reassignment surgery patients. Selected studies reported on 1,684 patients with an overall complication rate of 32.5% and a reoperation rate of 21.7% for non-esthetic reasons. The most common complication was stenosis of the neo-meatus (14.4%). Wound infection was associated with an increased risk of all tissue-healing complications. Use of sacrospinous ligament fixation (SSL) was associated with a significantly decreased risk of prolapse of the neovagina. The authors concluded that gender-affirmation surgery is important in the treatment of gender dysphoric patients, but there is a high complication rate in the reported literature. Variability in technique and complication reporting standards makes it difficult to assess the accurately the current state of MtF gender reassignment surgery. Further research and implementation of standards is necessary to improve patient outcomes.

Manrique et al (2018) conducted a systematic review of retrospective studies on the outcomes of MtF vaginoplasty to minimize surgical complications and improve patient outcomes for transgender patients. Forty-six studies met the authors eligibility criteria. A total of 3716 cases were analyzed. The results showed the overall incidence of complications as follows: 2% fistula, 14% stenosis and strictures, 1% tissue necrosis, and 4% prolapse. Patient-reported outcomes included a satisfaction rate of 93% with overall results, 87% with functional outcomes, and 90% with esthetic outcomes. Ability to have orgasm was reported in 70% of patients. The regret rate was 1%. The authors concluded that multiple surgical techniques have demonstrated safe and reliable means of MtF vaginoplasty with low overall complication rates and with a significant improvement in the patient's quality of life. Studies using different techniques in a similar population and standardized patient-reported outcomes are required to further analyze outcomes among the different procedures and to establish best-practice guidelines.

Van Damme et al. (2017) conducted a systematic review of the effectiveness of pitch-raising surgery performed in MtF transsexuals. Twenty studies were included: eight using cricothyroid approximation, six using anterior glottal web formation and six using other surgery types or a combination of surgical techniques. A substantial rise in postoperative frequency was identified. The majority of patients seemed satisfied with the outcome. However, none of the studies used a control group and randomization process. Further investigation regarding long-term results using a stronger study design is necessary.

Gaither et al. (2017) retrospectively reviewed the records of 330 MtF patients from 2011 to 2015, to assess surgical complications related to primary penile inversion vaginoplasty. Complications included granulation tissue, vaginal pain, wound separation, labial asymmetry, vaginal stenosis, fistula formation, urinary symptoms including spraying stream or dribbling, infection, vaginal fissure or vaginal bleeding. Median age at surgery was 35 years, and median follow-up in all patients was 3 months. The results showed that 95 of the patients presented with a postoperative complication with the median time to a complication being 4.4 months. Rectoneovaginal fistulas developed in 3 patients, and 30 patients required a second operation. Age, body mass index and hormone replacement therapy were not associated with complications. The authors concluded that penile inversion vaginoplasty is a relatively safe procedure. Most complications due to this surgery develop within the first 4 months postoperatively. Age, body mass index and hormone replacement therapy are not associated with complications and, thus, they should not dictate the timing of surgery.

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An ECRI special report systematically reviewed the clinical literature to assess the efficacy of treatments for gender dysphoria. The authors identified limited evidence from mostly low-quality retrospective studies. Evidence on gender reassignment surgery was mostly limited to evaluations of MtF individuals undergoing vaginoplasty, facial feminization surgery and breast augmentation. Outcomes included mortality, patient satisfaction, physical well-being, psychological-related outcomes, quality of life, sexual-related outcomes, suicide and adverse events. Concluding remarks included the need for standardized protocols and prospective studies using standardized measures for correct interpretation and comparability of data (ECRI, 2016).

Morrison et al. (2016) conducted a systematic review of the facial feminization surgery literature. Fifteen studies were included, all of which were either retrospective or case series/reports. The studies covered a variety of facial feminization procedures. A total of 1121 patients underwent facial feminization surgery, with seven complications reported, although many studies did not explicitly comment on complications. Satisfaction was high, although most studies did not use validated or quantified approaches to address satisfaction. The authors noted that further studies are needed to better compare different techniques to more robustly establish best practices. Prospective studies and patient-reported outcomes are needed to establish quality of life outcomes for patients.

Frey et al. (2016) conducted a systematic review of metoidioplasty and radial forearm flap phalloplasty (RFFP) in FtM transgender genital reconstruction. Eighteen studies were included: 7 for metoidioplasty and 11 for RFFP. The quality of evidence was low to very low for all included studies. In studies examining metoidioplasty, the average study size and length of follow-up were 54 patients and 4.6 years, respectively (1 study did not report [NR]). Eighty-eight percent underwent a single-stage reconstruction, 87% reported an aesthetic neophallus (3 NR) and 100% reported erogenous sensation (2 NR). Fifty-one percent of patients reported successful intercourse (3 NR) and 89% of patients achieved standing micturition (3 NR). In studies examining RFFP, the average study size and follow-up were 60.4 patients and 6.23 years, respectively (6 NR). No patients underwent single-stage reconstructions (8 NR). Seventy percent of patients reported a satisfactorily aesthetic neophallus (4 NR) and 69% reported erogenous sensation (6 NR). Forty-three percent reported successful penetration of partner during intercourse (6 NR) and 89% achieved standing micturition (6 NR). Compared with RFFP, metoidioplasty was significantly more likely to be completed in a single stage, have an aesthetic result, maintain erogenous sensation, achieve standing micturition and have a lower overall complication rate. The authors reported that, although the current literature suggests that metoidioplasty is more likely to yield an "ideal" neophallus compared with RFFP, any conclusion is severely limited by the low quality of available evidence.

Using a retrospective chart review, Buncamper et al. (2016) assessed surgical outcome after penile inversion vaginoplasty. Outcome measures were intraoperative and postoperative complications, reoperations, secondary surgical procedures and possible risk factors. Of 475 patients who underwent the procedure, 405 did not have additional full-thickness skin grafts while 70 did have grafts. Median follow-up was 7.8 years. The most frequently observed intraoperative complication was rectal injury (2.3 percent). Short-term postoperative bleeding that required transfusion (4.8 percent), reoperation (1.5 percent) or both (0.4 percent) occurred in some cases. Major complications were three (0.6 percent) rectoneovaginal fistulas, which were successfully treated. Revision vaginoplasty was performed in 14 patients (2.9 percent). Comorbid diabetes was associated with a higher risk of local infection, and use of psychotropic medication predisposed to postoperative urinary retention. Successful vaginal construction without the need for secondary functional reoperations was achieved in the majority of patients.

Bouman et al. (2016) prospectively assessed surgical outcomes of primary total laparoscopic sigmoid vaginoplasty in 42 transgender women with penoscrotal hypoplasia. Mean follow-up time was 3.2 ± 2.1 years. The mean operative duration was 210 ± 44 minutes. There were no conversions to laparotomy. One rectal perforation was recognized during surgery and immediately oversewn without long-term consequences. The mean length of hospitalization was 5.7 ± 1.1 days. One patient died as a result of an extended-spectrum beta-lactamase-positive necrotizing fasciitis leading to septic shock, with multiorgan failure. Direct postoperative complications that needed laparoscopic reoperation occurred in three cases (7.1 percent). In seven cases (17.1 percent), long-term complications needed a secondary correction. After 1 year, all patients had a functional neovagina with a mean depth of 16.3 ± 1.5 cm.

Despite the significant increase in genital gender affirming surgery (GAS) within the past 50 years, there is limited data regarding hair removal practices in preparation for genital GAS. Genital GAS involves reconstruction of the genitals to match a patient's identified sex. The use of hair-bearing flaps in this procedure may result in postoperative intra-vaginal and intra-urethral hair growth and associated complications, including lower satisfaction with genital GAS. In 2016, Zhang et al. conducted a literature review, recommendations from experience, and a practical laser hair removal (LHR) approach to hair removal prior to genital GAS.

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Horbach et al. (2015) conducted a systematic review of vaginoplasty techniques in MtF individuals with gender dysphoria. Twenty-six studies were included (mostly retrospective case series of low to intermediate quality). Outcome of the penile skin inversion technique was reported in 1,461 patients and bowel vaginoplasty in 102 patients. Neovaginal stenosis was the most frequent complication in both techniques. Sexual function and patient satisfaction were overall acceptable, but many different outcome measures were used. Quality of life was only reported in one study. Comparison between techniques was difficult due to the lack of standardization. The authors concluded that the penile skin inversion technique is the most researched surgical procedure. Outcome of bowel vaginoplasty has been reported less frequently but does not seem to be inferior. The available literature is heterogeneous in patient groups, surgical procedure, outcome measurement tools and follow-up. There is a need for prospective studies with standardized surgical procedures, larger patient groups and longer follow-up periods. Uniformity in outcome measurement tools such as validated questionnaires and scores for sexual function and quality of life is mandatory for correct interpretation and comparability of data.

Bouman et al. (2014) conducted a systematic review of surgical techniques and clinical outcomes of intestinal vaginoplasty. Twenty-one studies were included (n=894). All studies had a retrospective design and were of low quality. Prevalence and severity of procedure-related complications were low. The main postoperative complication was introital stenosis, necessitating surgical correction in 4.1% of sigmoid-derived and 1.2% of ileum-derived vaginoplasties. Neither diversion colitis nor cancer was reported. Sexual satisfaction rate was high, but standardized questionnaires were rarely used. Quality of life was not reported. The authors concluded that prospective studies, using standardized measures and questionnaires, are warranted to assess functional outcomes and quality of life.

Djordjevic et al. (2013) evaluated 207 patients who underwent single-stage metoidioplasty, comparing two different surgical techniques of urethral lengthening. The procedure included lengthening and straightening of the clitoris, urethral reconstruction and scrotoplasty with implantation of testicular prostheses. Buccal mucosa graft was used in all cases for dorsal urethral plate formation and joined with one of the two different flaps: longitudinal dorsal clitoral skin flap (n=49) (group 1) and labia minora flap (n=158) (group 2). The median follow-up was 39 months. The total length of reconstructed urethra ranged from 9.1 to 12.3 cm in group 1 and from 9.4 to 14.2 cm in group 2. Voiding while standing was significantly better in group 2 (93%) than in group 1 (87.82%). Urethral fistula occurred in 16 patients in both groups. Overall satisfaction was noted in 193 patients. The authors concluded that combined buccal mucosa graft and labia minora flap was the method of choice for urethroplasty in metoidioplasty, minimizing postoperative complications.

In a non-randomized study, Dhejne et al. (2011) evaluated mortality, morbidity and criminal rates after gender reassignment surgery in 324 individuals (MtF n=191; FtM n=133). Random population controls (10:1) were matched by birth year and birth sex or reassigned final sex. The authors reported substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts and psychiatric hospitalizations in sex-reassigned individuals (both MtF/FtM) compared to a healthy control population. FtMs had a higher risk for criminal convictions.

Murad et al. (2010) conducted a systematic review to evaluate the effects of hormone therapy on patients undergoing gender reassignment surgery. The authors identified 28 eligible studies, all of which were observational and most lacked controls. These studies enrolled 1833 participants with gender dysphoria (1093 MtF; 801 FtM). After gender reassignment surgery, individuals reported improvement in gender dysphoria (80%), psychological symptoms (78%), sexual function (72%) and quality of life (80%). The authors concluded that very low quality evidence suggests that gender reassignment, that includes hormonal interventions, is likely to improve gender dysphoria, psychological functioning and comorbidities, sexual function and overall quality of life.

Sutcliffe et al. (2009) systematically reviewed five individual procedures for MtF gender reassignment surgery: clitoroplasty, labiaplasty, orchiectomy, penectomy and vaginoplasty. Further evaluations were made of eight surgical procedures for FtM gender reassignment surgery: hysterectomy, mastectomy, metoidioplasty, phalloplasty, salpingo-oophorectomy, scrotoplasty/placement of testicular prostheses, urethroplasty and vaginectomy. Eighty-two published studies (38 MtF; 44 FtM) were included in the review. For MtF procedures, the authors found no evidence that met the inclusion criteria concerning labiaplasty, penectomy or orchiectomy. A large amount of evidence was available concerning vaginoplasty and clitoroplasty procedures. The authors reported that the evidence concerning gender reassignment surgery in both MtF and FtM individuals with gender dysphoria has several limitations including lack of controlled studies, lack of prospective data, high loss to follow-up and lack of validated assessment measures. Some satisfactory outcomes were reported, but the magnitude of benefit and harm for individual surgical procedures cannot be estimated accurately using the current available evidence.

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World Professional Association for Transgender Health (WPATH)

WPATH, formerly known as the Harry Benjamin International Gender Dysphoria Association, is an advocacy group devoted to transgender health. WPATH guidelines (2012) present eligibility and readiness criteria for transition-related treatment, as well as competencies of health care providers.

WPATH describes the transition from one gender to another in the following three stages:

- Living in the gender role consistent with gender identity
- The use of cross-sex hormone therapy after living in the new gender role for a least three months
- Gender-affirmation surgery after living in the new gender role and using hormonal therapy for at least 12 months

Clinical Practice Guidelines

American Academy of Pediatrics (AAP)

In a 2018 policy statement entitled Ensuring Comprehensive Care and Support for Transgender and Gender- Diverse Children and Adolescents, the AAP states the following regarding surgery: Surgical approaches may be used to feminize or masculinize features, such as hair distribution, chest, or genitalia, and may include removal of internal organs, such as ovaries or the uterus (affecting fertility). These changes are irreversible. Although current protocols typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family.

American College of Obstetrics and Gynecology (ACOG)

An ACOG committee opinion (2021) provides guidance on health care for transgender and gender diverse individuals. The document does not make specific recommendations regarding surgery but does provide an overview of surgical procedures and education for clinicians who care for transgender patients before and after surgery.

Endocrine Society

Endocrine Society practice guidelines (Hembree et al., 2017) addressing endocrine treatment of gender-dysphoric/ gender-incongruent persons makes the following recommendations regarding surgery for sex reassignment and gender confirmation:

- Suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country (Recommendation based on low quality evidence).
- A patient pursue genital gender-affirming surgery only after the mental health practitioner (MHP) and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being (Strong recommendation based on low quality evidence).
- Surgery is recommended only after completion of at least one year of consistent and compliant hormone treatment unless hormone therapy is not desired or medically contraindicated (Ungraded Good Practice Statement).
- The physician responsible for endocrine treatment medically clears individual for surgery and collaborates with the surgeon regarding hormone use during and after surgery (Ungraded Good Practice Statement).
- Recommend that clinicians refer hormone treated transgender individuals for genital surgery when (Strong recommendation based on very low quality evidence):
  - The individual has had a satisfactory social role change
  - The individual is satisfied about the hormonal effects
  - The individual desires definitive surgical changes
- Suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement (Recommendation based on very low quality evidence)

University of California, San Francisco (UCSF) Center of Excellence for Transgender Health

The UCSF Center of Excellence evidence-based guidelines for the primary and gender-affirming care of transgender and gender nonbinary people address various surgical procedures, including risks, complications, approaches and perioperative and postoperative care (Deutsch, 2016).

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U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Gender transformation surgeries are procedures, and therefore, not subject to FDA regulation. However, medical devices, drugs, biologics, or tests used as a part of these procedures may be subject to FDA regulation. See the following website to search by product name. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August 24, 2021)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2021	Documentation Requirements • Updated list of applicable CPT codes with associated documentation requirements; added 15878, 15879, 54400, 54401, and 54405 Supporting Information • Archived previous policy version 2021T0580K

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Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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Clinical UM Guideline

Subject: Gender Affirming Surgery
Guideline #: CG-SURG-27
Status: Revised

Publish Date: 05/20/2021
Last Review Date: 05/13/2021

Description

This document addresses gender affirming surgery (also known as sex affirmation surgery, gender or sex reassignment surgery, gender or sex confirmation surgery). Gender affirming surgery is a treatment option for gender dysphoria, a condition in which a person experiences persistent incongruence between gender identity and sexual anatomy at birth. Gender affirming surgery is not an isolated intervention; it is part of a complex process involving multiple medical, psychiatric and psychologic, and surgical specialists working in conjunction with each other and the individual to achieve successful behavioral and medical outcomes. Before undertaking gender affirming surgery, medical and psychological evaluations, medical therapies and behavioral trials are undertaken to help ensure that surgery is an appropriate treatment choice for the individual.

Note: Please refer to the following documents for additional information, including the use of these and other procedures for individuals with gender dysphoria that *are not related to gender affirming surgery*:

- ANC.00007 Cosmetic and Reconstructive Services: Skin Related
- ANC.00008 Cosmetic and Reconstructive Services of the Head and Neck
- ANC.00009 Cosmetic and Reconstructive Services of the Trunk and Groin
- CG-SURG-12 Penile Prosthesis Implantation
- SURG.00023 Breast Procedures: including Reconstructive Surgery, Implants and Other Breast Procedures

Note: Voice therapy is not addressed in this document, as it is not a surgical procedure.

Medically Necessary: In this document, procedures are considered medically necessary if there is a significant functional impairment AND the procedure can be reasonably expected to improve the functional impairment.

Reconstructive: In this document, procedures are considered reconstructive when intended to address a significant variation from normal related to accidental injury, disease, trauma, treatment of a disease or a congenital defect.

Note: Not all benefit contracts/certificates include benefits for reconstructive services as defined by this document. Benefit language supersedes this document.

Cosmetic: In this document, procedures are considered cosmetic when intended to change a physical appearance that would be considered within normal human anatomic variation. Cosmetic services are often described as those that are primarily intended to preserve or improve appearance.

Clinical Indications

NOTE: Procedures to address postoperative complications of gender affirming surgery procedures (for example, stenosis, scarring, chronic infection, or pain) are not considered separate gender affirming surgery procedures.

NOTE: Reversal of a prior gender affirming surgery procedure is considered gender affirming surgery and the medical necessity criteria below apply.

Medically Necessary:

Gender affirming pelvic or gonadal surgery (which may consist of a combination of the following: *hysterectomy, orchiectomy, ovariectomy, or salpingo-oophorectomy*), is considered **medically necessary** when *all* of the following

criteria are met:

A. The individual is at least 18 years of age; **and**
B. The individual has capacity to make fully informed decisions and consent for treatment; **and**
C. The individual has been diagnosed with gender dysphoria (see Discussion section for diagnostic criteria); **and**
D. For individuals without a medical contraindication or intolerance, the individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician; **and**
E. If the individual has significant medical or mental health issues present, they must be reasonably well controlled. If the individual is diagnosed with severe psychiatric disorders and impaired reality testing (for example, psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated; **and**
F. Two referrals from qualified mental health professionals* who have independently assessed the individual. If the first referral is from the individual's psychotherapist, the second referral should be from a person who has only had an evaluative role with the individual. Two separate letters, or one letter signed by both (for example, if practicing within the same clinic) are required. The letter(s) must have been signed within 12 months of the request submission.

Gender affirming genital surgery (which may consist of a combination of the following: *clitoroplasty, labiaplasty, metoidioplasty, penectomy, phalloplasty, scrotoplasty, urethroplasty, vaginectomy, vaginoplasty, or placement of penile or testicular prostheses*), is considered **medically necessary** when *all* of the following criteria are met:

A. The individual is at least 18 years of age; **and**
B. The individual has capacity to make fully informed decisions and consent for treatment; **and**
C. The individual has been diagnosed with gender dysphoria (see Discussion section for diagnostic criteria); **and**
D. For individuals without a medical contraindication or intolerance, the individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician; **and**
E. Documentation** that the individual has completed a minimum of 12 months of successful continuous full time real-life experience in the new gender, across a wide range of life experiences and events that may occur throughout the year (for example, family events, holidays, vacations, season-specific work or school experiences). This includes coming out to partners, family, friends, and community members (for example, at school, work, and other settings); **and**
F. Regular participation in psychotherapy throughout the real-life experience when recommended by a treating medical or behavioral health practitioner; **and**
G. If the individual has significant medical or mental health issues present, they must be reasonably well controlled. If the individual is diagnosed with severe psychiatric disorders and impaired reality testing (for example, psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated; **and**
H. Two referrals from qualified mental health professionals* who have independently assessed the individual. If the first referral is from the individual's psychotherapist, the second referral should be from a person who has only had an evaluative role with the individual. Two separate letters, or one letter signed by both (for example, if practicing within the same clinic) are required. The letter(s) must have been signed within 12 months of the request submission.

*At least one of the professionals submitting a letter must have a doctoral degree (for example, Ph.D., M.D., Ed.D., D.Sc., D.S.W., or Psy.D) or a master's level degree in a clinical behavioral science field (for example, M.S.W., L.C.S.W., Nurse Practitioner [N.P.], Advanced Practice Nurse [A.P.R.N.], Licensed Professional Counselor [L.P.C.], and Marriage and Family Therapist [M.F.T.]) and be capable of adequately evaluating co-morbid psychiatric conditions. One letter is sufficient if signed by two providers, one of whom has met the specifications set forth above.

**The medical documentation should include the start date of living full time in the new gender. Verification via communication with individuals who have related to the individual in an identity-congruent gender role, or requesting documentation of a legal name change, may be reasonable in some cases.

The use of hair removal procedures to treat tissue donor sites for a planned phalloplasty or vaginoplasty procedure is considered **medically necessary.**

Reconstructive

Gender affirming chest surgery (*augmentation, mastectomy, or reduction*) is considered **reconstructive** when *all* of the following criteria have been met:

A. The individual is at least 18 years of age (see *Further Considerations* section below for individuals under 18 years of age); **and**
B. The individual has capacity to make fully informed decisions and consent for treatment; **and**
C. The individual has been diagnosed with gender dysphoria (see Discussion section for diagnostic criteria); **and**
D. If the individual has significant medical or mental health issues present, they must be reasonably well controlled. If the individual is diagnosed with severe psychiatric disorders and impaired reality testing (for example, psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated; **and**
E. *For gender affirming breast augmentation procedures only:* for individuals without a medical contraindication or intolerance, the individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician, and insufficient breast development has occurred; **and**
F. Existing chest appearance demonstrates significant variation from normal appearance for the experienced gender (note: each procedure requested should be considered separately as some procedures may be cosmetic and others may be reconstructive); **and**
G. One letter, signed by the referring qualified mental health professional* who has independently assessed the individual, is required; the letter must have been signed within 12 months of the request submission.

Nipple reconstruction, including tattooing, following a gender affirming mastectomy that meets the reconstructive criteria above is considered **reconstructive.**

Gender affirming facial surgery† is considered **reconstructive** when *all* of the following criteria have been met:

A. The individual is at least 18 years of age; **and**
B. The individual has capacity to make fully informed decisions and consent for treatment; **and**
C. The individual has been diagnosed with gender dysphoria (see Discussion section for diagnostic criteria); **and**
D. For individuals without a medical contraindication or intolerance, the individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician; **and**
E. If the individual has significant medical or mental health issues present, they must be reasonably well controlled. If the individual is diagnosed with severe psychiatric disorders and impaired reality testing (for example, psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated; **and**
F. Existing facial appearance demonstrates significant variation from normal appearance for the experienced gender; **and**
G. The procedure directly addresses variation from normal appearance for the experienced gender (note: each procedure requested should be considered separately as some procedures may be cosmetic and others may be reconstructive); **and**
H. One letter, signed by the referring qualified mental health professional* who has independently assessed the individual, is required; the letter must have been signed within 12 months of the request submission.

†See Discussion section for a list of procedures included in this group of procedures

Gender affirming voice modification surgery is considered **reconstructive** when *all* of the following criteria have been met:

A. The individual is at least 18 years of age; **and**
B. The individual has capacity to make fully informed decisions and consent for treatment; **and**
C. The individual has been diagnosed with gender dysphoria (see Discussion section for diagnostic criteria); **and**
D. *For gender masculinization only:* for individuals without a medical contraindication or intolerance, the individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician; **and**
E. If the individual has significant medical or mental health issues present, they must be reasonably well controlled. If the individual is diagnosed with severe psychiatric disorders and impaired reality testing (for example, psychotic

episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated; **and**

F. Existing vocal presentation demonstrates significant variation from normal for the experienced gender; **and**
G. One letter, signed by the referring qualified mental health professional* who has independently assessed the individual, is required; the letter must have been signed within 12 months of the request submission.

Not Medically Necessary:

The following gender affirming surgical procedures are considered **not medically necessary** when one or more of the medical necessary or reconstructive criteria above have not been met:

A. Clitoroplasty
B. Hysterectomy
C. Labiaplasty
D. Metoidioplasty
E. Orchiectomy
F. Ovariectomy
G. Penectomy
H. Phalloplasty
I. Salpingo-Oophorectomy
J. Scrotoplasty
K. Urethroplasty
L. Vaginectomy
M. Vaginoplasty

Cosmetic and Not Medically Necessary:

The following procedures, when requested alone or in combination with other procedures, are considered **cosmetic and not medically necessary** when applicable reconstructive criteria above have not been met, or when used to improve the gender specific appearance of an individual who has undergone or is planning to undergo gender affirming surgery, including, but not limited to, the following:

A. Abdominoplasty
B. Bilateral mastectomy
C. Blepharoplasty
D. Breast augmentation
E. Brow lift
F. Calf implants
G. Face liff
H. Facial bone reconstruction
I. Facial implants
J. Gluteal augmentation
K. Hair removal (for example, electrolysis or laser) and hairplasty, when the criteria above have not been met
L. Jaw reduction (jaw contouring)
M. Lip reduction/enhancement
N. Lipofilling/collagen injections
O. Liposuction
P. Nose implants
Q. Pectoral implants
R. Rhinoplasty
S. Thyroid cartilage reduction (chondroplasty)
T. Voice modification surgery

Further Considerations:

A provider with experience treating adolescents with gender dysphoria may request further consideration of a gender affirming chest procedure case in an individual under 18 years old when they meet all other gender affirming chest procedure criteria above (including prior mental health evaluation) by contacting a Medical Director. *(Further information is*

available in the Discussion/General Information section of this document titled 'Gender Affirming Surgery in Individuals Under the Age of 18').

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

17380	Electrolysis epilation, each 30 minutes [when done to treat tissue donor sites for a planned phalloplasty or vaginoplasty procedure]
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue [when specified as permanent hair removal by laser to treat tissue donor sites for a planned phalloplasty or vaginoplasty procedure]
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
53420	Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; first stage
53425	Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; second stage
53430	Urethroplasty, reconstruction of female urethra
54125	Amputation of penis; complete
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54660	Insertion of testicular prosthesis
54690	Laparoscopy, surgical; orchiectomy
55180	Scrotoplasty; complicated
55899	Unlisted procedure, male genital system [when specified as metoidioplasty or phalloplasty with penile prosthesis]
56625	Vulvectomy, simple; complete
56800	Plastic repair of introitus
57110	Vaginectomy, complete removal of vaginal wall;
57291	Construction of artificial vagina; without graft
57292	Construction of artificial vagina; with graft
57295	Revision (including removal) of prosthetic vaginal graft; vaginal approach
57296	Revision (including removal) of prosthetic vaginal graft; open abdominal approach
57426	Revision (including removal) of prosthetic vaginal graft, laparoscopic approach
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s);
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less;
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g;
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)

HCPCS

C1813	Prosthesis, penile, inflatable

C2622	Prosthesis, penile, non-inflatable
L8699	Prosthetic implant, not otherwise specified [when specified as testicular or penile prosthesis]

ICD-10 Procedure

0HDSXZZ	Extraction of hair, external approach [when done to treat tissue donor sites for a planned phalloplasty or vaginoplasty procedure]
0UQG0ZZ	Repair vagina, open approach
0UQJ0ZZ-0UQJXZZ	Repair clitoris [by approach; includes codes 0UQJ0ZZ, 0UQJXZZ]
0UT20ZZ-0UT2FZZ	Resection of bilateral ovaries [by approach; includes codes 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ]
0UT70ZZ-0UT7FZZ	Resection of bilateral fallopian tubes [by approach; includes codes 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ]
0UT90ZZ-0UT9FZZ	Resection of uterus [by approach; includes codes 0UT90ZZ, 0UT94ZZ, 0UT97ZZ, 0UT98ZZ, 0UT9FZZ]
0UTC0ZZ-0UTC8ZZ	Resection of cervix [by approach; includes codes 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ]
0UTG0ZZ-0UTG8ZZ	Resection of vagina [by approach; includes codes 0UTG0ZZ, 0UTG4ZZ, 0UTG7ZZ, 0UTG8ZZ]
0UTJ0ZZ-0UTJXZZ	Resection of clitoris [by approach; includes codes 0UTJ0ZZ, 0UTJXZZ]
0UTM0ZZ-0UTMXZZ	Resection of vulva [by approach; includes codes 0UTM0ZZ, 0UTMXZZ]
0VRC0JZ	Replacement of bilateral testes with synthetic substitute, open approach
0VTC0ZZ-0VTC4ZZ	Resection of bilateral testes [by approach; includes codes 0VTC0ZZ, 0VTC4ZZ]
0VTS0ZZ-0VTSXZZ	Resection of penis [by approach; includes codes 0VTS0ZZ, 0VTS4ZZ, 0VTSXZZ]
0VUS07Z-0VUSX7Z	Supplement penis with autologous tissue substitute [by approach, includes codes 0VUS07Z, 0VUS47Z, 0VUSX7Z]
0VUS0JZ-0VUSXJZ	Supplement penis with synthetic substitute [by approach; includes codes 0VUS0JZ, 0VUS4JZ, 0VUSXJZ]
0VUS0KZ-0VUSXKZ	Supplement penis with nonautologous tissue substitute [by approach; includes codes 0VUS0KZ, 0VUS4KZ, 0VUSXKZ]
0W4M070	Creation of vagina in male perineum with autologous tissue substitute, open approach
0W4M0J0	Creation of vagina in male perineum with synthetic substitute, open approach
0W4M0K0	Creation of vagina in male perineum with nonautologous tissue substitute, open approach
0W4N071	Creation of penis in female perineum with autologous tissue substitute, open approach
0W4N0J1	Creation of penis in female perineum with synthetic substitute, open approach
0W4N0K1	Creation of penis in female perineum with nonautologous tissue substitute, open approach

ICD-10 Diagnosis

F64.0-F64.9	Gender identity disorders
Z87.890	Personal history of sex reassignment

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met.

When services may be Reconstructive when criteria are met:

CPT

11920-11922	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less [when specified for nipple/areola reconstruction after breast surgery; includes codes 11920, 11921, 11922]
11950-11954	Subcutaneous injection of filling material (eg, collagen) [includes codes 11950, 11951, 11952, 11954]
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)
15771-15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs
15773-15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet
15876	Suction assisted lipectomy, head and neck
15877	Suction assisted lipectomy, trunk [when specified as breast liposuction for breast reduction]
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue [when specified as

	injection of a dermal soft tissue filler]
19303	Mastectomy, simple, complete
19318	Breast reduction
19325	Breast augmentation with implant
19350	Nipple/areola reconstruction
21120-21123	Genioplasty [includes codes 21120, 21121, 21122, 21123]
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137-21139	Reduction forehead [includes codes 21137, 21138, 21139]
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)
21188	Reconstruction midface, osteotomies (other than LeFort type) and bone grafts (includes obtaining autografts)
21193-21194	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy [with or without bone graft]
21195-21196	Reconstruction of mandibular rami and/or body, sagittal split [with or without internal rigid fixation]
21198	Osteotomy, mandible, segmental
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21215	Graft, bone; mandible (includes obtaining graft)
21230	Graft; rib cartilage, autogenous, to face, chin, nose or ear (includes obtaining graft)
21235	Graft; ear cartilage, autogenous, to nose or ear (includes obtaining graft)
21270	Malar augmentation, prosthetic material
30400-30420	Rhinoplasty, primary [includes codes 30400, 30410, 30420]
30430-30450	Rhinoplasty, secondary [includes codes 30430, 30435, 30450]
31599	Unlisted procedure, larynx [when specified as thyroid cartilage chondroplasty, tracheal shave, or voice modification surgery such as anterior glottal web formation, cricothyroid approximation, vocal cord shortening]

HCPCS

L8600	Implantable breast prosthesis, silicone or equal
Q2026	Injection, Radiesse, 0.1 ml
Q2028	Injection, sculptra, 0.5 mg

ICD-10 Procedure

0H0V07Z-0H0V0KZ	Alteration of bilateral breast, open approach; [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0H0V07Z, 0H0V0JZ, 0H0V0KZ]
0HBV0ZZ-0HBV8ZZ	Excision of breast, bilateral [by approach; includes codes 0HBV0ZZ, 0HBV3ZZ, 0HBV7ZZ, 0HBV8ZZ]
0HRW07Z-0HRXXKZ	Replacement of nipple [by approach; includes codes 0HRW07Z, 0HRW0JZ, 0HRW0KZ, 0HRW3JZ, 0HRW3KZ, 0HRW37Z, 0HRWX7Z, 0HRWXJZ, 0HRWXKZ, 0HRX07Z, 0HRX0JZ, 0HRX0KZ, 0HRX3JZ, 0HRX3KZ, 0HRX37Z, 0HRXX7Z, 0HRXXJZ, 0HRXXKZ]
0NB10ZZ	Excision of frontal bone, open approach
0NB80ZZ	Excision of nasal bone, open approach
0NBM0ZZ	Excision of right zygomatic bone, open approach
0NBN0ZZ	Excision of left zygomatic bone, open approach
0NBR0ZZ	Excision of maxilla, open approach
0NBT0ZZ	Excision of right mandible, open approach
0NBV0ZZ	Excision of left mandible, open approach
0NU107Z-0NU10KZ	Supplement frontal bone, open approach; [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0NU107Z, 0NU10JZ, 0NU10KZ]
0NUB07Z-0NUB0KZ	Supplement nasal bone, open approach; [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0NUB07Z, 0NUB0JZ,

	0NUB0KZ]
0NUM07Z-0NUN0KZ	Supplement zygomatic bone, open approach; [right or left, with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0NUM07Z, 0NUM0JZ, 0NUM0KZ, 0NUN07Z, 0NUN0JZ, 0NUN0KZ]
0NUR07Z-0NUR0KZ	Supplement maxilla, open approach; [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0NUR07Z, 0NUR0JZ, 0NUR0KZ]
0NUT07Z-0NUV0KZ	Supplement mandible, open approach; [right or left, with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0NUT07Z, 0NUT0JZ, 0NUT0KZ, 0NUV07Z, 0NUV0JZ, 0NUV0KZ]
0W0407Z-0W040KZ	Alteration of upper jaw, open approach [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0W0407Z, 0W040JZ, 0W040KZ]
0W040ZZ	Alteration of upper jaw, open approach
0W0507Z-0W050KZ	Alteration of lower jaw, open approach [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0W0507Z, 0W050JZ, 0W050KZ]
0W050ZZ	Alteration of lower jaw, open approach
0WU407Z-0WU40KZ	Supplement lower jaw, open approach [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0WU407Z, 0WU40JZ, 0WU40KZ]
0WU507Z-0WU50KZ	Supplement lower jaw, open approach [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0WU507Z, 0WU50JZ, 0WU50KZ]

ICD-10 Diagnosis

F64.0-F64.9	Gender identity disorders
Z87.890	Personal history of sex reassignment

When services are Cosmetic and Not Medically Necessary:
For the procedure and diagnosis codes listed above when reconstructive criteria are not met or when the code describes a procedure designated in the Clinical Indications section as cosmetic and not medically necessary.

Discussion/General Information (Return to Clinical Indications)

The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth edition (DSM-5) provides criteria for the diagnosis of gender dysphoria. The DSM-5 criteria are widely recognized as the community standard by which individuals suspected of gender dysphoria are evaluated and diagnoses are confirmed. The DSM-5 criteria for gender dysphoria are as follows:

Gender dysphoria in Children*

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by at least six of the following (one of which must be Criterion A1):
    1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender, different from one's assigned gender).
    2. In boys (assigned gender), a strong preference for cross dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to wearing of typical feminine clothing.
    3. A strong preference for cross-gender roles in make-believe play or fantasy play.
    4. A strong preference for toys, games, or activities stereotypically used or engaged in by the other gender.
    5. A strong preference for playmates of the other gender.
    6. In boys (assigned gender), a strong rejection of typically masculine toys, games and activities and a strong avoidance of rough and tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games and activities.
    7. A strong dislike of one's sexual anatomy.
    8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.
B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.
    Specify if:
    With a disorder of sex development (e.g., a congenital adrenogenital disorder such as 2.55.2 [E25.0] congenital adrenal hyperplasia or 259.0 [E34.50] androgen insensitivity syndrome)
    Coding note: Code the disorder of sex development as well as gender dysphoria.

Gender dysphoria in Adolescents and Adults*

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by at least two of the following:
   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (on in young adolescents, the anticipated secondary sex characteristics).
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
   3. A strong desire for the primary and /or secondary sex characteristics of the other gender.
   4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.
   Specify if:
   With a disorder of sex development (e.g., a congenital adrenogenital disorder such as 2.55.2 [E25.0] congenital adrenal hyperplasia or 259.0 [E34.50] androgen insensitivity syndrome)
   Coding note: Code the disorder of sex development as well as gender dysphoria.
   Specify if:
   Post transition: The individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one cross-sex medical procedure or treatment regimen- namely regular cross-sex treatment or gender reassignment surgery confirming the desired gender (e.g., appendectomy, vaginoplasty in the natal male; mastectomy or phalloplasty in the natal female).

   *From: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. DSM-5. American Psychiatric Association. Washington, DC. May 2013. Page 451-459.

The World Professional Association for Transgender Health's (WPATH) Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People, Seventh Version (2012) provides recommendations for care of individuals with gender dysphoria. The SOC states,

> The SOC are intended to be flexible in order to meet the diverse health care needs of transsexual, transgender, and gender-nonconforming people. While flexible, they offer standards for promoting optimal health care and guiding the treatment of people experiencing gender dysphoria.

and

> Clinical departures from the *SOC* may come about because of a patient's unique anatomic, social, or psychological situation; an experienced health professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies.

Any variations from recommendations by WPATH within this guideline may reflect where SOC standards are, for example, not based on published medical evidence.

Procedures for the chest, also known as "top surgery", and those for the groin and reproductive organs, also known as "bottom surgery", do not need to be done in conjunction. Additionally, individuals undergoing top surgery do not need to subsequently undergo bottom surgery, or vice versa. The selection of appropriate procedures should be based on the needs of the individual in relation to the treatment of their diagnosis of gender dysphoria. The WPATH SOC addresses this issue, "The SOC do not specify an order in which different surgeries should occur. The number and sequence of surgical procedures may vary from patient to patient, according to their clinical needs."

Gender Affirming Pelvic and Gonadal Procedures

Procedures addressing pelvic and gonadal anatomy in individuals with gender dysphoria are conducted to achieve the desired physical anatomy and function aligning with the individual's experienced gender. Gender affirming pelvic and gonadal procedures have been shown in many studies to provide significant functional improvement in multiple areas (Becker, 2018; Butler, 2019; Cardoso da Silva, 2016; Castellano, 2015; De Cuypere, 2005; de Vries, 2014; Djordjevic

2009; Guss, 2015; Hage, 2006; Jeltestad, 2018; Lawrence, 2006; Miller, 2019; Murad, 2010; Olson-Kennedy, 2018; Owen-Smith, 2018; Papadopulos, 2015; Simbar, 2018; Terrier, 2014; Tucker, 2018; van de Grift, 2017; Weigert, 2013; Wernick, 2019; Wierckx, 2011). These improvements include gender dysphoria-related symptoms such as psychological distress, depression, anxiety, and acceptance of the individual's body. Additionally, the available literature also demonstrates significant benefits related to quality of life and overall well-being.

The medical necessity criteria above for pelvic and gonadal procedures are based on several sources including the WPATH SOC, published peer-reviewed studies and expert opinion. In addition to having an established gender dysphoria diagnosis, individuals seeking gender affirmation surgery must be of the age of legal majority in the country in which they are seeking care (in the United states: 18 years of age). Individuals seeking irreversible surgical procedures should have the capacity to make fully informed decisions, and any significant medical or mental health issues should be reasonably well controlled. Gender affirming surgical procedures present significant medical and psychological risks, and the results are difficult to reverse (Djordjevic, 2016).

Published peer-reviewed studies have shown that hormonal therapy and real-life experience living as the other gender, as well as social support and acceptance by peer and family groups, improve psychological outcomes in individuals undergoing gender affirming surgery (Eldh, 1997; Landen, 1998). Monstrey (2001) described the importance of close cooperation between the medical and behavioral specialties required for proper treatment of individuals with gender dysphoria who wish to undergo gender affirming surgery. Similar findings were reported earlier by Schlatterer (1996). One study of 188 subjects undergoing gender affirming surgery found that dissatisfaction with surgery was highly associated with sexual preference, psychological co-morbidity, and poor pre-operative body image and satisfaction (Smith, 2005).

While this document does not address the medical necessity of hormone therapy, when indicated, it is administered under medical supervision and begins the gender transition process by altering body hair, breast size or development, skin appearance and texture, body fat distribution, the size and function of sex organs, and other characteristics, including voice deepening. The WPATH guidelines support using hormonal therapy prior to pelvic and gonadal procedures.

For individuals undergoing gender affirming genital procedures, real-life experience living as the desired gender is important to validate the individual's desire and ability to incorporate into their desired gender role within their social network and daily environment. This generally involves gender-specific appearance (garments, hairstyle, etc.), involvement in various activities in the desired gender role including work or academic settings, legal acquisition of a gender appropriate first name, and acknowledgement by others of the new gender role. With regard to real-life experience, the WPATH states:

> The criterion noted above for some types of genital surgeries – i.e., that patients engage in 12 continuous months of living in a gender role that is congruent with their gender identity – is based on expert clinical consensus that this experience provides ample opportunity for patients to experience and socially adjust in their desired gender role, before undergoing irreversible surgery. As noted in section VII, the social aspects of changing one's gender role are usually challenging – often more so than the physical aspects. Changing gender role can have profound personal and social consequences, and the decision to do so should include an awareness of what the familial, interpersonal, educational, vocational, economic, and legal challenges are likely to be, so that people can function successfully in their gender role. Support from a qualified mental health professional and from peers can be invaluable in ensuring a successful gender role adaptation (Bockting, 2008).
>
> The duration of 12 months allows for a range of different life experiences and events that may occur throughout the year (e.g., family events, holidays, vacations, season-specific work or school experiences). During this time, patients should present consistently, on a day-to-day basis and across all settings of life, in their desired gender role. This includes coming out to partners, family, friends, and community members (e.g., at school, work, other settings).
>
> Health professionals should clearly document a patient's experience in the gender role in the medical chart, including the start date of living full time for those who are preparing for genital surgery. In some situations, if needed, health professionals may request verification that this criterion has been fulfilled: They may communicate with individuals who have related to the patient in an identity-congruent gender role, or request documentation of a legal name and/or gender marker change, if applicable.

Gender Affirming Chest Surgery:

Gender affirming chest surgery in individuals with gender dysphoria is reconstructive, in that the procedure is intended to address the significant variation from normal appearance for the experienced gender. The evidence addressing gender affirming chest surgery for the treatment of gender dysphoria supports a consistent association between surgery and satisfaction with breast appearance, psychological and sexual well-being, and body image and attractiveness; however, evidence supporting improvements in functional outcomes (for example, quality of life, gender dysphoria symptoms, or sequelae of severe illness, including crisis visits, suicide attempts, etc.) is less clear (Becker, 2018; Miller, 2019; Olson-Kennedy, 2018; Weigert, 2013). Criteria for chest surgery are generally consistent with genital/gonadal surgery including requirements related to age, capacity to consent, diagnosis of gender dysphoria, and reasonably well controlled concomitant physical and mental health conditions.

For individuals born with male anatomy and considering gender affirming breast surgery, hormone therapy results in the development of at least some breast tissue in most cases. Breast development generally occurs within the first 12 months (although development may continue through 2-3 years of therapy) (De Blok, 2020a). Published studies have reported that final breast size varies significantly, anywhere from no growth to a C-cup, although the average individual achieves an A-cup in size. WPATH notes "Although not an explicit criterion, it is recommended that patients undergo feminizing hormone therapy (minimum 12 months) prior to gender affirming breast augmentation surgery. The purpose is to maximize breast growth in order to obtain better surgical (aesthetic) results." To establish a reconstructive intent, it is important that an individual has undergone a minimum of 12 months of continuous hormonal therapy (when recommended by a mental health professional), and insufficient breast development has occurred.

Gender Affirming Chest Surgery in Individuals Under the Age of 18 (Return to Clinical Indications)

Further consideration of a gender affirming chest procedure in select individuals under 18 years of age may be appropriate; there may exist extenuating circumstances, such as the level of maturity of the individual, duration of dysphoric symptoms, medical and mental health, and other factors, that should be considered in consultation with a provider with experience treating adolescents with gender dysphoria. The WPATH SOC provides the following guidance for individuals under the age of 18:

> Genital surgery should not be carried out until (i) patients reach the legal age of majority to give consent for medical procedures in a given country, and (ii) patients have lived continuously for at least 12 months in the gender role that is congruent with their gender identity. The age threshold should be seen as a minimum criterion and not an indication in and of itself for active intervention.
>
> Chest surgery in FtM patients could be carried out earlier, preferably after ample time of living in the desired gender role and after one year of testosterone treatment. The intent of this suggested sequence is to give adolescents sufficient opportunity to experience and socially adjust in a more masculine gender role, before undergoing irreversible surgery. However, different approaches may be more suitable, depending on an adolescent's specific clinical situation and goals for gender identity expression.

Gender Affirming Facial Surgery (Return to Clinical Indations)

In some cases, an individual's facial features may be outside of what is perceived as normal for their experienced gender. Gender affirming facial surgery in individuals with gender dysphoria is considered reconstructive, in that the procedure is intended to address as a significant variation from normal appearance for the experienced gender.

The published data regarding gender affirming facial surgery generally support associations between surgery and the likelihood of being properly identified by the experienced gender by observers; however, evidence supporting improvements in functional outcomes (for example, quality of life, gender dysphoria symptoms, or sequelae of severe illness, including crisis visits, suicide attempts, etc.) is less clear (Ainsworth, 2010; Cohen, 2018; Fisher, 2020; Morrison, 2020). There is some data to demonstrate that the long-term use of hormone therapy does quantifiably femininize or masculinize facial features, thus extended use of hormone therapy prior to facial feminization may be warranted in some circumstances (Tebbens, 2019).

The WPATH does not recommend specific criteria for the use of facial feminization procedures. Instead, they note the following:

> Unfortunately, in the field of plastic and reconstructive surgery (both in general and specifically for gender-related surgeries), there is no clear distinction between what is purely reconstructive and what is purely cosmetic. Most plastic surgery procedures actually are a mixture of both reconstructive and cosmetic components.

> While most professionals agree that genital surgery and mastectomy cannot be considered purely cosmetic, opinions diverge as to what degree other surgical procedures (e.g., breast augmentation, facial feminization surgery) can be considered purely reconstructive. Although it may be much easier to see a phalloplasty or a vaginoplasty as an intervention to end lifelong suffering, for certain patients an intervention like a reduction rhinoplasty can have a radical and permanent effect on their quality of life, and therefore is much more medically necessary than for somebody without gender dysphoria.

Individuals with gender dysphoria who undergo gender affirming procedures may seek additional procedures to further alter their facial appearance when existing facial appearance demonstrates significant variation from normal appearance for the experienced gender. Such procedures may include the following:

- Facial bone reconstruction
- Facial implants
- Jaw reduction (jaw contouring)
- Lip reduction/enhancement
- Lipofilling/collagen injections
- Liposuction
- Nose implants
- Rhinoplasty
- Thyroid cartilage reduction (chondroplasty)

Gender Affirming Voice Modification Surgery

Gender affirming voice modification surgery is considered reconstructive for individuals when existing vocal presentation demonstrates significant variation from normal for the experienced gender. WPATH notes:

> Some transsexual, transgender, and gender-nonconforming people will undergo voice feminization surgery. (Voice deepening can be achieved through masculinizing hormone therapy, but feminizing hormones do not have an impact on the adult MtF (sic: male-to-female) voice.) There are varying degrees of satisfaction, safety, and long-term improvement in patients who have had such surgery. It is recommended that individuals undergoing voice feminization surgery also consult a voice and communication specialist to maximize the surgical outcome, help protect vocal health, and learn nonpitch related aspects of communication. Voice surgery procedures should include follow-up sessions with a voice and communication specialist who is licensed and/or credentialed by the board responsible for speech therapists/speech-language pathologists in that country.

WPATH notes that voice surgery to obtain a deeper voice in individuals desiring body masculinization is rare but may be recommended in some cases, such as when hormone therapy has been ineffective.

Published data evaluating gender affirming voice modification surgery is limited to postoperative satisfaction and vocal outcomes; functional outcomes (for example, quality of life, gender dysphoria symptoms, or sequelae of severe illness, including crisis visits, suicide attempts, etc.) have not been specifically assessed (Kim, 2020).

Referral Letters (Return to Clinical Indications)

An independent assessment of an individual by a qualified mental health professional is considered standard of care before an individual undergoes a gender affirming surgical procedure.

The SOC states the following regarding referral letters in support of gender affirming surgery:

> The recommended content of the referral letters for surgery is as follows:
>
> 1. The client's general identifying characteristics;
> 2. Results of the client's psychosocial assessment, including any diagnoses;
> 3. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date;
> 4. An explanation that the criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery;
> 5. A statement about the fact that informed consent has been obtained from the patient;
> 6. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this.

While the SOC also states:

For providers working within a multidisciplinary specialty team, a letter may not be necessary, rather, the assessment and recommendation can be documented in the patient's chart.

Additionally, the SOC provides the following recommendations regarding the credentials for mental health professionals who work with adults presenting with gender dysphoria:

1. A master's degree or its equivalent in a clinical behavioral science field. This degree, or a more advanced one, should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent for that country.
2. Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Diseases for diagnostic purposes.
3. Ability to recognize and diagnose coexisting mental health concerns and to distinguish these from gender dysphoria.
4. Documented supervised training and competence in psychotherapy or counseling.
5. Knowledgeable about gender-nonconforming identities and expressions, and the assessment and treatment of gender dysphoria.
6. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

This statement from the SOC does not govern CG-SURG-27. A letter including all of the recommended items should be included in surgical requests.

Other Guidelines

In late 2017, the Endocrine Society released a clinical practice guideline for the endocrine treatment of gender-dysphoric/gender-incongruent persons (Hembree, 2017). This publication was co-sponsored by the American Association of Clinical Endocrinologists, the American Society of Andrology, the European Society for Pediatric Endocrinology, the European Society of Endocrinology, the Pediatric Endocrine Society, and WPATH. Among other recommendations this document includes the following:

2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment, and are requesting treatment should initially undergo treatment to suppress pubertal development. (2 | ⊕⊕○○)
2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty. (2 |⊕⊕○○)
2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. (1 | ⊕⊕○○)
2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years. (1 |⊕⊕○○)
2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 |⊕○○○)
5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being. (1 |⊕⊕○○)
5.2. We advise that clinicians approve genital gender affirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)
5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)
5.4. We recommend that clinicians refer hormone treated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 |⊕⊕○○○)

5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 |⊕⊕○○).

Note: "MHP" is the Endocrine Society's abbreviation for "mental health professional".

Hair removal Procedures

In many instances, the creation of a neovagina or a urethra for a neopenis requires an autologous skin graff from the forearm or thigh. Such skin may be excessively hairy, which will impair the function of the newly constructed organ if not permanently removed. Pre-operative permanent hair removal treatments to these areas may be warranted to prevent post-operative complications.

Procedures to Address Postoperative Complications of Gender Affirming Surgery and Reversal Surgery (Return to Clinical Indications)

Procedures to address postoperative complications of a prior gender affirming surgery (for example, scarring, stenosis, infection, etc.) are not considered a separate gender affirming surgery procedure and are not addressed in this document.

Reversal of a prior gender affirming surgery procedure is rare and is considered gender affirming surgery. According to the literature on this issue, the predominant factor in requests for reversals are regret, which has been further associated with age greater than 30 at first surgery, personality disorders, early loss of both parents, social instability, preoperative sexual orientation for heterosexual male-to-female (MtF) individuals, degree of social support, secondary transsexualism, early decision to undergo surgery and dissatisfaction with surgical results (Blanchard, 1989; Landén, 1998; Lawrence, 2003; Lindemalm, 1986 and 1987; Olsson, 2006).

Djordjevic (2016) reported on the outcomes of surgical reversal surgery in MtF individuals wishing to transition back to male. While the main focus of this paper is related to surgical outcomes, the authors reported on characteristics of the participating subjects and contributing factors to the reversal decisions. The seven subjects had an absence of "real-life experience" prior to surgery, absence or inappropriate hormonal treatment, recommendations by inexperienced professionals, and insufficient hormonal therapy and medical follow-up. Furthermore, they failed to fulfill the complete diagnostic criteria for GID. The authors concluded that the main factor contributing to regret was absence of proper pretreatment assessment. In their reversal protocol, each subject was required to have recommendations from three well-known WPATH psychiatrists prior to reversal procedures.

The available evidence indicates the importance of thorough preoperative physical and psychological evaluation and treatment as being a critical factor in postoperative success. As noted above, these aspects of the treatment process are critical to sufficiently prepare an individual for the social, physical, and mental ramifications of the decision to undergo gender affirming surgery.

The clinical evidence addressing the satisfaction and quality of life following gender affirming surgery is limited, and the reported findings are mixed (Cardoso da Silva, 2016; Castellano, 2015). It is important that proper and thorough pre-operative work-up and preparation be conducted in individuals considering such life-altering procedures. Additionally, long-term post-operative follow-up, including availability of mental health services, may also contribute to satisfaction with surgical results.

Other Procedures

Additional surgeries have been proposed to improve the gender appropriate appearance of the individual. Such procedures may be considered cosmetic and are not reconstructive when intended to change a physical appearance that would be considered within normal human anatomic variation or are primarily intended to preserve or improve appearance irrespective of gender-defining features.

Such procedures may include the following when one or more of the medical necessary or reconstructive criteria above have not been met:

A. Abdominoplasty
B. Bilateral mastectomy
C. Blepharoplasty
D. Breast augmentation
E. Brow lift
F. Face lift
G. Facial bone reconstruction

H. Facial implants
I. Gluteal implants
J. Hair removal (for example, electrolysis or laser) and hairplasty
K. Jaw reduction (jaw contouring)
L. Lip reduction/enhancement
M. Lipofilling/collagen injections
N. Liposuction
O. Nose implants
P. Pectoral implants
Q. Rhinoplasty
R. Thyroid cartilage reduction (chondroplasty)
S. Voice modification surgery

WPATH notes that other surgeries for assisting in body feminization or masculinization may include suction-assisted lipoplasty (contour modeling) of the waist, face-lift, blepharoplasty (rejuvenation of the eyelid), gluteal augmentation (implants/lipofilling), liposuction, lipofilling, pectoral implants, and "various aesthetic procedures." Such procedures are considered cosmetic when intended to change a physical appearance that would be considered within normal human anatomic variation or are primarily intended to preserve or improve appearance.

Review Considerations:

Reconstructive procedures address features that are distinctly and directly related to gender appearance (or in the case of gender affirming voice modification surgery, vocal presentation), when documentation sufficiently demonstrates significant variation from what is considered normal for the experienced gender. When multiple procedures are requested, each procedure should be considered separately as some procedures may be cosmetic and others may be reconstructive. Procedures primarily intended to preserve or improve appearance (that is: independent of any gender-defining feature or overall gender appearance) are considered cosmetic.

Peer Reviewed Publications:

1. Ainsworth TA, Spiegel JH. Quality of life of individuals with and without facial feminization surgery or gender reassignment surgery. Qual Life Res. 2010; 19(7):1019-24.
2. Becker I, Auer M, Barkmann C, Fuss J, et al. A cross-sectional multicenter study of multidimensional body image in adolescents and adults with gender dysphoria before and after transition-related medical interventions. Arch Sex Behav. 2018; 47(8):2335-2347.
3. Becking AG, Tuinzing DB, Hage JJ, Gooren LJ. Facial corrections in male to female transsexuals: a preliminary report on 16 patients. J Oral Maxillofac Surg. 1996; 54(4):413-418.
4. Blanchard R, Steiner BW, Clemmensen LH, Dickey R. Prediction of regrets in postoperative transsexuals. Can J Psychiatry. 1989; 34(1):43-45.
5. Bradley SJ, Zucker KJ. Gender identity disorder: a review of the past 10 years. J Am Acad Child Adolesc Psychiatry. 1997; 36(7):872-880.
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Gender affirmation
Gender confirmation
Sex affirmation
Sex change
Sex confirmation
Sex reassignment

Status	Date	Action
Revised	05/13/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated title and rest of document to replace "reassignment" with "affirming". Alphabetized procedures in MN statements. Revised gender dysphoria criteria in all MN statements. Added "or intolerance" to hormone therapy in related MN criteria. Clarified hair removal MN statement. Moved bilateral mastectomy from MN to Reconstructive section. Added breast augmentation and breast reduction procedures to Reconstructive section. Moved gender affirming facial feminization procedures and voice modification surgery from Cosmetic and NMN to Reconstructive section. Removed voice therapy from scope of document. Clarified the NMN statement and Cosmetic and NMN statement. Revised Further Considerations statement to include breast augmentation and breast

		reduction procedures. Updated Discussion and References sections. Updated Coding section with additional codes for facial and chest surgery.
Revised	02/11/2021	MPTAC review. Clarified note regarding number of letters required for mastectomy procedures. The phrase "cosmetic" was clarified to read "cosmetic and not medically necessary". Updated Description, Coding and References sections.
	12/16/2020	Updated Coding section with 01/01/2021 CPT changes, revised descriptors for codes 19318, 19325; removed deleted ICD-10-PCS codes.
Revised	08/13/2020	MPTAC review. Added penile prostheses to MN statement addressing phalloplasty procedures. Updated Description and References sections. Reformatted Coding section and added codes 54400, 54401, 54405, 55899, C1813, C2622, L8699.
Revised	05/14/2020	MPTAC review. Added text to MN statement for mastectomy referring reader to see Further Considerations section for individuals under 18 years of age. Added new Further Considerations section addressing mastectomy procedures for individuals under 18 years of age. Updated Description, Discussion, References and Index sections.
	04/01/2020	Updated Coding section; added CPT 19318 and removed deleted code 19304.
Revised	11/07/2019	MPTAC review. Updated title and document contents to replace "sex reassignment" with "gender reassignment" and "his or her" with "their". Made minor language revisions to Clinical Indications section. Clarified MN statement regarding hair removal procedures. Added text to the Background section regarding WPATH recommendations for the content of referral letters. Updated Discussion and References sections. Updated Coding section with 01/01/2020 CPT changes; noted 19304 is deleted effective 12/31/2019.
Revised	01/24/2019	MPTAC review. Revised MN criteria for bilateral mastectomy to require one referral letter. Added new notes addressing treatment of postoperative complications and reversal procedures. Updated Discussion, Coding, and References sections.
Revised	11/08/2018	MPTAC review. Added criteria for referral letters to mastectomy MN statement.
Revised	03/22/2018	MPTAC review.
Revised	02/23/2018	Behavioral Health Subcommittee review. Clarification of mastectomy criteria to remove specification that a female must be transitioning to be a male. Clarification of several Cosmetic indications.
	01/01/2018	The document header wording updated from "Current Effective Date" to "Publish Date." Updated Coding section; removed CPT 55970, 55980 (not applicable).
Revised	08/03/2017	MPTAC review.
Revised	07/21/2017	Behavioral Health Subcommittee review. Added note regarding timing of "top" and "bottom" surgical procedures. Added new statement regarding nipple reconstructions following mastectomy. Updated Coding and References sections.
Revised	02/02/2017	MPTAC review.
Revised	01/20/2017	Behavioral Health Subcommittee review. Updated criteria regarding confirmation of female gender prior to bilateral mastectomy in female-to-male transitions. Updated Reference sections.
Revised	08/04/2016	MPTAC review.
Revised	07/29/2016	Behavioral Health Subcommittee review. Updated formatting in the Clinical Indications section. Added bilateral mastectomy to MN section with criteria. Updated Reference sections. Updated Coding section to include 10/01/2016 ICD-10-CM changes.
Revised	05/05/2016	MPTAC review. Revised title from "Gender Reassignment Surgery" to "Sex Reassignment Surgery". Updated Coding, Rationale and Discussion section.
Revised	02/04/2016	MPTAC review.
Revised	01/29/2016	Behavioral Health Subcommittee review. Added new medically necessary statement addressing the use of hair removal procedures to treat tissue donor sites for a planned phalloplasty or vaginoplasty procedure. Added additional procedures to Cosmetic statement. Updated Coding and Rationale sections. Removed ICD-9 codes from Coding section.
Revised	08/06/2015	MPTAC review.
Revised	07/31/2015	Behavioral Health Subcommittee review. Revised text regarding educational and professional qualifications required for individuals submitting referral letters to include master's-level practitioners. Added text to referral letter criteria, requiring that letters need to be no more than 12 months old at time of request. Revised criteria regarding

		hormone therapy requirements. Replaced the word 'surgeries' with 'procedures' in Cosmetic statement. Added note to Cosmetic section.
Reviewed	08/14/2014	MPTAC review.
Reviewed	08/08/2014	Behavioral Health Subcommittee review.
Revised	08/08/2013	MPTAC review.
Revised	07/26/2013	Behavioral Health Subcommittee review. Revised document text to align with new DSM-5 terminology and diagnostic criteria. Updated Discussion and Reference sections.
Revised	08/09/2012	MPTAC review.
Revised	08/03/2012	Behavioral Health Subcommittee review. Created separate criteria sets for gonad and reproductive organ procedures and for external genital procedures in alignment with the WPATH SOC7. Deleted the criteria requiring 12 months of continuous living in desired gender role from the reproductive organ procedures criteria set. Deleted criteria requiring "Demonstrable knowledge of the required length of hospitalizations, likely complications, and post-surgical rehabilitation requirements of various surgical approaches". Deleted "not due to chromosomal abnormality" from medically necessary criteria. Updated Coding, Discussion and Reference sections.
Revised	02/16/2012	MPTAC review.
Revised	02/10/2012	Behavioral Health Subcommittee review. Significantly revised the medically necessary to align with new 2012 WPATH Standards of Care document. Updated Rationale and Reference sections.
Reviewed	05/19/2011	MPTAC review.
Reviewed	05/13/2010	MPTAC review. Updated Reference section.
Reviewed	11/19/2009	MPTAC review. Updated Coding section with 01/01/2010 CPT changes.
Reviewed	11/20/2008	MPTAC review. Updated Coding section.
Reviewed	11/29/2007	MPTAC review. Updated Coding section with 01/01/2008 CPT changes.
New	12/07/2006	MPTAC initial guideline development.

Federal and State law, as well as contract language including definitions and specific coverage provisions/exclusions, and Medical Policy take precedence over Clinical UM Guidelines and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Clinical UM Guidelines, which address medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Clinical UM Guidelines periodically. Clinical UM guidelines are used when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether or not to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the back of the member's card.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, Inc. d/b/a WHITMAN-WALKER HEALTH 1377 R Street NW Washington, DC 20009; THE TRANSLATIN@ COALITION 3055 Wilshire Boulevard, Suite 350 Los Angeles, CA 90010; LOS ANGELES LGBT CENTER 1625 Schrader Boulevard Los Angeles, CA 90028; BRADBURY-SULLIVAN LGBT COMMUNITY CENTER 522 West Maple Street at Bayard Rustin Way Allentown, PA 18101; AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC. d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY 1133 19th Street NW, Suite 302 Washington, DC 20036; AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS 4514 Chester Avenue Philadelphia, PA 19143; SARAH HENN, MD, MPH c/o Steptoe & Johnson LLP 1330 Connecticut Avenue NW Washington, DC 20036; RANDY PUMPHREY, D.MIN, LCC, BCC c/o Steptoe & Johnson LLP 1330 Connecticut Avenue NW Washington, DC 20036;	Case No. **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

ROBERT BOLAN, MD
c/o Steptoe & Johnson LLP
1330 Connecticut Avenue NW
Washington, DC 20036; and

WARD CARPENTER, MD
c/o Steptoe & Johnson LLP
1330 Connecticut Avenue NW
Washington, DC 20036,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue SW
Washington, D.C. 20201;

ALEX M. AZAR II, in his official capacity as Secretary of U.S. Department of Health and Human Services,
200 Independence Avenue SW
Washington, D.C. 20201;

ROGER SEVERINO, in his official capacity as Director, Office for Civil Rights, U.S. Department of Health and Human Services,
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201; and

SEEMA VERMA, in her official capacity as Administrator for the Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244,

Defendants.

INTRODUCTION

1. A person's access to health care should not be contingent on their sex, gender identity, transgender status, sexual orientation, race, national origin, age, disability, or religion. When people go to a doctor's office, hospital, or an emergency room seeking treatment, they expect and are entitled to receive care appropriate to meet their health needs without regard to who they are or the type of health care they seek.

2. Yet, in the midst of a global pandemic, the Trump Administration's Department of Health and Human Services ("HHS") has sought to diminish protections from discrimination in health care because of a person's sex, gender identity, transgender status, sexual orientation, race, national origin, age, or disability.

3. HHS has taken these actions notwithstanding and despite the decision of the Supreme Court of the United States on June 15, 2020 holding that discrimination on the basis of a person's transgender status or sexual orientation is discrimination on the basis of sex. *See Bostock v. Clayton Cty., Ga.*, 590 U.S. ___, 2020 WL 3146686 (June 15, 2020).

4. As of the filing of this Complaint, and in less than six months, approximately 2.25 million people in the United States have tested positive for COVID-19, resulting in approximately 120,000 deaths to date.[1] The United States is facing a public health crisis. During these difficult times, Americans need the security and peace of mind that they will be able to access the health care they need and require. The government should be doing everything within its capacity to protect and preserve the safe and effective delivery of health care to all patients regardless of their sex, gender identity, transgender status, sexual orientation, race,

[1] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19): Cases in the U.S.*, https://perma.cc/38HG-JUBB (last visited June 21, 2020).

national origin, age, or disability. Yet, HHS is doing exactly the opposite, adopting positions that fly in the face of its stated mission to "enhance and protect the health and well-being of all Americans by providing for effective health and human services."[2]

5. Recognizing the paramount importance of providing people with prompt, effective, and nondiscriminatory access to health care, Congress has taken repeated and concerted efforts to improve access to health care and bar discrimination within the health care industry.

6. Section 1557 of the Patient Protection and Affordable Care Act ("ACA"), 42 U.S.C. § 18116, specifically and explicitly protects against discrimination in the provision of health care services. Section 1557 prohibits discrimination based on sex, race, color, national origin, age, and disability.

7. In 2016, HHS promulgated a final rule, developed over the course of six years and two notice-and-comment periods, to implement the nondiscrimination requirements of Section 1557. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (May 18, 2016) (formerly codified at 45 C.F.R. pt. 92) (the "2016 Final Rule"). Consistent with Section 1557's nondiscrimination mandate, the 2016 Final Rule made clear that health care providers and insurers may not discriminate against lesbian, gay, bisexual, transgender, and queer ("LGBTQ") people in making medical and coverage decisions. Doing so constitutes discrimination on the basis of sex, which the 2016 Final Rule specifically defined to include discrimination on the basis of gender identity and sex stereotyping, among other criteria.

[2] U.S. Dep't of Health & Human Servs., *About HHS*, HHS.GOV, https://perma.cc/CY5N-RBPH.

8. The 2016 Final Rule also included specific guidance about how Section 1557's sex discrimination prohibition applies to transgender people, including access to and coverage of gender-affirming health services.

9. In addition, the 2016 Final Rule confirmed, based on the plain statutory language of Section 1557, that all enforcement mechanisms available under the statutes listed in Section 1557 are available to any person regardless of the person's protected characteristic, establishing a unitary legal standard for all violations of the statute. It also confirmed that Section 1557 prohibits not only intentional discrimination, but conduct and practices that have the effect of subjecting individuals to discrimination on the basis of their sex.

10. Since the 2016 Final Rule went into effect, it has led to a dramatic decrease in discriminatory policies and practices.[3]

11. Now, however, with next-to-no legal, medical, or reasoned policy foundation, and contrary to the opinions of professional medical and public health organizations,[4] HHS has issued a revised regulation under Section 1557 (the "Revised Rule") that rolls back the 2016 Final Rule and limits the protections for LGBTQ people, among others. *See* Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg.

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[3] *See, e.g.*, Sharita Gruberg and Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, Center for American Progress (Mar. 7, 2018), https://perma.cc/CTP2-UMEJ.

[4] *See, e.g.*, Letter from James L. Madara, MD, Exec. Vice President/CEO, American Medical Association, to The Hon. Alex M. Azar II, Sec'y, U.S. Dep't Health & Hum. Servs. (Aug. 13, 2019), https://perma.cc/9N7N-JJ3G; Letter from Saul Levin, MD, MPA, FRCP-E, CEO & Med. Dir., American Psychiatric Association, to Sec'y Alex Azar II, U.S. Dep't Health & Hum. Servs. (Aug. 9, 2019), https://perma.cc/YUG9-E6SW; Letter from Katherine B. McGuire, Chief Advocacy Officer, American Psychological Association, to U.S. Dep't Health & Hum. Servs. (Aug. 13, 2019), https://perma.cc/LE65-6Q63.

37,160 (June 19, 2020) (to be codified at 42 C.F.R. pts. 438, 440, & 460 and 45 C.F.R. pts. 86, 92, 147, 155, & 156).

12. Although the Revised Rule cannot change the law, it is part of the Trump Administration's concerted and aggressive effort to undermine protections for LGBTQ people, including Section 1557's nondiscrimination protections and the regulatory structure and administrative processes the 2016 Final Rule established. Multiple provisions in the Revised Rule threaten to confuse and mislead patients, health care providers, and insurers and will result in increased discrimination and substantial harm to precisely those vulnerable communities that Section 1557 is intended to protect, like LGBTQ people and their families.

13. Relying on essentially one federal district court opinion, the Revised Rule arbitrarily and capriciously repeals entirely the 2016 Final Rule's definition of discrimination on the basis of sex, which specifically included discrimination based on gender identity and sex stereotyping, as well as related provisions prohibiting discrimination against transgender individuals. The elimination of this definition not only invites health care insurers and providers to discriminate against LGBTQ people seeking health care, but it also introduces substantial confusion among health care providers and insurers regarding their legal obligations and the right of the populations they serve to be free from sex discrimination, particularly in light of the Supreme Court's decision in *Bostock* v. *Clayton County, Georgia*, 590 U.S. __, 2020 WL 3146686, which held that discrimination based on transgender status or sexual orientation "necessarily entails discrimination based on sex." *Id.* at *11.

14. The Revised Rule, which HHS publicly released three days prior to the Supreme Court's ruling in *Bostock*, recognizes that "a holding by the U.S. Supreme Court on the meaning of 'on the basis of sex' under Title VII will likely have ramifications for the definition of 'on the

basis of sex' under Title IX," because "Title VII case law has often informed Title IX case law with respect to the meaning of discrimination 'on the basis of sex.'" 85 Fed. Reg. 37,168. However, undeterred from their goal to foster discrimination against LGBTQ people, HHS published the Revised Rule, without any changes, four days after the Supreme Court's decision in *Bostock*.

15. To be clear, *Bostock*'s holding that discrimination on the basis of sexual orientation or transgender status constitutes discrimination on the basis of sex forecloses HHS's attempts to deny the full protection of Section 1557 to LGBTQ individuals and patients in health care settings.

16. The Revised Rule also eliminates the unitary legal standard for enforcement of violations of Section 1557, replacing it with a fractured approach that will complicate and make it more difficult to bring discrimination claims under Section 1557, particularly claims of intersectional discrimination. The Revised Rule's elimination of the explicit recognition of private rights of action and the availability of compensatory damages under Section 1557 also will confuse the public and mislead individuals into not asserting their legal rights.

17. In addition, the Revised Rule imports broad and sweeping exemptions for discrimination based on personal religious or moral beliefs from the identified statutes in Section 1557 *and* other statutes, including the Religious Freedom Restoration Act (42 U.S.C. § 2000bb *et seq.*), which Section 1557 does not reference. These exemptions invite individual health care providers, health care entities, and insurers across the country to opt out of treating patients, including many transgender patients, if they believe doing so would compromise their faith.

18. These exemptions will adversely affect health care providers that serve and treat the LGBTQ community and their LGBTQ patients because (1) their individual health care

employees may decline to serve patients based on religious objections, and (2) their ability to refer patients to other providers will be impaired, as the Revised Rule would invite discrimination against their LGBTQ patients.

19. HHS's attempt to create new religious exemptions in Section 1557 is contrary to law and endangers patients' health in the name of advancing the religious beliefs of those who are entrusted with caring for them—a result sharply at odds with HHS's stated mission to "enhance and protect the health and well-being of all Americans" and to "provid[e] for effective health and human services."[5]

20. The Revised Rule also arbitrarily and capriciously eliminates the requirement that covered entities post notices informing individuals about nondiscrimination requirements and their rights and also cuts back the safeguards that the 2016 Final Rule implemented for patients with Limited English Proficiency ("LEP"), weakening protections for LEP patients and depriving families and individuals of adequate care.

21. In addition, the Revised Rule limits the scope of Section 1557, cutting back on the entities subject to Section 1557. Despite the plain language of Section 1557, the Revised Rule excludes health programs and activities that HHS funds but are not established or administered under Title I of the ACA and health insurance plans outside of Title I of the ACA that do not receive Federal financial assistance. Not only is this action inconsistent with Section 1557, it will cause drastic reductions in protections for LGBTQ people.

22. The Revised Rule also amends a series of unrelated regulations issued under statutes other than Section 1557 by deleting references to sexual orientation and gender identity discrimination. HHS does not have the authority to make these changes within the rulemaking

[5] U.S. Dep't of Health & Human Servs., *About HHS*, HHS.GOV, https://perma.cc/CY5N-RBPH.

challenged, and these changes are not supported by any analysis or evidence. The Revised Rule is intended only to send a message that a person's LGBTQ identity is not recognized and LGBTQ people can be subjected to discrimination.

23. The Revised Rule's cost-benefit analysis is fatally flawed, incomplete, and unreasonable. Specifically, HHS fails to account for the increased costs to patients, insurers, and the health care system at large stemming from discrimination against LGBTQ and other patients.

24. The Revised Rule, if allowed to go into effect, will undermine the progress achieved so far in eradicating health care discrimination against LGBTQ people in a broad array of health care programs and entities by inviting health care insurers and providers once again to discriminate against them, while also discouraging LGBTQ people from seeking health care in the first instance.

25. In adopting the Revised Rule, HHS acted arbitrarily and capriciously, in excess of its statutory authority, and not in accordance with the law in violation of the Administrative Procedure Act ("APA") (5 U.S.C. § 551 *et seq.*). The Revised Rule also violates the Equal Protection Guarantee and Due Process Clause of the Fifth Amendment, and the Free Speech and Establishment Clauses of the First Amendment to the United States Constitution.

26. The Revised Rule is causing and will continue to cause irreparable harm to LGBTQ people and health care providers. The Revised Rule should be declared unlawful, enjoined, and vacated.

JURISDICTION AND VENUE

27. This Court has jurisdiction pursuant to 28 U.S.C. § 1331, as this action arises under the laws of the United States and United States Constitution; 28 U.S.C. § 1346, as a civil action against the United States founded upon the Constitution, an Act of Congress, or an

executive regulation; and 28 U.S.C. § 1361, as an action to compel an officer or agency to perform a duty owed to plaintiffs.

28. Jurisdiction also is proper under the Administrative Procedure Act, 5 U.S.C. §§ 701-706. Defendants' issuance of the Revised Rule on June 19, 2020, constitutes a final agency action that is subject to judicial review under 5 U.S.C. §§ 702, 704, and 706.

29. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory, injunctive, and other relief pursuant to 28 U.S.C. §§ 2201-2202 and 5 U.S.C. §§ 705-706.

30. Venue is proper in this district under 28 U.S.C. § 1391(b)(1), (b)(2), & (e)(1) because at least one plaintiff resides in this judicial district, a substantial part of the events or omissions giving rise to this action occurred in this district, and each defendant is an agency of the United States or an officer of the United States sued in their official capacity.

PARTIES

A. Plaintiffs

31. Plaintiffs are two private health care facilities that provide health care services to LGBTQ people and many individuals and families with LEP (Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health and the Los Angeles LGBT Center) ("private health care provider plaintiffs"); two organizations that provide a wide range of services to the LGBTQ community, including people and families with LEP (the TransLatin@ Coalition and Bradbury-Sullivan LGBT Community Center) ("LGBTQ-services plaintiffs"); two national associations of health professionals (American Association of Physicians for Human Rights d/b/a GLMA: Health Professionals Advancing LGBTQ Equality and AGLP: The Association of LGBTQ Psychiatrists) ("health professional association plaintiffs"); and three individual physicians and

one behavioral health provider who work for the private health care provider plaintiffs ("individual provider plaintiffs").

32. The private health care provider plaintiffs (Whitman-Walker Health and the Los Angeles LGBT Center) and the individual provider plaintiffs assert claims on their own behalf and also on behalf of their patients and recipients of services, who face barriers to asserting their own claims and protecting their own interests.

33. The LGBTQ-services plaintiffs (the TransLatin@ Coalition and the Bradbury-Sullivan LGBT Community Center) assert claims on their own behalf and also on behalf of the recipients of their services who face barriers to asserting their own claims and protecting their own interests.

34. The TransLatin@ Coalition also asserts claims on behalf of its transgender and gender nonconforming members, including members who are leaders of affiliated community organizations serving Latinx transgender and gender nonconforming people.

35. The health professional association plaintiffs (GLMA and AGLP) assert claims on their own behalf and on behalf of their members and also on behalf of the LGBTQ patients whose interests they represent and the patients whom their members treat who face barriers to asserting their own claims and protecting their own interests.

36. Plaintiffs assert different but complementary interests and share the common objective of maintaining an effective, functioning health care system that protects patients' dignity and their rights to access health services. Plaintiffs also support providing informed access to comprehensive, medically appropriate care to LGBTQ patients, including gender-affirming care for transgender persons, without discrimination based on a patient's sex, gender

identity, transgender status, or sexual orientation and in accordance with medical and ethical standards of care.

37. Plaintiff **Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health**, a Federally Qualified Health Center located in Washington, D.C., has a special mission to serve the LGBTQ community and persons living with HIV of every sexual orientation and gender. More than 280 medical, behavioral health and dental professionals, lawyers and paralegals, support staff and administrators provide a range of services, including medical and community health care, transgender care and services, behavioral-health services, dental-health services, legal services, insurance-navigation services, and youth and family support. In 2019, Whitman-Walker provided health care services to 20,760 individuals. More than 10% of those individuals identified as transgender or gender nonconforming. Almost 45% of health care patients – and 60% of those who provided information on their sexual orientation – identified as lesbian, gay, bisexual, or otherwise non-heterosexual. More than 9% of patients had limited English proficiency. Whitman-Walker receives various forms of federal funding from HHS and from institutions affiliated with or funded by HHS, including but not limited to funds under the Public Health Services Act ("PHSA"), direct grants, funding under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, 42 U.S.C. § 300ff *et seq.* ("Ryan White funding"), funds under the 340B Drug Discount Program, and research grants from the Centers for Disease Control and Prevention and the National Institutes of Health, and Medicaid and Medicare reimbursements. Whitman-Walker also receives funds from the Health Resources and Service Administration ("HRSA") and is a Federally Qualified Heath Center. In 2019, Whitman-Walker's federally funded research contracts and grants totaled more than $7 million. Whitman-Walker is subject to Section 1557 of the ACA and the Revised Rule.

38. Plaintiff **Dr. Sarah Henn** is the Chief Health Officer of Whitman-Walker. Dr. Henn oversees all health care-related services at Whitman-Walker and maintains a panel of patients for whom she provides direct care. Whitman-Walker's patient population, including patients to whom Dr. Henn provides direct care and whose care she oversees, includes many patients who have experienced refusals of health care or who have been subjected to disapproval, disrespect, or hostility from medical providers outside of Whitman-Walker because of their actual or perceived sexual orientation, gender identity, or transgender status. Many of Dr. Henn's patients and those whose care she oversees are, therefore, apprehensive or fearful of encountering stigma and discrimination in health care settings because of their past experiences. Such experiences will increase as a result of the Revised Rule. In addition to overseeing medical care of patients and working with her own patients, Dr. Henn oversees Whitman-Walker's Research Department and is personally involved in a number of clinical research projects, including as the Leader of Whitman-Walker's Clinical Research Site for the AIDS Clinical Trials Group funded by the National Institutes of Health.

39. Plaintiff **Dr. Randy Pumphrey** is Senior Director of Behavioral Health at Whitman-Walker. As Senior Director of Behavioral Health, Dr. Pumphrey oversees Whitman-Walker's portfolio of mental-health services and substance-use-disorder-treatment services and maintains a panel of patients for whom he provides direct behavioral health care. In 2019, Whitman-Walker provided mental-health or substance-use-disorder-treatment services to more than 1,800 patients, many of whom identify as LGBT or are living with HIV. Many, if not most, of the patients to whom Dr. Pumphrey provides direct care and whose behavioral health care he oversees face considerable stigma and discrimination as people living with HIV, sexual or gender minorities, or people of color. They have experienced difficulty finding therapists or

other mental-health or substance-use-disorder professionals who are understanding and welcoming of their sexual orientation, gender identity, or transgender status. These experiences of discrimination will increase as a result of the Revised Rule.

40. Plaintiff **The TransLatin@ Coalition** is a nationwide 501(c)(3) nonprofit membership organization that advocates for the interests of transgender and gender nonconforming individuals, particularly Latinx people, and provides direct services to the transgender community, including leadership development, educational services, and employment services. The TransLatin@ Coalition currently has a presence in Los Angeles, California; Washington, D.C.; Chicago, Illinois; New York, New York; Atlanta, Georgia; Houston, Texas; and Tucson, Arizona. The TransLatin@ Coalition has thousands of individual members across the United States, including transgender and gender nonconforming Latinx individuals who have experienced or fear discrimination based on their sex, transgender status, national origin, or LEP status in health care. This includes individual transgender and gender nonconforming Latinx members like Bamby Salcedo, who resides in California, and Arianna Lint, who resides in Florida. Ms. Salcedo and Ms. Lint have experienced discrimination in health care because of their transgender status and fear the Revised Rule will make it more likely they will encounter discrimination in health care again. The TransLatin@ Coalition's membership also includes leaders of affiliated community organizations that serve Latinx transgender and gender nonconforming people across the country, such as Arianna's Center headquartered in Florida and with offices in Puerto Rico, Community Estrella in Georgia, and the Fundación Latinoamericana de Accion Social (FLAS) in Texas. The Coalition and its members advocate for policy changes at the local, state, and federal levels, and conducts research regarding homelessness, health and health care, and employment in the transgender Latinx

community. Through its Center for Violence Prevention & Transgender Wellness, the Coalition also provides direct services to transgender, gender nonconforming, and intersex people in the City of Los Angeles. Many of the members of the Coalition and the individuals they and the Coalition serve are immigrants, some living with HIV/AIDS. The Coalition and its members serve many communities in which English is not the primary language spoken and a number of individuals in these communities are not fluent in English.

41. Plaintiff **Los Angeles LGBT Center** is located in Los Angeles, California. Its mission is to build a world in which LGBT people thrive as healthy, equal, and complete members of society. The LA LGBT Center offers programs, services, and advocacy spanning four broad categories: health, social services and housing, culture and education, and leadership and advocacy. The LA LGBT Center has more than 750 employees and provides services to more LGBT people than any other organization in the world, with about 500,000 client visits per year, including LEP patients. LA LGBT Center receives funds under the PHSA. Approximately 80% of the LA LGBT Center's funding originates from the federal government, including but not limited to Ryan White funding; direct funding from the Centers for Disease Control and Prevention; discounts under the 340B Drug Discount Program; grants under section 330 of the PHSA; grants from HRSA's Bureau of Primary Health Care under which the LA LGBT Center is a Federally Qualified Health Center; and Medicaid and Medicare reimbursements. The LA LGBT Center is an entity subject to Section 1557 of the ACA and the Revised Rule.

42. Plaintiff **Dr. Robert Bolan** is the Chief Medical Officer of the LA LGBT Center. He oversees the delivery of health care for over 20,000 patients who come to the LA LGBT Center and personally treats approximately 300 patients. More than 90% of these patients identify as LGBT, many of them coming from different areas of California and other States to

obtain services in a safe and affirming environment. Dr. Bolan also oversees the LA LGBT Center's Research Department. Dr. Bolan and the providers he supervises treat patients who identify as transgender and who require gender-affirming treatment, including medically necessary health care for gender dysphoria. Many of Dr. Bolan's patients and many of the patients of the providers he supervises at the LA LGBT Center already have experienced traumatic and discriminatory denials of health care based on their sexual orientation, gender identity, transgender status, or HIV status at the hands of providers outside the LA LGBT Center, including by health care providers who have expressed religious or moral objections to treating them. These experiences will increase as a result of the Revised Rule.

43. Plaintiff **Dr. Ward Carpenter** is the Co-Director of Health Services at the LA LGBT Center. Dr. Carpenter is a nationally recognized expert in the field of transgender medicine. In his role as Co-Director of Health Services, Dr. Carpenter oversees the healthcare of more than 25,000 patients who come to the LA LGBT Center and personally treats 150 patients. All of Dr. Carpenter's patients identify within the LGBT community and approximately 30% are people living with HIV. These patients come from different areas of California and other States to obtain services in a safe and affirming environment. Dr. Carpenter's patient population is disproportionately low-income and experiences high rates of chronic medical conditions, homelessness, unstable housing, and extensive trauma history. In addition, many of Dr. Carpenter's patients, as well as the patients of the other medical providers he supervises at the Center, already have experienced traumatic and discriminatory denials of healthcare based on their sexual orientation, gender identity, transgender status, or HIV status at the hands of providers outside the LA LGBT Center, including by healthcare providers who have expressed

religious or moral objections to treating them. These experiences will increase as a result of the Revised Rule.

44. Plaintiff **Bradbury-Sullivan LGBT Community Center** is a 501(c)(3) nonprofit organization based in Allentown, Pennsylvania, and incorporated in Pennsylvania. It is dedicated to securing the health and well-being of LGBTQ people of the Greater Lehigh Valley. It provides a variety of programs and services for the LGBTQ community, including HIV/STI testing, health care-enrollment events, health promotion programs for LGBTQ adults and youth, support groups, and a free legal clinic. Bradbury-Sullivan Center also provides referrals to LGBT-welcoming health care providers. Patrons of Bradbury-Sullivan Center often seek health care services from other health care organizations, including religiously affiliated organizations. Bradbury-Sullivan Center works with patrons who have experienced discriminatory treatment when seeking health care services from such organizations, and it advocates on behalf of those patrons by providing referrals to LGBT-welcoming agencies and providers, training agencies to provide LGBT-welcoming services, and, when necessary, communicating with agencies to inform them of their legal obligations to serve LGBT people. Bradbury-Sullivan Center also conducts research documenting health disparities in the LGBT community and performs related community-education efforts to improve public health within the LGBT community. Bradbury-Sullivan Center receives pass-through funding from HHS through the Assistance Programs for Chronic Disease Prevention and Control, State Public Health Approaches to Ensuring Quitline Capacity funded in part by Prevention and Public Health Fund, State Physical Activity and Nutrition, Injury Prevention and Control Research and State and Community Based Programs, National State-Based Tobacco Control Programs, Maternal and Child Health Services Block Grant, and in the past also has received Ryan White funding.

45. Plaintiff **American Association of Physicians For Human Rights, Inc. d/b/a GLMA: Health Professionals Advancing LGBTQ Equality** (formerly known as the Gay & Lesbian Medical Association) is a 501(c)(3) nonprofit membership organization based in Washington, D.C. and incorporated in California. GLMA is a national organization committed to ensuring health equity for lesbian, gay, bisexual, transgender, queer, and all sexual and gender minority individuals, and equality for health professionals in such communities in their work and learning environments. To achieve this mission, GLMA utilizes the scientific expertise of its diverse multidisciplinary membership to inform and drive advocacy, education, and research. GLMA works with professional accreditation bodies and health professional associations on standards, guidelines, and policies that address LGBTQ health and protect individual patient health and public health in general. GLMA also represents the interests of hundreds of thousands of LGBTQ health professionals and millions of LGBTQ patients and families across the United States. GLMA's membership includes approximately 1,000 member physicians, nurses, advanced practice nurses, physician assistants, researchers and academics, behavioral health specialists, health-profession students, and other health professionals throughout the country. Their practices represent the major health care disciplines and a wide range of health specialties, including primary care, internal medicine, family practice, psychiatry, pediatrics, obstetrics/gynecology, emergency medicine, neurology, and infectious diseases.

46. Plaintiff **AGLP: The Association of LGBTQ Psychiatrists** is a 501(c)(3) nonprofit membership organization based in Philadelphia, Pennsylvania. AGLP is a national organization of 450 LGBTQ+ psychiatrists that educates and advocates on LGBTQ mental-health issues. It is the oldest association of LGBTQ+ professionals in the country. AGLP represents the interests of its members, LGBTQ+ patients, and the patients whom AGLP

members treat in working to influence policies relevant to the LGBTQ+ community and advocating for its members' patients. AGLP's goals are to foster a fuller understanding of LGBTQ+ mental-health issues; research and advocate for the best mental healthcare for the LGBTQ community; develop resources to promote LGBTQ mental health; create a welcoming, safe, nurturing, and accepting environment for members; and provide valuable and accessible services to our members. AGLP also assists medical students and residents in their professional development; encourages and facilitates the presentation of programs and publications relevant to LGBTQ concerns at professional meetings; and serves as liaison with other minority and advocacy groups within the psychiatric community. Some of the institutions in which AGLP's members work receive various forms of federal funding directly or indirectly via federal programs. AGLP's members therefore are subject to Section 1557 of the ACA and the Revised Rule.

B. Defendants

47. Defendant **United States Department of Health and Human Services** is a cabinet department of the federal government, headquartered in the District of Columbia. HHS promulgated the Revised Rule and is responsible for its enforcement. HHS is an "agency" within the meaning of the APA. 5 U.S.C. § 551(1).

48. Defendant **Alex M. Azar, II** is the Secretary of HHS. He is sued in his official capacity. Secretary Azar is responsible for all aspects of the operation and management of HHS, including the adoption, administration, and enforcement of the Revised Rule, and with implementing and fulfilling HHS's duties under the United States Constitution and the APA.

49. Defendant **Roger Severino** is the Director of the Office of Civil Rights ("OCR") at HHS. He is sued in his official capacity. Director Severino is responsible for all aspects of the operation and management of OCR, including the adoption, administration, and enforcement

of the Revised Rule. As an HHS law enforcement agency, OCR is supposed to ensure equal access to health and human services by enforcing civil rights laws such as Section 1557.

50. Defendant **Seema Verma** is the Administrator for the Centers for Medicare and Medicaid Services ("CMS"), a component of HHS. She is sued in her official capacity. Administrator Verma is responsible for all aspects of the operation and management of CMS, including the adoption, administration, and enforcement of the Revised Rule as it pertains to regulations relating to the establishment and operation of ACA exchanges; in the marketing and design practices of health insurance issuers under the ACA; in the administration, marketing, and enrollment practices of Qualified Health Plans ("QHPs") under the ACA; in beneficiary enrollment and the promotion and delivery of services under Medicaid; and in the delivery of services under the Programs for All-Inclusive Care for the Elderly ("PACE").

FACTUAL ALLEGATIONS

I. Discrimination Against Transgender People Prior to the Affordable Care Act

51. Before the Affordable Care Act was enacted in 2010 during the Obama Administration, HHS documented many forms of discrimination against transgender people in accessing health care services, insurance coverage, and facilities.

52. The administrative record documents and demonstrates that, prior to the enactment of the ACA, transgender people experienced significant discrimination from entities providing health care, even for routine medical care. HHS reported that "[f]or transgender individuals, a major barrier to receiving care is a concern over being refused medical treatment based on bias against them." 81 Fed. Reg. 31,376, 31,460. For example, "[i]n a 2010 report, 26.7% of transgender respondents reported that they were refused needed health care. A 2011 survey revealed that 25% of transgender individuals reported being subject to harassment in medical settings." *Id.*

53. Some entities providing insurance or health care discriminated against transgender patients by refusing to cover medically necessary treatments for gender dysphoria in accordance with accepted standards of care. Gender dysphoria is a serious medical condition codified in the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) and International Classification of Diseases (ICD-11). The criteria for diagnosing gender dysphoria are set forth in the DSM-V (302.85). The World Professional Association for Transgender Health ("WPATH") publishes widely accepted standards of care for treating gender dysphoria. Leading medical organizations and federal courts have recognized the WPATH Standards of Care as the authoritative standards of care. The overwhelming consensus among medical experts and every major medical organization is that treatments for gender dysphoria, including surgical procedures, are effective, safe, and medically necessary when clinically indicated to alleviate gender dysphoria.

54. Prior to the enactment of the ACA, however, insurance companies routinely excluded coverage for transition-related care based on the misguided assumption that such treatments were cosmetic and experimental. Today, medical consensus recognizes that such exclusions have no basis in medical science.[6]

55. Those discriminatory exclusions prevented transgender people from obtaining medically necessary treatment for gender dysphoria. *See* 81 Fed. Reg. at 31,460. As a result, transgender people were more likely to lack health insurance and suffer significant health disparities, including high rates of untreated mental health needs, suicide attempts, and HIV. *Id.*

[6] *See* Decision No. 2576, National Coverage Determination 140.3: Transsexual Surgery at 18 (Docket No. A-13-87) (U.S. Dep't of Health & Human Servs. Appeals Bd. App. Div. 2014), https://perma.cc/3BGA-F9DH.

II. Section 1557 of the Affordable Care Act

56. On March 23, 2010, Congress enacted the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), recognizing the importance of providing patients with prompt and nondiscriminatory access to medical care and to information about all treatment options.

57. Section 1554 of the ACA provides:

> Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—
>
> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
>
> (2) impedes timely access to healthcare services;
>
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
>
> (4) restricts the ability of healthcare providers to provide full disclosure of all relevant information to patients making healthcare decisions;
>
> (5) violates the principles of informed consent and the ethical standards of healthcare professionals; or
>
> (6) limits the availability of healthcare treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114.

58. Section 1557 of the ACA protects against discrimination in the provision of health care services. It provides, in relevant part:

> Except as otherwise provided for in this title [I] (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of Title 29 [Section 504 of the Rehabilitation Act of 1973], be excluded from participation in, be denied the

> benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title [I] (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.

42 U.S.C. § 18116(a).

59. Section 1557 prohibits discrimination based on sex, including discrimination based on a patient's gender identity, transgender status, sexual orientation, and failure to conform to sex stereotypes, all of which are forms of sex discrimination. It also prohibits discrimination on the basis of race, color, national origin, age, and disability.

60. Section 1557 provides that "[t]he enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection." *Id.* § 18116(a).

61. Section 1557 further provides that the Secretary of HHS "may promulgate regulations to implement this section." *Id.* § 18116(c).

62. The ACA covers nearly every health care provider in the country.

III. The 2016 Final Rule

63. On May 18, 2016, HHS published a final rule implementing Section 1557. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (May 18, 2016) (formerly codified at 45 C.F.R. pt. 92) (the "2016 Final Rule"). A copy of the 2016 Final Rule is attached as **Exhibit 1**.

64. In implementing Section 1557's prohibition of discrimination "on the basis of . . . sex," the 2016 Final Rule defined "on the basis of sex" to include "discrimination on the basis of

. . . sex stereotyping, and gender identity." 81 Fed. Reg. at 31,467 (formerly codified at 45 C.F.R. § 92.4).[7]

65. The 2016 Final Rule defined "gender identity" as "an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual's sex assigned at birth." *Id.* In the 2016 Final Rule, HHS emphasized that "even where it is permissible to make sex-based distinctions, individuals may not be excluded from health programs and activities for which they are otherwise eligible based on their gender identity." 81 Fed. Reg. at 31,409.

66. The 2016 Final Rule defined "sex stereotypes" as

> stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. These stereotypes can include the expectation that individuals will consistently identify with only one gender and that they will act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes also include gendered expectations related to the appropriate roles of a certain sex.

81 Fed. Reg. at 31,468 (formerly codified at 45 C.F.R. § 92.4).

67. In defining "on the basis of sex" to include "discrimination on the basis of . . . sex stereotyping, and gender identity," HHS explained that "courts, including in the context of Section 1557, have recognized that sex discrimination includes discrimination based on gender

[7] Although OCR stated in 2016 "that current law is mixed on whether existing Federal nondiscrimination laws prohibit discrimination on the basis of sexual orientation as a part of their prohibitions on sex discrimination," 81 Fed. Reg. at 31388, the Supreme Court now has definitively answered this question by holding in *Bostock* that "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex." 2020 WL 3146686, at *7.

identity. Thus, we proposed to adopt formally this well-accepted interpretation of discrimination 'on the basis of sex.'" 81 Fed. Reg. at 31,387-88.

68. The 2016 Final Rule also prohibited discrimination based on association – that is, it prohibited discrimination against a person on the basis of the sex, race, color, national origin, age, or disability of "an individual with whom the individual or entity is known or believed to have a relationship or association." 81 Fed. Reg. at 31,472 (formerly codified at 92 C.F.R. § 209). HHS explained that a "prohibition on associational discrimination is consistent with longstanding interpretations of existing antidiscrimination laws, whether the basis of discrimination is a characteristic of the harmed individual or an individual who is associated with the harmed individual." 81 Fed. Reg. at 31,439. It also is consistent with the Age Discrimination Act, which includes a specific prohibition of discrimination based on association with an individual with a disability. *Id.*; *see also* 42 U.S.C. § 12182(b)(1)(E); 28 C.F.R. § 35.130(g).

69. The 2016 Final Rule also recognized that Section 1557 not only prohibits intentional discrimination on the basis of sex, it also prohibits conduct and practices "that *have the effect of subjecting individuals to discrimination* on the basis of sex," which can give rise to disparate impact claims. 81 Fed. Reg. at 31,470 (formerly codified at 45 C.F.R. § 92.101(b)(3)(ii)) (emphasis added).

70. The 2016 Final Rule applied to "every health program or activity, any part of which receives Federal financial assistance provided or made available by the Department; every health program or activity administered by the Department; and every health program or activity administered by a Title I entity." 81 Fed. Reg. at 31,466 (formerly codified at 45 C.F.R.

§ 92.2(a)). HHS estimated that the rule would "likely cover almost all licensed physicians because they accept Federal financial assistance." 81 Fed. Reg. at 31,445.

71. With respect to health care insurance providers or employee benefits plans, the 2016 Final Rule specifically required covered entities to treat individuals consistent with their gender identity. *See* 81 Fed. Reg. at 31,471 (formerly codified at 45 C.F.R. § 92.206). And it prohibited covered entities from having or implementing "a categorical coverage exclusion or limitation for all health care services related to gender transition," 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.207(b)(4)), because such an exclusion is "discriminatory on its face," 81 Fed. Reg. at 31,456. In adopting these provisions, HHS explained that blanket "exclusions of coverage for all care related to gender dysphoria or associated with gender transition" were "outdated and not based on current standards of care." 81 Fed. Reg. at 31,429.

72. The "range of transition-related services" the 2016 Final Rule contemplated were "not limited to surgical treatments and may include, but [were] not limited to, services such as hormone therapy and psychotherapy, which may occur over the lifetime of the individual." 81 Fed. Reg. at 31,435-36.

73. Consistent with the plain language of Section 1557, which provides that the "enforcement mechanisms provided for and available under such title VI, title IX, section 794, *or* such Age Discrimination Act shall apply for purposes of violations" of Section 1557, 42 U.S.C. § 18116(a) (emphasis added), the 2016 Final Rule adopted a unitary legal standard for addressing discrimination in health care and enforcing Section 1157. The 2016 Final Rule provided: "The enforcement mechanisms available for and provided under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, *or* the Age Discrimination Act of 1975 shall apply for purposes of

Section 1557 as implemented by this part." 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.301) (emphasis added).

74. In the preamble to the 2016 Final Rule, HHS clarified that *all* enforcement mechanisms available under the statutes listed in Section 1557 are available for purposes of Section 1557 enforcement, regardless of an individual's protected characteristic or characteristics. Otherwise, different enforcement mechanisms and standards would apply depending on whether an individual's claim is based on her sex, race, age, or disability. 81 Fed. Reg. at 31,439-40. HHS thus interpreted Section 1557 as "authorizing a private right of action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation." *Id.* at 31,440.

75. The 2016 Final Rule also specifically recognized that a private right of action is available under Section 1557 and compensatory damages are available. *See* 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. §§ 92.301(b), 92.302(d)). HHS explained that its "interpretation of Section 1557 as authorizing compensatory damages is consistent with our interpretations of Title VI, Section 504, and Title IX." 81 Fed. Reg. at 31,440.

76. The 2016 Final Rule did not incorporate Title IX's blanket religious exemption because Section 1557 "contains no religious exemption." 81 Fed. Reg. at 31,380. In declining to import Title IX's religious exemption, HHS further explained that "Title IX and its exemption are limited in scope to educational institutions, and there are significant differences between the educational and health care contexts that warrant different approaches." *Id.* HHS noted that "a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results." *Id.*

77. After a careful and deliberate analysis, HHS determined that a "more nuanced approach in the health care context" was warranted. *Id.* The 2016 Final Rule provided: "Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required." 81 Fed. Reg. at 31,466 (formerly codified at 45 C.F.R. § 92.2(b)(2)).

78. The 2016 Final Rule also included provisions to ensure that the approximately 25 million Americans who are Limited English Proficient (LEP)[8] have access to the health care they need. The 2016 Final Rule required health care providers and other covered entities to post nondiscrimination notices and include taglines in the top 15 languages spoken throughout the state with all significant publications and communications. *See* 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.8).

79. The 2016 Final Rule also included standards that governed access to language assistance services for LEP individuals by requiring that language interpreters be "qualified" and that when covered entities video interpretation services to LEP individuals, it be real-time and high quality. *See* 81 Fed. Reg. at 31,470-71 (formerly codified at 45 C.F.R. § 92.201).

80. The promulgation of the 2016 Final Rule led to a decrease in discriminatory policies and practices.[9] For example, a recent study of 37 states in the federal marketplace

[8] U.S. Census Bureau, *Language Spoken at Home*, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1601 (2018), https://perma.cc/Z452-RSWR; U.S. Census Bureau, Characteristics of People by Language Spoken at Home, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1603, https://perma.cc/R59J-HG4K.

[9] *See* Gruberg & Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, https://perma.cc/CTP2-UMEJ.

showed that, in 2019, 97% of plans did not contain blanket exclusions of transition-related care.[10]

IV. The Trump Administration's Proposed Revision to the 2016 Final Rule

81. On June 14, 2019, the Trump Administration issued a Notice of Proposed Rulemaking, proposing to "make substantial revisions" to the 2016 Final Rule, including repealing certain provisions. *See* Notice of Proposed Rulemaking, *Nondiscrimination in Health and Health Education Programs or Activities*, 84 Fed. Reg. 27,846, 27,848 (June 14, 2019) ("Proposed Rule").

82. In an attempt to explain why it was reversing course merely three years after the 2016 Final Rule went into effect, HHS stated it was revising the implementing regulations "to better comply with the mandates of Congress, address legal concerns, relieve billions of dollars in undue regulatory burdens, further substantive compliance, reduce confusion, and clarify the scope of Section 1557 in keeping with existing civil rights statutes and regulations prohibiting discrimination on the basis of race, color, national origin, sex, age, and disability." 84 Fed. Reg. at 27,846.

83. HHS further claimed that the 2016 Final Rule "exceeded its authority under Section 1557, adopted erroneous and inconsistent interpretations of civil rights law, caused confusion, and imposed unjustified and unnecessary costs." *Id.* at 27,849.

84. These purported justifications do not withstand scrutiny.

85. HHS received nearly 200,000 comments during the public comment period. The comments that HHS received identified and expressed concerns about many of HHS's proposed

[10] Out2Enroll, *Summary of Findings: 2020 Marketplace Plan Compliance with Section 1557*, https://perma.cc/WU25-C9BN. This finding is consistent with summaries from 2017, 2018, and 2019.

revisions, including many of the same issues that form the basis of this complaint. Commenters emphasized that the following actions, taken individually or combined, will cause immediate and irreparable harm to LGBTQ people and their families:

a. Eliminating the definition of "on the basis of sex" and the specific prohibition on discrimination on the basis of gender identity and sex stereotyping is arbitrary and capricious, not the result of reasoned decision-making, contrary to law, and invites covered health care providers and insurers to discriminate against transgender people;

b. Eliminating a unitary legal standard for enforcing violations of Section 1557 and replacing it with a fractured and complex set of procedures is contrary to the plain language of Section 1557 and Congress's intent, and will complicate and make it more difficult to bring discrimination claims, particularly claims of intersectional discrimination;

c. Incorporating sweeping religious exemptions is contrary to the statutory language of Section 1557 and will create significant burdens on patients and providers;

d. Eliminating notice requirements and critical language access provisions that ensure LEP individuals can access necessary health care is arbitrary and capricious, contrary to statutory intent, and will make it more difficult for LEP patients to understand their health care rights, communicate with doctors and other health care workers, and navigate complex insurance and medical documents with specialized terminology, and cause an increase in patients who will delay or not seek care at all;

e. Excluding from Section 1557 health programs and activities that HHS administers but are not established under Title I of the ACA and health insurance plans outside of Title I of the ACA that do not receive Federal financial assistance is inconsistent with Section 1557 and will cause drastic reductions in protections for LGBTQ people;

f. Eliminating gender identity and sexual orientation protections in unrelated regulations is procedurally improper, arbitrary and capricious, and contrary to law; and

g. Eliminating protections relating to discrimination on the basis of association is arbitrary and capricious and contrary to law.

V. The Revised Rule

86. Despite the significant concerns raised during the comment period, HHS published the Revised Rule in the Federal Register on June 19, 2020, making only "minor and primarily technical corrections." *See* Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160, 37,161 (June 19, 2020). A copy of the Revised Rule is attached as **Exhibit 2** and incorporated by reference.

87. In adopting the Revised Rule, HHS failed to address adequately many of the serious issues commenters raised, including concerns that the proposed elimination of the definition of "on the basis of sex," which the 2016 Final Rule defined to include gender identity and sex stereotyping, would invite discrimination against LGBTQ people. *See* 85 Fed. Reg. at 37,165, 37,180.

88. Relying essentially on one federal district court opinion—*Franciscan Alliance, Inc.* v. *Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016)—which the preamble cites more than 40 times, HHS takes the position that "the ordinary public meaning of the term 'sex' in Title IX is

unambiguous" and refers to a "biological binary meaning of sex," 85 Fed. Reg. at 37,178-80, and discrimination on the basis of sex under Title IX does not encompass discrimination on the basis of gender identity or sex stereotyping, 85 Fed. Reg. at 37,183-86.

89. HHS explicitly rejected comments urging it to wait until the Supreme Court decided *Bostock* and related cases because of the potential implications for the Revised Rule. *See* 85 Fed. Reg. at 37,168. Despite acknowledging that "a holding by the U.S. Supreme Court on the meaning of 'on the basis of sex' under Title VII will likely have ramifications for the definition of 'on the basis of sex' under Title IX," because "Title VII case law has often informed Title IX case law with respect to the meaning of discrimination 'on the basis of sex,'" *id.*, HHS stated it was sticking with the position the federal government had taken in *Bostock* and related cases that "discrimination 'on the basis of sex' in Title VII and Title IX does not encompass discrimination on the basis of sexual orientation or gender identity," *id.*

90. HHS further asserted that even if the Supreme Court determined that the prohibition on sex discrimination in Title VII encompassed gender identity and sexual orientation, such a ruling may not fully address the implications for the health care context. 85 Fed. Reg. at 37,168.

91. Among other revisions, the Revised Rule:

a. Repeals the definition of "on the basis of sex" and the specific prohibition of discrimination on the basis of gender identity and sex stereotyping, *see* 85 Fed. Reg. at 37,161-62;

b. Repeals the unitary legal standard for enforcing violations of Section 1557 and eliminates provisions recognizing a private right of action and compensatory damages, *see* 85 Fed. Reg. at 37,162;

c. Incorporates sweeping religious exemptions, *see id.*;

d. Repeals notice requirements and access to language provisions, *see id.*;

e. Excludes from the scope of Section 1557 certain health programs and activities and health insurance plans, *see id.*;

f. Repeals gender identity and sexual orientation protections in unrelated regulations, *see id.*; and

g. Repeals provisions relating to discrimination on the basis of association, *see id.*

92. These changes are arbitrary and capricious, not the process of reasoned decision-making, contrary to the statutory language and Congress's intent, not in accordance with law, in excess of HHS's statutory authority, and unconstitutional.

VI. HHS's Repeal of the Definition of "On the Basis of Sex" and Protections Against Discrimination on the Basis of Gender Identity and Sex Stereotyping Is Arbitrary and Capricious and Contrary to Law

93. Section 1557 prohibits sex discrimination. In line with that prohibition, the 2016 Final Rule included a definition of "on the basis of sex" that explicitly prohibited discrimination on the basis of gender identity and sex stereotyping, among other grounds. *See* 81 Fed. Reg. at 31,467 (formerly codified at 45 C.F.R. § 92.4).

94. The Revised Rule repeals entirely the 2016 Final Rule's definition of discrimination "on the basis of sex," without providing a different definition. Although HHS's Notice of Proposed Rulemaking stated HHS was declining to define the term because "of the likelihood that the Supreme Court will be addressing the issue in the near future," 84 Fed. Reg. at 27,857, HHS did not wait for the Supreme Court to decide whether discrimination on the basis of "sex" encompasses discrimination against LGBTQ people.

95. Instead, it staked its elimination of the definition of "on the basis of sex" on the *Franciscan Alliance* decision and the government's position in the *Bostock* litigation "that discrimination 'on the basis of sex' in Title VII and Title IX does not encompass discrimination on the basis of sexual orientation or gender identity." 85 Fed. Reg. at 37,168.

96. The Supreme Court now has conclusively rejected that position, holding "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual on the basis of sex." *Bostock*, 2020 WL 3146686, at *7. *Bostock*'s conclusion that discrimination "on the basis of sex" encompasses claims of discrimination based on transgender status and sexual orientation affirms the validity of the substantial body of case law that formed the basis of the 2016 Final Rule. *See* 81 Fed. Reg. at 31,387-90, 31,392.

97. The Revised Rule's repeal of the definition of "on the basis of sex" and elimination of the protections for LGTBQ people against discrimination is contrary to law and will invite health care insurers and providers to discriminate against LGBTQ people seeking health care. It also introduces substantial confusion among health care providers and insurers regarding their legal obligations and the right of the populations they serve to be free from discrimination, particularly in light of the Supreme Court's ruling in *Bostock*.

98. The Revised Rule also eliminates the provisions in the 2016 Final Rule specifically requiring covered entities to treat individuals consistent with their gender identity and prohibiting covered entities from having or implementing "a categorical coverage exclusion or limitation for all health care services related to gender transition." *Compare* 81 Fed. Reg. at 31,471-72 (formerly codified at 45 C.F.R. §§ 92.101(b)(3)-(4)), *with* 85 Fed. Reg. at 37,187-88.

99. HHS claims this provision inappropriately interfered with the ethical and medical judgment of health professionals. *See* 85 Fed. Reg. at 37,187-88. However, as the 2016 Final Rule demonstrates, prohibiting the exclusion or denial of health programs or activities on the basis of an individual's LGBTQ status does not prevent medical providers from providing appropriate medical advice.

100. The Revised Rule also eliminates the provision in the 2016 Final Rule that prohibited a covered entity from discriminating against an individual based on those with whom they are known or believed to have a relationship or to be associated. *Compare* 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.209), *with* 85 Fed. Reg. at 37,199-200. The 2016 Final Rule grounded this provision on a thorough examination of existing case law. *See* 81 Fed. Reg. at 31,438-39.

101. Former Section 92.209 accurately reflected current law. HHS has provided no good reason to eliminate it. Its decision to do so is arbitrary and capricious and contrary to the law, in violation of the APA.

VII. The Revised Rule's Repeal of the Unitary Standard Is Arbitrary and Capricious and Contrary to Law

102. Section 1557 provides: "The enforcement mechanisms provided for and available under such title VI, title IX, section 794, *or* such Age Discrimination Act shall apply for purposes of violations of [Section 1557]." 42 U.S.C. § 18116(a) (emphasis added). Congress's use of the disjunctive "or" indicates that the enforcement mechanisms applicable under any of the incorporated statutes are available to every claim of discrimination under Section 1557, regardless of the particular type of discrimination.

103. During the notice-and-comment period on the 2016 Final Rule, commenters pointed to the plain language of Section 1557 and asked HHS to "clarify that all enforcement

mechanisms available under the statutes listed in Section 1557 are available to each Section 1557 plaintiff, regardless of the plaintiff's protected class. Thus, for example, an individual could bring a race claim under the Age Act procedure and an age claim under the Title VI procedure." 81 Fed. Reg. at 31,439.

104. As commenters emphasized, by enacting Section 1557, Congress intended to create a new health-specific, anti-discrimination cause of action subject to a singular standard regardless of a person's protected characteristic. Otherwise, different enforcement mechanisms and standards would apply depending on whether an individual's claim is based on their sex, race, national origin, age, or disability, in which case a person who faces intersectional discrimination – that is, discrimination based on more than one ground – would have different remedies and enforcement mechanisms for the same conduct under the same law. *Id.* at 31,439-40.

105. In response, HHS stated: "OCR interprets Section 1557 as authorizing a private right of action for claims of disparate impact on the basis of any of the criteria enumerated in the legislation." *Id.* at 31,440.

106. The 2016 Final Rule specified, consistent with this interpretation, that Section 1557 not only prohibits intentional discrimination on the basis of sex, but also conduct and practices "that *have the effect of subjecting individuals to discrimination* on the basis of sex" – conduct that can give rise to disparate impact claims based on sex. 81 Fed. Reg. at 31,470 (formerly codified at 45 C.F.R. § 92.101(b)(3)(ii)) (emphasis added).

107. The 2016 Final Rule implemented Section 1557's directives regarding enforcement by promulgating 45 C.F.R. § 92.301, which provided: "The enforcement mechanisms available for and provided under Title VI of the Civil Rights Act of 1964, Title IX

of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, *or* the Age Discrimination Act of 1975 shall apply for purposes of Section 1557 as interpreted by this part." 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.301(a)) (emphasis added).

108. In addition, the 2016 Final Rule specified that a private right of action is available under Section 1557 and compensatory damages are available. *See* 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. §§ 92.301(b), 92.302(d)). HHS explained that its "interpretation of Section 1557 as authorizing compensatory damages is consistent with our interpretations of Title VI, Section 504, and Title IX." 81 Fed. Reg. at 31,440.

109. Under these regulations, individuals bringing claims of intersectional discrimination, i.e., discrimination based on multiple characteristics, would not need to litigate their claims under different standards and different enforcement mechanisms.

110. The Revised Rule, however, without reasoned explanation, rejects the 2016 Final Rule's establishment of a unitary legal standard and enforcement mechanism under Section 1557, limiting the remedies available from claims of discrimination based on a characteristic listed in Section 1557 to only those remedies available under the statute from which the characteristic was incorporated. HHS acknowledged commenters raised concerns about intersectional discrimination but brushed them aside by noting that OCR accepts complaints that allege discrimination based on more than one protected status. 85 Fed. Reg. at 37,199-200.

111. HHS claims the 2016 Final Rule applied the enforcement mechanisms in existing statutes "in a confusing and inconsistent manner," 85 Fed. Reg. at 37,202, and resulted in "a new patchwork regulatory framework unique to Section 1557 covered entities," 85 Fed. Reg. at 37,162.

112. The 2016 Final Rule accomplished precisely the opposite. It established a consistent, unitary legal standard and enforcement mechanism as Section 1557 contemplates. It is HHS's arbitrary and capricious elimination of a unitary standard that creates a confusing and patchwork approach, applying different remedies and enforcement mechanisms to discriminatory conduct that arises under a single statute – Section 1557.

113. The Revised Rule also eliminates, without providing a reasoned explanation, the provisions in the 2016 Final Rule expressly recognizing a private right of action to "challenge a violation of Section 1557 or this part." *Compare* 81 Fed. Reg. at 31,472 (formerly codified 45 C.F.R. § 92.302(d)), *with* 85 Fed. Reg. at 37,203.

114. HHS eliminated the private right of action provision even though the existence of such a right is clear from the statutory language of Section 1557, which explicitly references and incorporates the "enforcement mechanisms" of four civil rights laws, all of which have a private right action, and even though every court that has ruled on the question has held that the statutory language of Section 1557 confers a private right of action.

115. The Revised Rule also eliminates, without providing a reasoned explanation, § 92.301(b) of the 2016 Final Rule that recognized "[c]ompensatory damages for violations of Section 1557 are available in appropriate administrative and judicial actions brought under this rule." 81 Fed. Reg. at 31,472 (formerly codified 45 C.F.R. § 301(b)). The only justification HHS offers is that "the Department has concluded that its enforcement of Section 1557 should conform to the Department of Justice's Title VI Manual," which states that "under applicable Federal case law, compensatory damages are generally unavailable for claims based solely on a Federal agency's disparate impact regulations." 85 Fed. Reg. at 37,202.

116. HHS ignores entirely its own statement in the preamble to the 2016 Final Rule that its interpretation of Section 1557 as authorizing compensatory damages was consistent with HHS's "interpretations of Title VI, Section 504, and Title IX," as providing for compensatory damages. *See* 81 Fed. Reg. at 31,440. HHS's elimination of the provision recognizing the availability of compensatory damages also is inconsistent with controlling U.S. Supreme Court decisions holding that damages are available under these civil rights statutes.

117. HHS's unreasonable interpretation of Section 1557 is arbitrary, capricious, and contrary to law in that it fails to follow the statutory language of Section 1557 and apply each of the "enforcement mechanisms" available under each of the civil rights statutes incorporated into Section 1557 to every claim of discrimination arising under Section 1557 regardless of the basis. HHS's arbitrary and capricious elimination of provisions recognizing a private right of action under Section 1557 and the availability of compensatory damages likewise is contrary to the plain language of the statute and the law.

118. Although HHS cannot change the law, its fracturing of the consolidated procedures established in the 2016 Final Rule undermines Congress's intent to create a new, health-specific anti-discrimination cause of action and will make it more difficult to bring discrimination claims under Section 1557. HHS's elimination of the private right of action and compensatory damages provisions also will confuse the public and mislead some persons into not asserting their legal rights.

VIII. The Revised Rule's Incorporation of Sweeping Religious Exemptions Conflicts with the Statutory Language of Section 1557 and Is Inappropriate in the Health Care Context

119. The 2016 Final Rule included a provision stating that covered entities do not have to comply with Section 1557 if doing so would violate applicable federal statutory protections

for religious conscience and freedom. *See* 81 Fed. Reg. at 31,466 (formerly codified at 45 C.F.R. § 92.2(b)(2)).

120. HHS considered incorporating Title IX's blanket religious exemptions into Section 1557, but after careful consideration and deliberation, HHS declined to do so in the 2016 Final Rule. 81 Fed. Reg. at 31,379-80. Title IX's religious exemption by its terms applies only to educational institutions and programs, not health care providers or health plans. It protects religiously-controlled educational institutions and programs from requirements that violate their religious tenets. *See* 20 U.S.C. § 1681(a)(3); 34 C.F.R. § 106.12. For example, religious schools that believe only men can be priests, rabbis, or ministers are not required to admit women to training programs for the priesthood, rabbinate, or ministry.

121. In declining to import Title IX's blanket religious exemption into Section 1557, HHS explained that Section 1557, unlike Title IX, does not include a religious exemption. It further explained that Title IX's blanket exemption would be inappropriate in the health care setting because it is framed for educational institutions, which are very different from health care settings, and those differences "warrant different approaches." 81 Fed. Reg. at 31,380.

122. HHS noted that, unlike the educational context where individuals may select a religious educational institution by choice, in the health care context, individuals may have limited or no choice of providers. *Id.* In addition, "a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results." *Id.*

123. HHS determined that a "more nuanced approach in the health care context" was warranted. *Id.* As a result, the 2016 Final Rule provided: "Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious

freedom and conscience, such application shall not be required." 81 Fed. Reg. at 31,466 (formerly codified at 45 C.F.R. § 92.2(b)(2)).

124. The Revised Rule upends this nuanced and carefully considered approach by explicitly identifying and incorporating sweeping religious exemptions from a number of different statutes. Not only does the Revised Rule incorporate the Title IX religious exemptions, it also incorporates "definitions, exemptions, affirmative rights, or protections" from unrelated statutes. 85 Fed. Reg. at 37,245 (to be codified at 45 C.F.R. § 92.6(b)).

125. The inclusion of sweeping religious exemptions in Section 1557 is contrary to the statutory language of Section 1557, which by its terms does not incorporate any exemptions from Title IX or any other statute. Section 1557 expressly incorporates the enforcement mechanisms from four civil rights statutes, but pointedly does not incorporate the religious exemptions from Title IX or any other statute.

126. Religiously affiliated hospitals and health care systems occupy a large and growing percentage of health care markets. The Revised Rule's sweeping religious exemptions to Section 1557's prohibitions on discrimination will invite these institutions to allow their religious beliefs to determine patient care, contrary to medical standards and the health of an increasing number of individuals.

127. The Revised Rule also invites individual health care providers to deny care to LGBTQ patients on the basis of their individual religious beliefs. It prioritizes the protection of individual conscience and religious freedom rights over ensuring that LGBTQ people receive the health care to which they are entitled. *See* 85 Fed. Reg. at 37,206.

128. The Revised Rule's religious exemptions disproportionately harm LGBTQ people, who often are refused health care because of their sexual orientation or gender identity.

According to a 2018 study, 8% of LGBTQ people were refused health care because of their sexual orientation, and 29% of transgender people were denied care because of their gender identity.[11]

129. When LGBTQ people are denied care, it becomes difficult and sometimes impossible to find another provider, especially for those who live in rural areas and for transgender people. In one recent study, 18% of LGBTQ people said it would be very difficult if not impossible to find the same type of service in another hospital. Outside of a metropolitan area, 41% of respondents stated that, if they were denied treatment, it would be very difficult if not impossible to find the same service at a different location.[12]

130. These religious exemptions also will frustrate the ability of organizations who provide health care to LGBTQ patients to accomplish their missions. Individual health care providers employed by these organizations may choose to deny care to LGBTQ patients, claiming that doing so would violate their religious beliefs. This denial of care would harm the ability of these organizations to treat their patients effectively. These exemptions also would impair the ability of these organizations to refer their LGBTQ patients to other health care providers because they would be unsure whether these providers would invoke these exemptions to deny care to LGBTQ patients.

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[11] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People From Accessing Health Care*, Center for American Progress (Jan. 18, 2018), https://perma.cc/ZG7E-7WK8.

[12] *Id.*

IX. The Revised Rule's Elimination of Notices of Nondiscrimination Rights and Language Access Provisions Is Arbitrary and Capricious and Contrary to Statutory Intent

131. More than 25 million Americans are of LEP, meaning they speak, read, or write English less than "very well."[13] An estimated 6.5 million LEP adults are uninsured.[14]

132. The 2016 Final Rule contained a number of provisions to ensure that LEP patients understand their rights and are able to communicate fully and effectively with their providers and other health care staff. The 2016 Final Rule required covered entities to provide notice of nondiscrimination policies, including notice of availability of and how to access language assistance services. 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.8(a)).

133. In addition, covered entities were required to include taglines on all significant documents in the top fifteen languages spoken by individuals with LEP in their state. 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.8(d)(1)). Taglines are short statements that inform individuals of their right to language assistance and how to seek such assistance.

134. The 2016 Final Rule also required that a covered entity with at least 15 employees designate a specific individual or individuals with responsibility to oversee compliance with Section 1557, including LEP efforts, and investigate complaints and concerns and establish and adhere to a specific grievance procedure. 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.7).

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[13] *See* U.S. Census Bureau, *Language Spoken at Home*, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1601 (2018), https://perma.cc/Z452-RSWR; U.S. Census Bureau, *Characteristics of People by Language Spoken at Home*, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1603, https://perma.cc/R59J-HG4K.

[14] *See* Letter from Kathy Ko Chin, President & CEO, Asian & Pacific Islander American Health Forum, to Roger Severino, Dir., Office of Civil Rights, U.S. Dep't Health & Hum. Servs., at 21 (Aug. 13, 2019), https://perma.cc/6HWW-6833.

135. The Revised Rule repeals §§ 92.7 and 92.8 of the 2016 Final Rule, eliminating the notice and tagline requirements and the requirement to designate a specific individual to oversee Section 1557 compliance, including LEP efforts, and grievance procedure requirements. *See* 85 Fed. Reg. at 37,204.

136. The elimination of the notice, tagline, and LEP requirements is arbitrary and capricious and will result in some LEP patients failing to understand or assert their rights. It also will result in some LEP patients failing to receive adequate care because of the difficulties patients may have in understanding their providers or other staff, undermining the purpose and intent of the nondiscrimination provisions of Section 1557.

137. HHS has not explained how individuals will know about their rights and how elimination of notices will not deny LEP individuals meaningful access to health care.

X. The Revised Rule's Attempt to Narrow paduthe Scope of Health Programs and Activities Subject to Section 1557 is Arbitrary and Capricious and Contrary to Law

138. The plain language of Section 1557 prohibits discrimination based on sex, race, color, national origin, age, and disability under:

> any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under [Title I of the ACA] (or amendments).

42 U.S.C. § 18116(a).

139. The 2016 Final Rule correctly interpreted Section 1557 to cover all health-related operations and programs of any health care or health insurance provider, if any part of its operations receives Federal financial assistance; any other health program or activity that HHS administers; or any health insurance exchange or other entity established under ACA Title I or health insurance-exchange-related insurance plan.

140. The Revised Rule attempts to limit the scope of Section 1557 in two principal ways. First, it applies Section 1557's nondiscrimination protections only to health programs or activities of HHS that are administered under Title I of the ACA, not to other health programs and activities that HHS administers. 85 Fed. Reg. at 37,244 (to be codified at 45 C.F.R. § 92.3(a)(2)). Such a limitation excludes from Section 1557 numerous HHS health programs and activities, including health programs and activities of the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.

141. The Revised Rule's interpretation of the scope of Section 1557 is inconsistent with and contradicts the plain language of Section 1557, which states that it applies to "any program or activity that is administered by an Executive Agency." 42 U.S.C. § 18116(a). It does not limit Section 1557 to health programs and activities established or administered under ACA Title I.

142. Second, the Revised Rule erroneously declares that health insurers are not a "health program or activity" under Section 1557 and not subject to Section 1557's nondiscrimination prohibitions because, now according to HHS, they are not "principally engaged in the business of providing healthcare." 85 Fed. Reg. at 37,244-45 (to be codified at 45 C.F.R. § 92.3(c)).

143. By declaring that health insurance providers are not principally engaged in the business of providing health care, HHS purports to exclude health insurance providers from the requirements of Section 1557, except for plans offered on the Health Insurance Marketplace or Federally-facilitated Marketplace created under Title I and insurance plans outside of Title I that receive Federal financial assistance. For those health insurers that operate plans outside of Title I

but receive Federal financial assistance, the Revised Rule further limits the application of Section 1557 to only those operations that receive Federal financial assistance—all other operations of the insurer are excluded. 85 Fed. Reg. at 37,244 (to be codified at 45 C.F.R. § 92.3(b)).

144. This Revised Rule exempts many plans, products, and operations of many health insurance issuers, such as self-funded group health plans, the Federal Employees Health Benefits (FEHB) Program, and short-term limited duration insurance plans. 85 Fed. Reg. at 37,173-74.

145. To support its new interpretation, HHS contends that providing "health insurance" is different than providing "healthcare" and points to the definitions of "healthcare" and "health insurance" in unrelated statutes to support its distinction. 85 Fed. Reg. at 37,172-73.

146. But Section 1557 covers "health programs and activities," not just direct health care. Health insurance clearly is a health-related program or activity. It is what enables the vast majority of Americans to access health care. Indeed, health insurance companies design the health care individuals receive by determining benefits offered and establishing formularies, payment structures, and networks. They also conduct prior authorization and establish and evaluate other clinical coverage criteria, as well as exercise considerable control over the health care of enrollees—deciding which providers a patient may see, what hospitals they may visit, and what treatments or medications they may receive.

147. Neither the plain language of Section 1557 nor HHS's effort to rely on unrelated statutes supports HHS's unreasonable assertion that "healthcare" is different than "health insurance." Section 1557 explicitly provides that it covers "health programs and activities." Its scope is not limited to direct health care.

XI. The Revised Rule Arbitrarily and Capriciously Eliminates Gender Identity and Sexual Orientation Protections in Unrelated Regulations

148. The Revised Rule amends a series of unrelated regulations that had identified gender identity and sexual orientation as prohibited bases of discrimination, including regulations related to Medicaid State Plans, Programs for All-Inclusive Care for the Elderly (PACE), and ACA state health insurance exchanges and plans. The Revised Rule eliminates protections against gender identity and sexual orientation discrimination in those regulations. 85 Fed. Reg. at 37,218-22, 37,243.

149. These regulations were not issued pursuant to Section 1557 and do not interpret Section 1557. They were promulgated by CMS pursuant to the authority granted by several unrelated statutes. These unrelated regulations were not promulgated pursuant to HHS's authority to implement regulations under Section 1557.

150. For example, the Revised Rule amends regulations regarding Medicaid State Plans and Medicaid contractors, 42 C.F.R. §§ 438.3(d)(4), 438.206 (c)(2), and 440.262, which were issued pursuant to HHS's authority under Section 1902 of the Social Security Act to implement Section 1902(a)(19). That section directs HHS to "provide such safeguards as may be necessary to assure that eligibility for care and services under the [Medicaid] plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interest of the recipients." 42 U.S.C. § 1396a(a)(19); *see also* Medicaid and Children's Health Insurance Program (CHIP) Programs, 81 Fed. Reg. 27,498, 27,538-39, 27,666 (May 6, 2016).

151. Prior to the Revised Rule, 42 C.F.R. § 438.3(d)(4) provided: "The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, sexual orientation, gender identity, or disability and will

not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, sexual orientation, gender identity, or disability." The Revised Rule amends § 438.3(d)(4) to state: "The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, or disability." 85 Fed. Reg. at 37,243 (to be codified at 42 C.F.R. § 438.3(d)(4)).

152. PACE is a program for services for frail community-dwelling elderly persons, most of whom are Medicaid and Medicare dual eligible, to keep them in the community rather than moving to nursing homes. *See* 42 C.F.R. §§ 460.98, 460.112. HHS added sexual orientation to the list of protected categories of persons eligible for PACE services in 2006, explaining that "we do not believe anyone should be denied enrollment in PACE because of discrimination of any kind." Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions, 71 Fed. Reg. 71,244, 71,295 (Dec. 8, 2006).

153. Prior to the Revised Rule, 42 C.F.R. § 460.98(b)(3) provided: "The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment." The Revised Rule amends 42 C.F.R. § 460.98(b)(3) to state: "The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment." 85 Fed. Reg. at 37,243 (to be codified at 42 C.F.R. § 460.98(b)(3)). The Revised Rule also eliminates protections against sexual orientation

discrimination in 42 C.F.R. § 460.112(a). 85 Fed. Reg. at 37,220, 37,243 (to be codified at 42 C.F.R. § 460.112(a)).

154. Prohibitions of discrimination on the basis of sexual orientation and gender identity were added to regulations regarding group and individual market health insurance plans subject to the ACA and to ACA-created health insurance exchanges and qualified health plans. These prohibitions were added to further the ACA's aim of expanding insurance coverage, which discriminatory marketing practices and benefit designs can thwart. *See* 45 C.F.R. §§ 147.104(e), 155.120(c)(1)(ii), 155.220(j)(2)(i), 156.200(e), & 156.1230(b)(2); *see also* PPACA; Establishment of Exchanges and Qualified Health Plans, 77 Fed. Reg. 18,310, 18,319, 18,415 (March 27, 2012); PPACA; Health Insurance Market Rules, 78 Fed. Reg. 13,406, 13,417 (Feb. 27, 2013); PPACA; Exchange and Insurance Market Standards for 2015 and Beyond, 79 Fed. Reg. 30,240, 30,261 (May 27, 2014); PPACA; HHS Notice of Benefit and Payment Parameters for 2018, 81 Fed. Reg. 94,058, 94,064, 94,152 (Dec. 22, 2016).

155. The Revised Rule eliminates the prohibitions on gender identity and sexual orientation discrimination in these regulations. *See* 85 Fed. Reg. at 37, 219-21, 37,247-48 (to be codified at 45 C.F.R. §§ 147.104(e), 155.120(c)(1)(ii), 155.220(j)(2)(i), 156.200(e), & 156.1230(b)(2)).

156. HHS offers no legal, policy, or cost-benefit analysis for amending these regulations, including the effects they have had during the years they have been in place or the costs and benefits of amending them.

157. HHS's erroneous analysis of discrimination on the basis of sex under longstanding civil rights laws provides no justification for amending these regulations, which were promulgated to advance the goals of other statutory provisions.

158. HHS's amendment of these unrelated regulations to eliminate protections for LGBTQ people is arbitrary and capricious and without legal support.

XII. The Revised Rule's Cost-Benefit Analysis Is Arbitrary and Capricious

159. The Revised Rule fails to address adequately the direct and indirect costs that repeal of protections for LGBTQ people will have on patients, providers, insurers, and the overall health care system.

160. These costs take many forms, none of which the Revised Rule considers. First, out-of-pocket costs for necessary medical procedures will shift from insurers to patients and providers. Under the 2016 Final Rule, most insurers covered these services, but under the Revised Rule, insurers can deny coverage on the basis that these are cosmetic procedures, rather than medically necessary to alleviate gender dysphoria. Thus, many patients may forgo this necessary medical care due to the high cost of these procedures or cover the cost themselves. Providers also would lose out on the revenue from these procedures when patients cannot afford them.

161. Second, insurers' increased transgender exclusions and transgender patients' increased fear of discrimination by health care providers empowered by the Revised Rule will lead to transgender patients delaying or declining to seek care.[15] As such, transgender patients may develop comorbid conditions such as depression, anxiety, drug abuse, and other stress-related conditions. Treating these increased comorbid conditions will increase costs to patients, insurers, providers, and the health system overall.

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[15] *See* Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* at 12 (2010), https://perma.cc/9SEG-JD2K; *see also* S.E. James *et al.*, Nat'l Ctr. for Transgender Equality, *The Report of the 2015 U.S. Transgender Survey* at 98 (2016), https://perma.cc/9S9L-VJ9C.

162. Third, patients' delays or failures to obtain treatment will increase the direct cost of treating physical medical conditions and is a patient safety issue that can lead to poor patient outcomes. LGBTQ patients who fear discrimination may delay, or never receive, preventative care such as cancer screenings. Without regular screenings, LGBTQ patients will develop more advanced cancers and other health conditions. Because the cost of treating more advanced diseases far outweighs the cost of preventative care, the Revised Rule will increase costs to patients, insurers, providers, and the overall health care system.

163. The Revised Rule does not consider these costs associated with inviting discrimination against LGBTQ patients, and in particular those who are transgender. Ignoring such substantial costs makes the Revised Rule's cost-benefit analysis seriously flawed and arbitrary and capricious.

164. Indeed, the Revised Rule specifically admits HHS did not take the costs or harms to transgender patients into account, stating: "the Department also lacks the data necessary to estimate the number of individuals who currently benefit from covered entities' policies governing discrimination on the basis of gender identity who would no longer receive those benefits after publication of this rule." 85 Fed. Reg. at 37,225.

165. The costs of prohibiting sex-based discrimination against transgender people in health insurance coverage is minimal compared to the costs associated with inviting such discrimination. The 2016 Final Rule acknowledged this fact, stating that prohibiting discrimination against transgender consumers in health insurance "will have de minimis impact on the overall cost of care and on health insurance premiums." 81 Fed. Reg. at 31,456-57. Moreover, studies have found that providing coverage of transition-related care is extremely cost-effective and reduces costs in the long term. For example, a 2013 survey of employers

found that providing transition-related health care benefits has "zero or very low costs" and utilization rates of approximately 1 per 10,000 to 20,000 employees.[16] Another study found that the cost of providing coverage for treatment of gender dysphoria was about $0.016 per member per month. It also concluded that this small cost could reduce other costly health risks like depression and drug abuse.[17] Numerous other studies confirm these conclusions.[18]

166. The Revised Rule also fails to include in its cost-benefit analysis the costs associated with (1) eliminating gender identity nondiscrimination protections in the CMS regulations promulgated under different statutes, and (2) adopting the broad religious exemptions from Title IX and unrelated statutes. The costs of these changes include those associated with the increased discrimination that will result from the Revised Rule. Failing to consider these costs also makes the Revised Rule arbitrary and capricious.

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[16] Jody L. Herman, *Cost and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans*, The Williams Institute of the UCLA School of Law (Sept. 2013), https://perma.cc/D8J5-FACP.

[17] William V. Padula *et al.*, *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis*, 31 J. GEN. INTERN. MED. 394, 398 (Oct. 2015), https://perma.cc/74EW-LZPY.

[18] *See* Declaration of Raymond Edwin Mabus, Jr., former Secretary of the Navy, in Support of Plaintiff's Motion for Preliminary Injunction ¶ 41, *Doe* v. *Trump*, No. 1:17-cv-1597-CKK (Aug. 31, 2017), ECF No. 13-9, https://perma.cc/8ZU8-8NGE (concluding costs associated with providing health care to transgender service members was considered by a former Secretary of the Navy to be "budget dust, hardly even a rounding error"); Padula, *et al.*, *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis* at 398, https://perma.cc/74EW-LZPY (calculating the costs would be fewer than two pennies per month for every person with health insurance coverage in the United States); Cal. Dep't of Ins., Economic Impact Assessment: Gender Nondiscrimination in Health Insurance (Reg. File No. REG-2011-00023) (Apr. 13, 2012), https://perma.cc/QJ34-RVNQ (finding that costs of providing health care did not increase materially when employers adopted policies that prohibited discrimination against transgender individuals).

XIII. The Revised Rule Betrays Discriminatory Animus Against LGBTQ People

167. HHS's discriminatory animus in promulgating the Revised Rule is evident, as the promulgation of the Revised Rule is just the latest step in its multi-step erasure of LGBTQ people from health care-related nondiscrimination protections.

168. Defendant Severino has a history of anti-LGBTQ sentiments, advocacy, and comments. For example, in 2016, before he became Director of OCR, defendant Severino decried the 2016 Final Rule because it ran counter to some people's "moral, and religious beliefs about biology" and because, in his opinion, the 2016 Final Rule "create[d] special privileges, new protected classes, or new rights to particular procedures."[19]

169. In 2016, defendant Severino also denounced the Department of Justice's enforcement of Title IX's sex discrimination protections as they applied to transgender people as "using government power to coerce everyone, including children, into pledging allegiance to a radical new gender ideology."[20]

170. That same year, defendant Severino also stated that he believes transgender military personnel serving openly "dishonors" the service of other service members.[21] In addition, he referred to a transgender male student involved in a Title IX lawsuit as a "teen biological girl."[22]

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[19] Ryan Anderson & Roger Severino, *Proposed Obamacare Gender Identity Mandate Threatens Freedom of Conscience and the Independence of Physicians*, The Heritage Foundation (Jan. 8, 2016), https://perma.cc/5XKG-S79Z.

[20] Roger Severino, *DOJ's Lawsuit Against North Carolina Is Abuse of Power*, The Daily Signal (May 9, 2016), https://perma.cc/3FFM-KFMB.

[21] Roger Severino, *Pentagon's Radical New Transgender Policy Defies Common Sense*, CNSNews (July 1, 2016), https://perma.cc/VK37-5FP7.

[22] Roger Severino & Jim DeMint, *Court Should Reject Obama's Radical Social Experiment, The Heritage Foundation* (Dec. 14, 2016), https://perma.cc/N6K8-HQY5.

171. In 2018, it was reported that HHS's OCR was considering defining sex as "a person's status as male or female based on immutable biological traits identifiable by and before birth," a definition that is contrary to the legal, medical, and scientific understanding of sex.[23]

172. And in 2019, HHS issued a Notification of Nonenforcement of Health and Human Services Grants Regulation, in which it stated that it would no longer enforce regulations that prohibit discrimination based on sex, sexual orientation, or gender identity in grant programs that HHS funds. 84 Fed. Reg. 63,809 (Nov. 19, 2019).

173. With defendant Severino now Director of OCR, defendants seek to eviscerate the nondiscrimination protections Severino denounced.

174. For example, HHS asserts that it considered adding gender identity and sexual orientation discrimination to a definition of "sex" or discrimination "on the basis of sex" under Title IX, but concluded doing so was "inappropriate to do so in light of the ordinary public meaning of discrimination on the basis of sex under Title IX" and because "[a]s a policy matter," state and local entities "are better equipped to address with sensitivity issues of gender dysphoria, sexual orientation, and any competing privacy interests, especially when young children or intimate settings are involved." 85 Fed. Reg. at 37,222. Not only has the Supreme Court rejected HHS's position on the definition of "sex" under Title VII, but the notion that health care protections for LGBTQ people are at odds with "young children" is as offensive as it is telling.

175. As another example, although HHS declares that its position on the meaning of sex discrimination "will not bar covered entities from choosing to grant protections on the basis

[23] Erica L. Green, Katie Benner & Robert Pear, '*Transgender' Could Be Defined Out of Existence Under Trump Administration*, N.Y. Times (Oct. 21, 2018), https://perma.cc/YQR6-YN2F.

of sexual orientation and gender identity that do not conflict with any other Federal law," 85 Fed. Reg. at 37,222, HHS also states that a covered entity's refusal to make distinctions on the basis of sex "could in some cases violate personal privacy interests and so create a hostile environment under Title IX." 85 Fed. Reg. at 37,184. This assertion and the cases cited have nothing to do with Section 1557 and what facilities should be available to a patient in a health care setting.

176. HHS also fails to acknowledge that no cognizable legal claim exists based on having to share a restroom or other single-sex facility with a transgender person. HHS's suggestion to the contrary, *see* 85 Fed. Reg. at 37,190-91, is inconsistent with the rule of law and not a "reasonable" analysis. It serves only to heighten alarm among LGBTQ people and embolden those who attack them with frivolous assertions.

177. The Revised Rule reflects HHS's animosity toward LGBTQ people.

XIV. The Revised Rule Creates Immediate and Irreparable Harms

178. The Revised Rule cannot change the law and the courts will determine the meaning of Section 1557. However, HHS's rules have a substantial effect on health care providers and institutions, as well as on the public. The Revised Rule will result in increased discrimination against LGBTQ people, including those with LEP, by health care providers and health insurers. This increased discrimination will directly and irreparably injure plaintiffs, their members, their patients, and the individuals whom they serve.

A. The Revised Rule Will Increase LGBTQ Discrimination by Health Care Providers and Staff and Cause Irreparable Harm to Plaintiffs and the Patients and Individuals They Serve

179. Discrimination delays or denies necessary health care. It also discourages LGBTQ people from seeking care and from fully disclosing personal information that health care providers need for proper diagnosis and treatment.

180. The Revised Rule sends a message to the health care industry and the LGBTQ community that federal law permits discrimination against LGBTQ patients.

181. Indeed, in its Notice of Proposed Rulemaking, HHS acknowledged the 2016 Final Rule "likely induced many covered entities to conform their policies and operations to reflect gender identity as protected classes [sic] under Title IX." 84 Fed. Reg. at 27,876. And in the Revised Rule, HHS acknowledges that some covered entities may revert to the policies and practices they had in place before the 2016 Final Rule. 85 Fed. Reg. at 37,225. OCR also estimates that 60% of the increase in its anticipated long-term caseload of claims of discrimination are attributable to discrimination claims based on the 2016 Rule's definition of sex discrimination with respect to gender identity and sex stereotyping, though OCR has not enforced such claims. 85 Fed. Reg. at 37,235.

182. HHS tries to minimize the harm the Revised Rule will create, repeatedly claiming that because a federal district court enjoined enforcement of claims based on the definition of sex discrimination in the 2016 Final Rule in December 2016 and later vacated those provisions, any harm would not be the result of the Revised Rule, which merely is maintaining the status quo. *See, e.g.*, 85 Fed. Reg. at 37,181-82, 37,192, 37,199, & 37,238.

183. HHS's position is disingenuous at best. HHS has issued a Revised Rule attempting to legislate that claims of discrimination based on LGBTQ status are not "cognizable" under Section 1557. 85 Fed. Reg. at 37,225.

184. Without complete protection from discrimination based on their sex, including discrimination based on their sexual orientation, gender identity, transgender status, or failure to conform to sex stereotypes, LGBTQ people will be discouraged from seeking the health care they need.

185. The Revised Rule also will discourage LGBTQ people from fully disclosing personal information related to their sexuality and gender that health care providers need for proper diagnosis.

186. The Revised Rule will harm plaintiffs, their patients, and the LGBTQ people whom they serve in multiple ways.

1. Harm to Patients and Individuals Whom Plaintiffs Serve

187. LGBTQ individuals and especially transgender and gender-nonconforming people already face particularly acute barriers to care and health disparities that will be compounded by the Revised Rule. A majority of LGBTQ patients fear going to health care providers because of past experiences of anti-LGBTQ bias in health care settings. Many LGBTQ patients report negative experiences, including hostility, discrimination, and denials of care, when they disclose to health care providers their sexual orientation, history of sexual conduct, gender identity, transgender status, or history of gender-affirming medical treatment, and related medical histories.

188. For example, multiple LGBTQ patients at Whitman-Walker have previously been refused medical care, including routine care unrelated to gender dysphoria, by providers outside of Whitman-Walker simply because they are LGBTQ. In one instance, a radiological technician refused to perform an ultrasound for testicular cancer on a transgender patient. In another, a health care worker at a dialysis clinic confronted a Whitman-Walker patient with end-stage renal disease and objected to being involved in the patient's care because of hostility to his sexual orientation. In another, after a Whitman-Walker patient—a transgender teenager—was hospitalized in a local hospital following a suicide attempt, the staff would only address or refer to the young person with pronouns inconsistent with their gender identity, exacerbating the teenager's acutely fragile state of mind. Local hospitals and surgeons have refused to perform

transition-related surgeries on Whitman-Walker transgender patients, even when they routinely perform the very same procedures on non-transgender patients, including in situations when the patient's insurance would have covered the procedure or when the patient was able to pay for the procedure. Many local primary-care physicians unaffiliated with Whitman-Walker have refused to prescribe hormone therapy for transgender patients. And multiple Whitman-Walker patients have been denied prescriptions by pharmacists. Behavioral-health providers at Whitman-Walker report that the vast majority of transgender patients—as many as four out of five—report instances of mistreatment or discrimination by health care providers, hospitals, clinics, doctors' offices, or other facilities outside of Whitman-Walker.

189. Patients of the LA LGBT Center report similar experiences of discrimination by other providers. One transgender patient, who developed profuse bleeding after surgery, was denied treatment at an emergency room and arrived at the LA LGBT Center in distress three days later, having lost a significant amount of blood. Another patient required extensive surgery to repair damage caused by a prior silicone breast-augmentation procedure. But she was turned down by an academic plastic-surgery center in Los Angeles because the surgeon said her health problems were caused by her own poor decision-making and she therefore would not be considered for treatment. By the time she was able to identify a surgeon who was willing to treat her, with the assistance of a physician at the LA LGBT Center, years had passed and her condition had become life-threatening. For patients at the LA LGBT Center, the ability to receive gender-affirming medical care can mean the difference between life and death.

190. In many geographic regions, a majority of LGBTQ people lack a provider whom they consider to be their personal doctor. As a result, when they seek health care services, they will encounter a health care provider with whom they do not have a relationship. This makes

them especially vulnerable to discriminatory treatment from providers who are not LGBTQ-affirming. For some medical specialties, there are only a handful of health care providers in the region who have the expertise necessary to treat a patient for a particular condition, so a denial of care from even one provider could make it practically impossible for an LGBTQ patient to receive any care at all.

191. In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that if they were turned away from a hospital, it would be very difficult or impossible to get the health care they need elsewhere.[24] The rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider. Even when they are able to get access to care, many LGBTQ individuals report that health care professionals have used harsh language toward them, refused to touch them, used excessive precaution, or blamed the individuals for their health status.[25]

192. Consequently, LGBTQ patients are disproportionately likely to delay preventative screenings and necessary medical treatment and therefore to end up with more acute health problems and outcomes, raising concerns about patient safety. Research has identified pervasive health disparities for LGBTQ people with respect to cancer, HIV, obesity, mental health, tobacco use, and more. In other words, LGBTQ people, who are disproportionately likely to need a wide range of routine medical care, already have reason to fear, and often do fear, negative consequences of "coming out" to health care providers about their sexual orientation, history of

[24] *See* Mirza & Rooney, *Discrimination Prevents LGBT People From Accessing Health Care*, https://perma.cc/ZG7E-7WK8.

[25] *Id.*

sexual conduct, gender identity, transgender status, history of gender-affirming medical treatment, and related medical histories.

193. The Revised Rule will exacerbate the acute health disparities LGBTQ people already face. The Revised Rule sends the message that discrimination on the basis of gender identity and sex stereotyping is permissible under federal law, which will increase the number of LGBTQ people who will be denied care.

194. The Revised Rule also encourages LGBTQ people to remain closeted to the extent possible when seeking medical care. But remaining closeted to a health care provider may result in significant adverse health consequences. For instance, a patient who conceals or fails to disclose a same-sex sexual history may not be screened for HIV or other relevant infections or cancers, or may not be prescribed preventative medications such as Pre-Exposure Prophylaxis or PrEP, which is extremely effective at preventing HIV transmission. Patients who fail fully to disclose their gender identity and sex assigned at birth may not undergo medically indicated tests or screenings (such as tests for cervical or breast cancer for some transgender men, or testicular or prostate cancer for some transgender women). The barriers to care are particularly high for transgender people. Nearly one-quarter of transgender people report delaying or avoiding medical care when sick or injured, at least partially because of fear of discrimination by and disrespect from health care providers.[26]

195. Patients remaining closeted to health care providers also results in increased costs to the health care system. For example, when a patient is closeted, medical providers may not order medically necessary tests or screenings, which has downstream effects such as

[26] *See* Mirza & Rooney, *Discrimination Prevents LGBT People From Accessing Health Care*, https://perma.cc/ZG7E-7WK8.

exacerbating a patient's distress and increasing costs to providers and the health care system as a whole for delayed treatment.

196. The Revised Rule will result in increased discrimination against LGBTQ people in the provision of health care and cause harm to the health of LGBTQ people and to public health generally.

2. Harm to Private Health Care Provider Plaintiffs, LGBTQ-Services Plaintiffs, and Health Professional Association Plaintiffs

197. The Revised Rule, which fosters discrimination against LGBTQ people in the provision of health care, frustrates plaintiffs' core missions of providing and advocating for affirming, high-quality care to all LGBTQ people and protecting against discrimination on the basis of LGBTQ status in the delivery of health care and services to patients.

198. In addition, because more LGBTQ patients will delay seeking health care, they will come to Whitman-Walker and the LA LGBT Center, the private health care provider plaintiffs who serve many LGBTQ patients, and members of the health professional association plaintiffs – GLMA and AGLP – with more acute conditions, diseases that are more advanced at diagnosis, less responsive to treatment, or no longer treatable. This delay will strain the resources of providers and increase costs for providers and patients and the health care system in general.

199. The discriminatory experiences LGBTQ patients have with other health care providers erode patients' trust in health care providers overall and thus also challenges the ability of plaintiffs to treat their patients effectively and provide appropriate services and referrals. To provide proper medical care and services to the LGBTQ community, plaintiffs rely on frank and complete communication with their patients and the individuals who seek their services. Plaintiffs need patients and individuals seeking services to fully disclose all aspects of their

health history, sexual history, and gender identity to provide appropriate care for the patients' health. Without full disclosure, plaintiffs are not able to treat adequately their patients. For instance, plaintiffs need to know patients' sexual history to know whether to test them for HIV or other infections or cancers. And plaintiffs need to be aware of patients' gender identity and sex assigned at birth to order proper screenings and tests – like cervical or breast cancer for some transgender men, or testicular or prostate cancer for some transgender women. The Revised Rule endangers the provider-patient relationship and will harm plaintiffs and their patients by discouraging full disclosure. This also means that medical and health care providers bear increased risk of malpractice when patients do not feel comfortable to fully disclose all aspects of their health history, sexual history, and gender identity.

200. The Revised Rule's effect of increasing discrimination by other providers will lead to increased demand for providers, entities, and individuals who serve the LGBTQ community, like Whitman-Walker, LA LGBT Center, the TransLatin@ Coalition (and its affiliated organizations like FLAS and Arianna's Center), Bradbury-Sullivan Center, and the members of GLMA and AGLP. This increased demand will place a strain on these plaintiffs' resources, leaving them unable to fulfill their organizational missions, spend sufficient time on each patient or individual seeking services, and provide care and services to all individuals. It also will harm LGBTQ people through increased wait times and delays of care that may worsen conditions.

201. In addition, Whitman-Walker, LA LGBT Center, the TransLatin@ Coalition (and some of its affiliated organizations like FLAS and Arianna's Center), and Bradbury-Sullivan Center, as well as the members of GLMA and AGLP and the individual provider plaintiffs, all refer patients to other health care providers. The Revised Rule will harm the ability of these

plaintiffs to refer LGBTQ patients to other providers because they will not know whether these providers will discriminate against their patients and/or refuse to treat their patients under the Revised Rule's personal religious or moral belief exemptions. Thus, these plaintiffs will be required to redirect their staff and resources from providing their own services to assisting patrons in determining who among the health care providers in the region will serve LGBTQ patients in a nondiscriminatory manner.

202. The Revised Rule also will burden the private health care provider and LGBTQ-services plaintiffs by precluding them from carrying out their organizational missions of providing affirming, non-discriminatory care to all LGBTQ patients based on the religious views of a single employee. The sweeping religious exemptions in the Revised Rule encourage individual employees to believe their discriminatory beliefs can prevail over their duties to patients – and to their fellow employees – posing barriers to patient care and creating burdens for the organizations. The private health care provider and LGBTQ-services plaintiffs may be forced to institute costly workarounds and duplicative staff to accommodate the religious views of a single employee, which also may result in unfairly burdening non-objecting employees. These increased costs also may result in a reduction of services and closure of programs, thus frustrating plaintiffs' institutional missions and core functions of providing comprehensive health care and other services to LGBTQ people.

3. Additional Harm to GLMA, AGLP, and Their Members

203. The Revised Rule also will create additional harms to the health professional association plaintiffs GLMA and AGLP, their members, the LGBTQ patients whose interests they represent, and the patients whom their members treat.

204. GLMA works with professional accreditation bodies, such as the Joint Commission, and health-professional associations, on standards, guidelines, and policies that

address LGBTQ health and protect individual patient health and public health in general. The Revised Rule prevents GLMA from achieving its goals with professional accreditation bodies by preventing such bodies from holding health care providers accountable for discrimination against LGBTQ people.

205. For a health care organization to participate in and receive federal payment from Medicare or Medicaid programs, the organization must obtain a certification of compliance with health and safety requirements. That certification is achieved based on a survey conducted either by a state agency on behalf of the federal government, or by a federally recognized national accrediting organization, like the Joint Commission. Accreditation surveys include requirements that health care organizations not discriminate on the basis of sex, sexual orientation, or gender identity in providing services or in employment. The Revised Rule presents a direct conflict with nondiscrimination standards the Joint Commission has adopted and all the major health-professional associations stating that health care providers should not discriminate in providing care for patients and clients because of sexual orientation or gender identity.

206. The Revised Rule invites health care organizations who discriminate against LGBTQ people to become accredited. The Revised Rule conflicts with GLMA's mission of achieving and enforcing accreditation standards relating to nondiscrimination.

207. Members of GLMA and AGLP also will be harmed by the Revised Rule because some members are employed by health care organizations that may rely on the religious and moral exemptions in the Revised Rule to deny care or discriminate against LGBTQ patients. The Revised Rule encourages religiously-affiliated health care employers to discriminate against employees who are GLMA or AGLP members for adhering to and enforcing their medical and

ethical obligations to treat all patients in a nondiscriminatory manner, including providing all medically-necessary care that is in LGBTQ patients' best interests.

208. In addition, the Revised Rule invites harassment and discriminatory treatment of GLMA and AGLP members in the workforce by fellow employees. The Revised Rule sends a message that discrimination against LGBTQ health care providers and their LGBTQ patients is permissible. GLMA and AGLP members and their LGBTQ patients are stigmatized and demeaned by this message that LGBTQ people are not deserving of legal protections in the health care context. The Revised Rule thus frustrates GLMA's and AGLP's missions of achieving and enforcing safe workspaces for LGBTQ health professionals and non-discriminatory health care services for their LGBTQ patients.

4. Additional Harm to the TransLatin@ Coalition, Its Members, and the Individuals it Serves

209. The Revised Rule also will harm the TransLatin@ Coalition, its members, its affiliated organizations, and the individuals whom the Coalition serves in that the harms the Revised Rule will exact on LGBTQ people, particularly those who are transgender, will be exacerbated for those with LEP. The Revised Rule's elimination of notice and tagline requirements will make it more difficult for LGBTQ people with LEP to be aware of their rights, which language services and aids are available, how to access such services, and how to handle discrimination and complaints. The health care system was already difficult to navigate for LEP individuals, and the Revised Rule serves to exacerbate those difficulties and undermines access to health care, health insurance, and legal redress. The Revised Rule will harm the TransLatin@ Coalition's mission and members by making it more difficult to access health care and by decreasing protections from discrimination.

210. The Revised Rule's elimination of the unitary standard also harms the TransLatin@ Coalition, its members, and individuals whom it serves by making it more difficult to bring claims of intersectional discrimination. Rather than being able to assert claims under a unitary standard, intersectional discrimination claims will be subject to different standards, enforcement mechanisms, and remedies based on which identities are at issue.

B. The Revised Rule Will Result in Increased Discrimination by Health Plans, Particularly Against Persons Seeking Gender-Affirming Care

211. Many private and public plans resist coverage of medically necessary procedures, whether through blanket exclusions of "sex change" or "sex transition" procedures, or through denials of coverage of specific procedures. Many plans that do not contain blanket exclusions still exclude many essential types of surgeries related to gender transition, such as facial or chest surgery.

212. Many insurers also deny coverage of other specific treatments needed to complete an individual's transition on the grounds that the procedure is "cosmetic" – either by relying on general plan language excluding cosmetic procedures or concluding that a procedure is not medically necessary. Examples of procedures that are categorically excluded as "cosmetic" in many plans and by many utilization reviewers include:

a. Surgeries of the head and face, such as hair transplant, scalp advancement, brow reduction, lip reduction or augmentation, rhinoplasty, cheek and chin contouring, jawline modification, blepheroplasty, and other facial feminization techniques for transgender women;

b. Laser hair removal and electrolysis, on the face and elsewhere on the body;

c. Surgeries involving the neck, such as cartilage reduction (modification of the Adam's Apple) and vocal feminization surgery;

d. Breast augmentation and reduction;

e. Other body contouring procedures, such as waist reduction, hip/buttocks implants, fat transfer, pectoral implants; and

f. Lessons/training to modify the vocal range.

213. Relying on its definition of "on the basis of sex" to include gender identity and to forbid discrimination against transgender individuals, the 2016 Final Rule helped persuade Medicaid administrators, insurance company personnel, and employee health plan sponsors to eliminate outdated exclusions and to agree to cover procedures when supported by evidence of medical necessity. Following its promulgation, the 2016 Final Rule led to a decrease in discriminatory policies and practices.[27] A recent study of 37 states in the federal marketplace showed that 97% of plans analyzed did not contain blanket exclusions of transition-related care in 2019.[28]

214. By eliminating the 2016 Final Rule's definition of "on the basis of sex" and the explicit prohibitions on "categorical coverage exclusion[s] or limitation[s] for all health services related to gender transition" and denials, limitations, or restrictions "for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual," 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.207(b)(4)-(5)), the Revised Rule invites reversal of much of this progress, leading to a

[27] Gruberg & Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, https://perma.cc/CTP2-UMEJ.

[28] Out2Enroll, *Summary of Findings: 2020 Marketplace Plan Compliance with Section 1557*, https://perma.cc/WU25-C9BN. This is consistent with summaries from 2017, 2018, and 2019.

reduction in coverage and access to medically necessary health care for transgender and gender nonconforming patients.

215. In addition, the Revised Rule's narrow interpretation of what constitutes a covered entity similarly will result in a reduction in coverage and access to medically necessary health care for transgender and gender nonconforming patients.

216. Increased discrimination by health insurance plans will harm plaintiffs and the patients and individuals whom they serve. Plaintiffs that provide health care services will face increased costs because many private and public plans will refuse to cover medically necessary procedures based on the Revised Rule's elimination of protections against gender identity discrimination. Plaintiffs, in turn, will be forced to either cover the costs of these medically necessary procedures, or turn away LGBTQ patients who need these services but cannot afford to pay for them out of pocket. Likewise, patients may forgo necessary medical care due to the high cost of these procedures or cover the cost themselves.

C. The Revised Rule Will Result in Increased Discrimination towards Patients with Limited English Proficiency

217. Language access protections are required to prevent discrimination based on national origin. These services are important because ineffective communication between health care providers and LEP patients for the purposes of diagnosis, treatment options, proper use of medication, obtaining informed consent, and insurance coverage can result in adverse health consequences or death.

218. The Revised Rule eliminates the requirement that covered entities take reasonable steps to provide meaningful access to "*each individual* with LEP eligible to be served or likely to be encountered" and replaces it with a general reference to "LEP individuals." *See, e.g.*, 85 Fed.

Reg. at 37,245. However, focusing on LEP individuals in general as opposed to each individual will result in some individuals not receiving the services they need for meaningful access.

219. In addition, the Revised Rule eliminates the existing requirement that non-discrimination notices include the availability of language assistance services and taglines in the top 15 languages spoken by LEP individuals in a state. HHS "acknowledges the potential of reduced awareness of the availability of language services by LEP individuals by the changes made in this rule, or downstream effects on malpractice claims due to less awareness," 85 Fed. Reg. at 37,235, yet HHS dismissed these negative effects claiming enforcement of Section 1557 will diminish them.

220. The Revised Rule will harm LEP patients, including members of the TransLatin@ Coalition and those the Coalition and its affiliated organizations (like FLAS and Arianna's Center) serve, as well as the LEP patients private health care provider plaintiffs serve, by diminishing or eliminating meaningful access to health care because they will not be aware of their rights or the programs or services available to them.

221. The weakening of protections for LEP individuals will result not only in poorer health outcomes for LEP individuals, but also in increased costs and burdens for plaintiffs. As a result of the Revised Rule, private health care and individual provider plaintiffs will face increased burdens due to fewer clients being aware of their language access rights and the likelihood that more people will turn to them for help in their language, rather than other covered health care providers.

222. For example, the weakening of protections for LEP individuals will harm LEP patients of private health care providers who get care elsewhere and who private health care providers need to refer outside their organizations for specialty care, as they will no longer

benefit from the notices, taglines, and additional language access provisions that are critical to ensure meaningful access to care.

223. The weakening of protections also will burden private health care and individual provider plaintiffs, as well as members of health professional association plaintiffs, because patients will come to them sicker due to inadequate care elsewhere, and more people may come to them because their LEP services will remain robust.

224. In addition, the weakening of protections for LEP individuals will harm private health care providers and individual provider plaintiffs, as well as members of health professional association plaintiffs, as it will place them at an increased risk for malpractice claims linked to inadequate language access.

FIRST CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(A)
Arbitrary and Capricious

225. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

226. Defendants are subject to the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq*.

227. The APA provides that courts must "hold unlawful and set aside agency action" that is "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A).

228. The Revised Rule is arbitrary and capricious because defendants' justifications for repealing critical anti-discrimination protections run counter to the evidence before the agency and disregard material facts and evidence, defendants fail to supply a reasoned explanation for their policy change from the 2016 Final Rule to the Revised Rule, defendants have failed to consider important aspects of the problem, including the Revised Rule's interference with

current law, and defendants failed to account properly for the costs and benefits of the Revised Rule.

229. The Revised Rule relies primarily on a single ruling and the federal government's litigation position in the *Bostock* case and related litigation to justify HHS's rejection of long-standing authority that has defined discrimination on the basis of sex in a variety of federal civil rights laws to include discrimination against individuals who are LGBTQ. The Supreme Court now has rejected HHS's position.

230. The Revised Rule also eliminates, contrary to statutory authority, the unitary legal standard for enforcement of violations of Section 1557, replacing it with a fractured approach that will complicate and make it more difficult to bring discrimination claims under Section 1557, particularly claims of intersectional discrimination.

231. The Revised Rule's elimination of the explicit recognition of private rights of action and the availability of compensatory damages under Section 1557 also will confuse the public and mislead many individuals into not asserting their legal rights.

232. In addition, contrary to the statutory language of Section 1557, the Revised Rule imports broad and sweeping exemptions for discrimination based on personal religious or moral belief from both the named statutes in Section 1557 and other statutes, like the Religious Freedom Restoration Act (42 U.S.C. § 2000bb *et seq.*), which Section 1557 does not reference. These exemptions invite individual health care providers, health care entities (hospitals, clinics etc.), and insurers across the country to opt out of treating patients, including many transgender patients, if they believe doing so would compromise their faith. Defendants' attempt to create new religious exemptions in Section 1557 is contrary to law and endangers patients' health in the name of advancing the religious beliefs of those who are entrusted with caring for them – a result

sharply at odds with HHS's stated mission, which is to "enhance and protect the health and well-being of all Americans" and to "provid[e] for effective health and human services." It also adversely affects health care providers that serve and treat the LGBTQ community because (1) individual health care employees may decline to serve patients based on religious objections, and (2) their ability to refer patients to other providers will be impaired, as the Revised Rule invites those other providers to discriminate against their LGBTQ patients.

233. The Revised Rule also arbitrarily limits the scope of Section 1557, cutting back on the entities subject to the statute, contrary to the plain language of Section 1557.

234. Defendants also have failed to provide a sufficient explanation for the decision to eliminate the references to sexual orientation and gender identity discrimination in unrelated regulations promulgated under different statutes. Neither the evidence before the agency nor the weight of the legal authority supports the elimination of these protections.

235. Defendants also have failed to provide a sufficient explanation for the decision to eliminate protections against discrimination on the basis of association. Neither the evidence before the agency nor the weight of the legal authority supports the elimination of these protections.

236. The Revised Rule also is arbitrary and capricious in that it eliminates the requirement of notice of nondiscrimination requirements and access to language protections without adequate justification, undermining the ACA's charge to ensure individuals have access to health care and health insurance.

237. The Revised Rule fails to consider important regulatory costs, including significant direct or indirect health costs to plaintiffs, their patients, and public health and safety.

238. The Revised Rule therefore is arbitrary, capricious, [or] an abuse of discretion" in violation of the APA. 5 U.S.C. § 706(2)(A).

239. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

SECOND CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(A)
Not in Accordance with Law

240. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

241. Under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law." 5 U.S.C. § 706(2)(A).

242. The Revised Rule is not in accordance with law because it conflicts with the Supreme Court's ruling in *Bostock* that discrimination on the basis of a person's sexual orientation or transgender status is discrimination on the basis of sex under Title VII, and rejects the well-established understanding of "sex" under longstanding civil rights laws as including such discrimination.

243. The Revised Rule's elimination of protections based on sexual orientation and gender identity in unrelated regulations promulgated under different statutes likewise conflicts with controlling legal authority regarding the meaning of "sex."

244. The Revised Rule's elimination of protections against discrimination on the basis of association contravenes existing case law and the underlying statutes and therefore is , not in accordance with law.

245. The Revised Rule conflicts with the statutory language and purpose of Section 1557 by failing to make the enforcement mechanisms provided by Title VI, Title IX, the Age

Discrimination Act, and the Rehabilitation Act available in the case of discrimination against a person based on any characteristic protected by these statutes.

246. The Revised Rule also conflicts with the statutory language of Section 1557 by importing broad and sweeping exemptions based on personal religious or moral belief from the identified statutes in Section 1557 and other statutes, including the Religious Freedom Restoration Act (42 U.S.C. § 2000bb *et seq.*), which Section 1557 does not reference.

247. In addition, the Revised Rule conflicts with the statutory language of Section 1557 by limiting the entities covered under Section 1557.

248. The Revised Rule violates Section 1554 of the ACA, which explicitly prohibits the Secretary of HHS from promulgating any regulation that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care" or "impedes timely access to health care services." 42 U.S.C. § 18114. The Revised Rule creates unreasonable barriers and impedes timely access to health care by reversing protections against discrimination of historically marginalized communities and eliminating access to language provisions.

249. The Revised Rule therefore is "not in accordance with law" as required by the APA. 5 U.S.C. § 706(2)(A).

250. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

THIRD CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(C)
Exceeds Statutory Authority

251. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

252. Under the APA, a court must "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

253. Federal agencies do not have the power to act unless Congress confers the power upon them. Defendants were not given the power to alter Section 1557's statutory terms, but that is precisely what the Revised Rule attempts to do. The Revised Rule unduly limits the explicit nondiscrimination protections against sex discrimination set forth in Section 1557 by purporting to preclude claims of discrimination based on an individual's LGBTQ status. It also places health care services for LGBTQ people, gender nonconforming people, and other consumers at risk without congressional authorization to make these changes.

254. The Revised Rule's elimination of a unitary legal standard to address violations of Section 1557 and limitation on the entities covered under Section 1557 likewise is contrary to the language and intent of Section 1557 and exceeds HHS's authority.

255. The Revised Rule also amends a series of unrelated regulations to conform with the Revised Rule. The Revised Rule erases not only existing protections for LGBTQ people in the 2016 Final Rule, but eliminates such protections in other regulations, which were promulgated pursuant to the authority granted by several different statutes, including Section 1321(a) and the provisions of the ACA, Social Security Act, and other statutory authority, not Section 1557.

256. The Revised Rule also eliminates notice requirements and access to language protections, undermining the ACA's central purpose to ensure individuals have access to health care and health insurance.

257. The Revised Rule therefore is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" in violation of the APA. 5 U.S.C. § 706(2)(C).

258. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

FOURTH CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(B)
and U.S. Constitution, Fifth Amendment, Equal Protection Component

259. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

260. Under the APA, a court must "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

261. The Fifth Amendment's Due Process Clause provides that no person shall be deprived of life, liberty, or property without due process of law.

262. The Due Process Clause includes within it a prohibition against the denial of equal protection of the laws by the federal government, its agencies, or its officials or employees.

263. The purpose and effect of the Revised Rule are to discriminate against plaintiffs, their patients, the individuals they serve, and their members based on their sex, gender identity, transgender status, gender nonconformity, and exercise of their fundamental rights, including the rights to bodily integrity and autonomous medical decision-making, and the rights to live and express oneself consistent with one's gender identity.

264. The Revised Rule also is intended to have and will have a disproportionate impact on LGBTQ people. The Revised Rule places an impermissible special burden on these individuals.

265. LGBTQ people have suffered a long history of discrimination and continue to suffer that discrimination. They are part of discrete and insular groups and lack the power to protect their rights through the political process.

266. Transgender people have a gender identity that differs from the sex assigned to them at birth. A person's gender identity is a core, defining trait fundamental to a person's sense of self and personhood.

267. Requiring a person to abandon their gender identity as a condition to equal treatment violates the Equal Protection Clause.

268. Discrimination on the basis of sex, including on the basis of gender identity, transgender status, sexual orientation, and failure to conform to sex stereotypes, is presumptively unconstitutional and subject to heightened scrutiny.

269. Similarly, discrimination based on the exercise of a fundamental right is presumptively unconstitutional and is subject to strict scrutiny.

270. The Revised Rule lacks a rational or legitimate justification, let alone the important or compelling one that is constitutionally required. The Revised Rule also lacks adequate tailoring under any standard of review.

271. Defendants' encouragement of discrimination against LGBTQ people deprives LGBTQ people of their right to equal dignity and stigmatizes them as second-class citizens.

272. The Revised Rule therefore violates the Equal Protection Clause of the Fifth Amendment of the U.S. Constitution and must be set aside under the APA and the Fifth Amendment.

273. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

FIFTH CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(B)
and U.S. Constitution, Fifth Amendment, Substantive Due Process

274. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

275. Under the APA, a court must "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

276. The Fifth Amendment's Due Process Clause protects individuals' substantive rights to be free to make certain decisions central to privacy, bodily autonomy, integrity, self-definition, intimacy, and personhood without unjustified governmental intrusion. Those decisions include the right to transition-related medical treatment, as well as the right to live openly and express oneself consistent with one's gender identity.

277. By encouraging health care providers and insurers to interfere with and unduly burden patients' access to medically necessary health care, the Revised Rule violates the rights of plaintiffs to privacy, liberty, dignity, and autonomy as guaranteed by the Fifth Amendment.

278. A person's gender identity and ability to live and express oneself consistent with one's gender identity without unwarranted governmental interference is a core aspect of each person's autonomy, dignity, self-definition, and personhood. By encouraging health care providers and insurers to deny or otherwise interfere with individuals' access to gender-affirming medical care, including surgical procedures, hormone therapy, and other medically necessary care, and by interfering with the ability of transgender and gender-nonconforming individuals to live and express themselves in accordance with their gender identities, the Revised Rule infringes on patients' interests in privacy, liberty, dignity, and autonomy protected by the Fifth Amendment.

279. There is no legitimate interest supporting the Revised Rule's infringement on patients' fundamental rights, let alone an interest that can survive the elevated scrutiny required to justify infringement of these fundamental rights.

280. The Revised Rule therefore violates the Due Process Clause of the Fifth Amendment of the U.S. Constitution and must be set aside under the APA and the Fifth Amendment.

281. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

SIXTH CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(B) and U.S. Constitution, First Amendment, Free Speech

282. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

283. Under the APA, a court must "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

284. The Free Speech Clause of the First Amendment to the United States Constitution declares: "Congress shall make no law . . . abridging the freedom of speech." U.S. Const. amend. I. The Free Speech Clause prohibits the government from "chilling" a person's right to free expression.

285. A person's disclosure of their transgender or gender nonconforming status, speech or expression that discloses gender identity, and a person's gendered speech and expressive conduct all receive constitutional protection under the First Amendment.

286. The Revised Rule has the purpose and effect of chilling constitutionally protected First Amendment activity. As a result of the Revised Rule, an increased number of LGBTQ

people will remain closeted in health care settings and to doctors, nurses, and other healthcare providers and will decline to disclose their sexual orientation, transgender status, or gender identity.

287. Further, an increased number of LGBTQ people will decline to engage in gendered speech and expression, including by declining to disclose related medical histories—even when that self-censorship impedes the ability of their health care providers to provide appropriate treatment and results in negative health consequences to the patients and to public health.

288. The Revised Rule will chill a patient of ordinary firmness from making such disclosures.

289. The Revised Rule violates the Free Speech Clause of the First Amendment because it impermissibly burdens the exercise of patients' constitutionally protected speech, expression and expressive conduct based on the content and viewpoint of patients' speech.

290. In addition, the Revised Rule is overbroad because it will chill protected First Amendment activity.

SEVENTH CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(B) and U.S. Constitution, First Amendment, Establishment Clause

291. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

292. Under the APA, a court must "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

293. The Establishment Clause of the First Amendment to the United States Constitution declares: "Congress shall make no law respecting an establishment of religion."

U.S. Const. amend. I. The Establishment Clause prohibits the government from favoring one religion over another, or religion over nonreligion.

294. The Establishment Clause permits the government to provide religious accommodations or exemptions from generally applicable laws only if, among other requirements, the accommodation (1) lifts a substantial, government-imposed burden on the exercise of religion, and (2) does not shift substantial costs or burdens onto a discrete class of third parties, without regard for the third parties' interests. In other words, the government may "accommodate" religion in accordance with the Free Exercise Clause, but it may not "promote" religion.

295. The Revised Rule violates the Establishment Clause by creating expansive religious exemptions for health care providers, plans, and employees at the expense of third parties – namely, plaintiffs, other providers, and most importantly the patients and the individuals whom plaintiffs serve. It invites health care providers, including insurance companies, hospitals, doctors, and nurses, to deny LGBTQ patients necessary medical treatment based on their religious beliefs.

296. The effect of the Revised Rule will be that patients who seek care at odds with the religious beliefs of a health care provider or employee of a health care provider may be delayed in receiving care (including emergency care) or denied care altogether.

297. The Revised Rule also will burden plaintiffs by precluding them from carrying out their organizational missions based solely on the religious views of a single employee.

298. In addition, plaintiffs will be harmed because their ability to refer LGBTQ patients to other providers will be affected in that they will not know whether these providers will discriminate against their patients and/or refuse to treat their patients under the Revised

Rule's personal religious or moral belief exemptions. Plaintiffs thus will be required to redirect their staff and resources from providing their own services to assisting patrons in determining who among the health care providers in the region will serve LGBTQ patients in a nondiscriminatory manner.

299. The Revised Rule violates the Establishment Clause because it:

(a) has the primary purpose and effect of favoring, preferring, and endorsing certain religious beliefs and certain religious denominations over others and over nonreligion;

(b) has the primary purpose and effect of preferring the religious beliefs of some people and institutions over the lives, health, and other rights and interests of third parties;

(c) impermissibly entangles government with religion;

(d) makes plaintiffs, their patients, and other third parties bear the costs and harms of objecting employees' religious beliefs or religious exercise; and

(e) imposes on plaintiffs a requirement to accommodate employees' religious objections without taking constitutionally required account of the actual burdens (if any) on the objectors or the effects on or harms to plaintiffs, their patients, or the greater public health.

300. Those who are denied coverage will suffer the stigma of government-sanctioned discrimination. They also will be forced to either endure significant psychological burdens or, if they can afford it, pay for treatment out-of-pocket. The Revised Rule favors religion at the expense of LGBTQ patients without regard for LGBTQ patients' interests. The Revised Rule contains no provision for balancing or accounting for a patient's right to care. Instead, it applies

categorically to deny patients the right to medical treatment based on a provider's religious or moral beliefs.

301. The Revised Rule therefore violates the Establishment Clause of the First Amendment of the U.S. Constitution and must be set aside under the APA and the Establishment Clause.

302. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

EIGHTH CLAIM FOR RELIEF
Equitable Relief to Preserve Remedy

303. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

304. The Revised Rule will become effective on August 18, 2020 unless it is enjoined. Plaintiffs are entitled to a full, fair, and meaningful process to adjudicate the lawfulness of the Revised Rule before being required to implement its far-reaching and harmful requirements.

305. Plaintiffs will suffer irreparable injury by implementation of the Revised Rule, which would erode hard-won trust between LGBTQ people and their health care providers, stigmatize and traumatize patients, interfere with medical procedures and operations, and result in delays and denials of care leading to physical harm and even death. Preliminary and permanent injunctive relief is needed to ensure that plaintiffs' injuries are fully remedied.

306. Injunctive relief also is needed to prevent the immediate harm resulting from the Revised Rule. Patients need assurance that they will receive complete, accurate information and timely and responsive medical care in an environment that protects their constitutional rights and does not expose them to stigma and harm. This Court should step in to protect plaintiffs' institutions, their patients, the individuals they serve, and their members, in addition to the

foremost principle guiding medical providers in responding to those in need of assistance and care – first, do no harm.

307. Accordingly, to ensure that plaintiffs receive meaningful relief should they prevail in this action, the Court should preliminarily and permanently enjoin defendants from implementing the Revised Rule.

REQUEST FOR RELIEF

Wherefore, plaintiffs pray that the Court grant the following relief:

A. Declare that the Revised Rule is unlawful and unconstitutional through a declaratory judgment under 28 U.S.C. § 2201(a) and 5 U.S.C. § 706(a);

B. Set aside and vacate the Revised Rule;

C. Preliminarily and permanently enjoin the implementation and enforcement of the Revised Rule;

D. Award reasonable attorneys' fees, costs, and expenses; and

E. Award any other further and additional relief the Court deems just and proper.

Dated: June 22, 2020

Respectfully submitted,

LAMBDA LEGAL DEFENSE
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* *Motion for admission pro hac vice pending.*

** *Application for admission to U.S. District Court for the District of Columbia forthcoming.*

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(b)(5)

Excerpt Text	Classification Comment Type	Organization
Comments associated with this issue are not used in the suggestions below.		
I support the proposed rule because it provides protections for LGBTQ+ people in health care settings. Health care is very important to us. And in fact it is the very mission of HHS to ensure the health and well-being of ALL Americans.	(b)(5)	
I support the proposed rule because it provides protections for LGBTQ+ people in health care settings and they deserve to be treated like anyone else. The mission of HHS is to ensure the health and well-being of ALL Americans and that includes LGBTQ+ people. We appreciate the rule's specificity regarding discrimination on the basis of sex which is proposed to include discrimination on the basis of sex stereotypes sex characteristics including intersex traits pregnancy or related conditions sexual orientation or and gender identity.		
The Wisconsin Bureau of Aging and Disability Resources supports the proposed rule to: • reinstate regulatory protections from discrimination on the basis of race color national origin sex age or disability in covered health programs and activities; • "create consistent procedural requirements for covered health programs and activities by requiring grievance procedures ... the designation of a responsible and the affirmative provision of civil rights notices;" • ensure each person with limited English proficiency "has meaningful access to covered health programs and activities;" • provide equal program access on the basis of sex and gender identity, and prohibit discrimination on the basis of sex related to pregnancy family or parental status. • "revise its policy regarding whether Medicare Part B payments constitute Federal financial assistance;" • "make limited amendments to the Centers for Medicare & Medicaid Services (CMS) Medicaid Children's Health Insurance Program (CHIP) and Program of All-Inclusive Care for the Elderly (PACE) nondiscrimination regulatory provisions as well as nondiscrimination provisions applicable to group and individual health insurance markets and Health Insurance Exchanges to clarify that discrimination on the basis of sex includes discrimination on the basis of sexual orientation and gender identity." As a disabled LGBTQ elder who actively volunteers with older gross discrimination and the me feasance in violating my expressly claimed and written HIPAA rights; fatefully reporting lab results; failure or refusal to treat and causing life-threatening illness; willful and fraudulent misdiagnoses; and maintaining and failing to correct stigmatizing false healthcare records I strongly support the proposed rule. Every day other LGBTQ+ elders also experience gross discrimination in healthcare settings. As with me this can have major implications for their overall health instituting medically incorrect treatment delaying care due to discrimination institutionalization on false pretenses choosing not to receive vital home and community based services like Meals on Wheels driving hours to find a doctor that will serve a transgender person or provide appropriate care struggling to have gender affirming care or any care paid for by their insurance and much more. hospital settings. When I went in for a pre-surgery physical for knee surgery the nurse practitioner who did my physical expressed her negative opinion about me directly and then she changed the gender marker on my paperwork from F to M. At this point in my transition I had legally changed my name my birth certificate my drivers license and my passport. After the surgery people kept coming into my room and asking me what pronouns to use even though my gender should have been clearly marked as F. After this happened a few times I asked why and was told my gender marker was M. I complained to the hospital ombudsman and he covered up by telling me it was a holdover from previous hospital patients. I found out later when I talked to my surgeon's secretary that the NP had called her and screamed at her for letting me come to the hospital with a gender marker of F. When I complained directly to the NP's boss she told me she would resolve things. However a year or two later when I went through the same surgery physical for another operation the same NP was there and she tried to do exactly the same thing again. I told her I'd be charged the marker would not only sue the hospital but would bring criminal charges against her as in my city there's an ordinance making gender discrimination illegal. BTW the ordinance was there the first time she changed the F to M and I guess that's why the hospital tried to cover up. There have been other times when medical staff have tried to discriminate as well but nothing as blatant as the knee surgery incident. For example I had a procedure where I got a lot of IV fluids and afterwards had to pee but couldn't get out of bed. The nurse asked me if I wanted a urinal. I told her I couldn't use a urinal (this was post bottom surgery) and she should have known that as she prepped me for the surgery which included shaving my groin. She tried to claim she never looked. She was physically about an inch from my vagina when she prepped me. She had to have seen the medical history notes that mention that I am transgender and took the opportunity to express her opinion.	(b)(5)	UBAC
I support the proposed rule because every day LGBTQ+ elders experience discrimination in healthcare settings. This can have major implications for their overall health. LGBTQ+ may delay care for fear of discrimination choose not to receive vital home and community based services like Meals on Wheels drive hours to find a doctor that will serve a transgender person struggle to have gender affirming care paid for by their insurance and much more.	(b)(5)	Wisconsin Bureau of Aging and Disability Resources in the Department of Health Services
I support the proposed rule because it restores nondiscrimination protections for patients and closes religious loopholes that undermine these protections. If HHS permits dangerously broad religious exemptions hospitals and medical providers can discriminate and deny vulnerable patients care based on the beliefs of executives and boards of directives. Patients must come first. They should receive appropriate care based on their best interests and medical standards. Protections against health care discrimination have a long history and must be enforced to prioritize patients' well-being. The proposed rule will in particular restore nondiscrimination protections for pregnant patients LGBTQ people individuals with limited English proficiency and people who have had abortions. The rule that the Trump Administration adopted in 2020 created confusion for patients and providers since the regulations were legally flawed and contradicted the vast majority of court decisions. The current proposed rule would help eliminate that confusion and strengthen and discrimination protections already in federal law by limiting religious exemptions to only what's required by statute HHS will restore critical protections against religiously motivated discrimination improving health care access and quality for millions of Americans. The proposed rule does not restrict individual freedoms. Instead it restores religious liability no longer favoring the religious beliefs of a few over the nondiscrimination protections and basic access to health care that the Affordable Care Act was intended to provide to all Americans. As a taxpayer and a health care consumer I strongly support the proposed rule and I encourage you to adopt it.		
I support the proposed rule because it provides protections for LGBTQ+ people in health care settings and this is very important. Additionally the mission of HHS is to ensure the health and well being of ALL Americans.		
I support the proposed rule because it provides protections for LGBTQ+ people in health care settings and this is very important. My niece is trans and I know many other trans or questioning young people and this access is vital to their health (both physical and mental). The mission of HHS is to ensure the health and well being of ALL Americans. The Biden-Harris administration has finally released a new proposed rule that takes major steps forward to protect LGBTQ+ people from health care discrimination.		
The Biden administration has just proposed changes to the regulations implementing Section 1557 that would restore and strengthen nondiscrimination protections and improve access to care for millions of people. If these proposed changes are adopted they will promote the health equity of Black Indigenous and people of color and increase access to coverage and care for those historically underserved because of race ethnicity language age disability and sex.Discrimination has no place in health care and it's critical that the Biden administration move forward with these protections to secure access to care free from any discrimination or prejudice.		
I support the proposed rule expanding protections for Section 1557. Everyone should have access to safe and affirming medical care— no one should ever have to face discrimination at the doctor. Please protect ALL Americans and pass this rule now."		

(b)(5)

A lo es regardless of the r sexual or entation or age should have health care
ready availab e whe never they need it and not to have to search for for months
and then be rejected if they do find a prov der. the same of course should also be
true to anyone seek ng he a

The Tennessee Disability Co lition strongly supports the proposed rule. It clarifies and strengthens nond scr minat on protections for people with disabilities and other populations that have experienced discrimination and barriers to receiving equally effective hea thcare

Tennessee Disability Coalition

OCR supports changes to clarify the application of nondiscr minatory requirements and provis ons as they apply to people with disab ties.

ND Protection & Advocacy Project

HHS should finalize the proposa s that ensure covered ent t es when providing or administering health related services or coverage do not discriminate on the basis of race color national or g n sex age disabi ty or gender identity and specifically transgender individuals. This includes denying cancel ng limiting or refusing to issue or renew a health insurance plan or policy; denying or limiting coverage of a c a m, or imposing additional cost sharing to such individuals. It is also important the covered entity should not engage in marketing practices or benefit des gns that discriminate against such individuals

URAC

While non-discrimination laws and regulations do not stop all bad behavior they do set expectations and are a good educational tool. We urge adoption of the proposed Section 1557 regulations.

FORGE, Inc.

Because the Proposed Rule w addresses the severe def cient es in the 2020 Rule and "ensur[e] that Section 1557's consist civil rights protections apply" broadly we urge you to finalize the Proposed Rule

Attorneys General of California, New York Massachusetts, and nineteen other States

The proposed rule [RIN 0945-AA17] is an affront to and offends the conscience rights of health care professionals and entities that seek to Do No Harm and to offer human cal and life giving care to the people they serve. Health care providers and insurers should not be coerced to perform or cover abortions or transgender procedures. A decision not to provide or cover abortion or transgender procedures is not sex discrimination. Provisions of the proposed rule that can be construed to require the provid ng for or coverage of such procedures violate rights of conscience and religious freedom as reflected in cu rrent federa conscience laws including the Weldon Amendment. For these reasons I oppose the abortion and gender identity provis ons of the proposed ru e

(b)(5)

Nelle ous meanings is to provide for the legit mate protection of people from both physica and moral (pertaining to the conscience soul inner core) harm. In world gone mad where pe sonal wants and desires replace truth [the reality of what is] it s dependent upon those entrusted w th a sacred duty to help others live n the truth. A fa ure or unwillingness to believe in truth does not cause it to not exist or to not be so. One can always tell when the truth is being subverted or sought to be suppressed and that is revealed when something false s created either by narrative lan ge or even by physica manipulat on. By narrative form the words such as pregnancy termination or reproductive hea th are are used to mask the reality of the word abortion wh ch s the willful kill ng of the developing baby n the womb of its mother. Another examp e s the use of transgender to describe a pe son's willful desire to assume the opposite b olog cal sexual nature of how they have developed in the womb of their mothe . This may happen by someone merely stating the words such as: a man say ng he s a woman or a woman saying she is a man. Often times th s happens all of a sudden changing from day to day or moment to moment as the need suits them. It may also happen by inte tional physical man pu lation such as is performed by surgery a severe and invasive means of try ng to make what is not meant to be into something someone wants to be. This s the greatest form of lie and abuse of the truth. In many instances in health care e ective surgeries (that wh ch s determined not to be necessary to sustain life or maintain it as it shou d be) are not covered expenses but merely to push an agenda or ideology all norms are cast aside and it is promoted as wanting to be seen as someth ng to be legitimate and held in high esteem. When government wants to impose such a lie and abuse upon its c t zens through mandates punishments and fines upon the very fabric of our country founded upon Judeao Chr stian pr nc ples of a Cre g ver pe sonal dign ty and enshr ned and upheld for centuries begins to crumble. There

(b)(5)

I strongly oppose this i gated and unconstitut onal rule to force doctors nurses and other healthcare professionals to perform abortions and gender m utilation surgeries. There are thousands of healthcare professionals who are will ng to pe form these procedures so this rule is s mply a way to pu nish and persecute people of faith. The federal government has no r ght to flagrantly violate the religious freedom of the thousands of people of faith who work in healthcare. This rule is unconstitutional punitive and wrong and I urge its re ection

Abortion is not health care because killing is not healing. The proposed rule [R N 0945-AA17] s an affront to and offends the conscience rights of health care professionals and entit es that seek to Do No Harm. Health care providers and insurers should not be coerced to perform or cover abortions. A dec sion not to provide or cover abortion is not sex d scr m nat on. Provis ons of the proposed rule that can be construed to require the prov ding for or coverage of abortion violate rights of conscience and religious freedom as reflected in current federal conscience laws including the Weldon Amendment. For these reasons I oppose the abortion prov sions of the proposed rule

If Joseph Meaney PhD is telling the truth then this rule w be a great bane to the citizens of this country as described by Joseph Meaney's PhD message.
Mandatorily call ng someone a gender of their choosing mandatorily choosing aft parts of a body mandatorily sacr fic ng out a baby from the womb is mandatorily evil. I pray you find it in your eternal soul to see that you are mandat ng evil. You can either mandate that murder as a heinous evil crime or you can mandate that murder is a moral and just action. You can either mandate someone to call someone a he/she or you can mandate freedom of speech. You can either mandate the choosing off of body parts or you can mandate a doctor's freedom to d agnose and treat God's ch ldren in the best way poss ble you can either mandate babies being sucked out of the womb or you can mandate a hea th care prov der's conscious religious moral and ethical objections to such treatment. The first amendment the very right of having a consciousness of you own is an issue. The 14th Amendment states " No State shall make or enforce any law wh ch shall abridge the pr v leges or mmu nities of c t zens of the United States, nor shall any State deprive any pe son of life liberty or property without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws." So if the "nondiscrim nation in Health Programs and Activ t es Proposa" is pursued it is a breaking of the law. Period
Im plic t bias kills. It impedes diagnosis and treatment and causes undue pain and irreparable ha m
You should add to this bi NO DISCRIMINATION ON THE THOUSENDS OF PEOPLE WHO ARE MAKING CHOICES ON THEIR HEALTH DIFFERENT FROM THE RECOMMENDATION OF THE CDC OR FDA WHO FA LED US THRUOUT COV D
No comments are associated with this issue

community parents united

(b)(5)

upport this proposed rule and its benefits for those living with serious illness C TAC is a national non-partisan not-for-profit coalition dedicated to ensuring that all those living with serious illness especially the sickest and most vulnerable receive comprehensive high- quality person- and family-centered care that s consistent with their goals and values and honors their dignity. C TAC is made up of over 130 national and regional organizations including patient and consumer advocacy groups practitioners health plans faith-based and community organizations and others who share a common vision of improving care for serious illness. The U.S.C-TAC defines serious illness as a health condition that carries a high risk of mortality and either negatively impacts a person's daily function or quality of life or excessively strains their family caregivers. This definition has been widely adopted including by the National Committee for Quality Assurance (NCQA) and the National Quality Forum (NQF). There are also health equity issues with this population as per a 2021 Commonwealth report on racial and ethnic health equity communities of color are more likely to die from treatable conditions and are at a higher risk for many chronic health conditions. The lack of access to health insurance and primary care means many are diagnosed only at a late or end-stage of illness when disease- modifying treatment is typically no longer effective. Those from historically disadvantaged communities who also have serious illness also experience poorer care and access. Those with serious illness therefore represent a vulnerable population and they require all the legal and regulatory support possible. Beyond racial and ethnic disparities individuals that identify as LGBTQ and their caregivers often experience challenges in accessing high quality palliative and advanced illness care due to ongoing hurdles related to provider communication perceptions of safety and acceptance and assessing and respecting patients' definitions of family and support. Additionally people from culturally and linguistically diverse

(b)(5)

The Coalition to Transform Advanced Care

We strongly support the proposed nondiscrimination rule to protect the rights of transgender nonbinary intersex and all other LGBTQ+ people to access safe and affirming health care. Our organization has supported hundreds if not thousands of people through issues accessing health care. This has included providers and/or health care centers that have declined care or actively discriminated against patients or potential patients because of their gender identity and health insurance companies who have declined to provide coverage for gender affirming services and treatments. Nobody should be afraid to see their doctor or go to the hospital for an emergency. Section 1557 can be a matter of life or death for transgender people living with HIV transgender people of color trans folks and others who already face intense discrimination and barriers to care. Without the enforcement of Section 1557 it gets harder to get ALL forms of healthcare from COVID-19 shots and physicals to x-rays and cancer screenings. Your department must hold doctors and insurers accountable when they break the law. The Affordable Care Act is the law of the land and transgender people are still legally protected from discrimination. Any threats to these protections or when Section 1557 is violated endanger the lives of transgender people

(b)(5)

Massachusetts Transgender Political Coalition

As Senior Director for LGBT Programs and Policies in the Mount Sinai Health System of New York's Office for Diversity and Inclusion and Assistant Professor of Medical Education in the Mount Sinai School of Medicine I am writing to express my full support for the proposed rule with particular attention to provisions that specifically clarify protections on the basis of sexual orientation or gender identity and intersex status. LGBTQ+ individuals continue to experience societal discrimination and discrimination and bias within healthcare that affects their access to affordable and effective prevention care and treatment. As a result this population continues to demonstrate significant health disparities especially at the intersection of other marginalized identities and socioeconomic status. To address these inequities and ensure full access to effective affordable and competent health care with dignity and respect across the country the federal government must explicitly include these protections on the basis of sexual orientation gender identity and intersex status so that LGBTQ+ people can be protected when seeking necessary health services. It is equally important to maintain protections within the ACA regulations to disallow religious exemptions based on sexual orientation and gender identity that do not take into account the harms to patients including their ability to access essential services. The Mount Sinai Health System is a nationally recognized leader in research and best practices for our LGBTQIA patients and their families and is a model for an effective compassionate and integrated system of care through our national by recognized Center for Transgender Medicine and Surgery. This Center both establishes and supports the science and excellent clinical care in LGBTQIA+ health and health care. We support the proposed rule's Nondiscrimination in Health Programs and Activities and urge you not to weaken any of the provisions as you move to finalize the rule.

(b)(5)

Mount Sinai Health System of New York

I strongly oppose this unconstitutional rule to force doctors nurses and other healthcare professionals to perform abortions and gender mutilation surgeries. There are thousands of healthcare professionals who are willing to perform these procedures so this rule is simply a way to punish and persecute people of faith. The federal government has no right to violate the religious freedom of the thousands of people of faith who work in healthcare. This rule is unconstitutional punitive and wrong and I urge its rejection.

(b)(5)

I am writing to express my deep concerns about the proposed changes of Section 1557 of the Affordable Care Act and the harmful impacts to my parental rights and children's rights and well being that will occur if these changes take place. I am concerned that if these proposed changes to Section 1557 of the ACA are allowed to stand they will be used against parents to force the insurance providers of employed parents/guardians to pay for student transgender and abortion procedures that currently under the Title IX proposal (if set stand) can be done WITHOUT the consent of the parent and or guardian. The proposed regulations would harm children's health and well-being by promoting chemical and surgical alterations that have irreversible life-altering consequences like sterility and life long sexual dysfunction interrupting healthy growth and development and other serious risks like loss of bone density cognitive problems blood clots cardiovascular disease and cancer WITHOUT holding teachers staff administrators third-party education facilitators and school board members liable. The proposed regulations would infringe our family's religious liberties. As a Christian this type of thing is not acceptable. these proposed changes to the Title IX regulations would be so harmful to our parental rights religious liberties children's well being children's First Amendment rights children's privacy and safety. Money is allocated to schools each year on a per student basis based on the number of children enrolled in school. I'm asking you to calculate and take into consideration the economic impact of concerned parents removing their children from public schools due to these proposed regulations. I strongly urge you to abandon these changes to the Title IX regulations.

(b)(5)

No comments are associated with this issue.

The rule must ask prohibit discrimination against patients based upon their medical choices in particular their refusal to modify the immune system through vaccination.

The rule specifically prohibits discrimination on the basis of "race color national origin sex age or disability in certain health programs and activities." Notably absent from the rule is any prohibition on discrimination against patients based on their medical choices in particular their refusal to modify their immune system through vaccination even though this type of discrimination is pervasive throughout the country.

Notably absent from the rule is any prohibition on discrimination against patients based on their medical choices in particular their refusal to modify their immune systems through vaccination even though this type of discrimination is pervasive throughout the country. In addition this discrimination has been propagated on medical considerations not science. The only way the HHS can gain back any credibility is to include Medical choice as a right protected from discrimination

(b)(5)

This rule specifically prohibits discrimination on the basis of race color national origin sex age or disability in certain health programs and activities. Notably absent from the rule is any prohibition on discrimination against patients based on their medical choices particularly the refusal to modify their immune system through vaccination even though this type of discrimination is pervasive throughout the country. This country was founded on freedom and the freedom to make medical decisions should be no different. I propose non-discrimination against individuals with immune systems that remain unmodified by injected pharmaceuticals.
No comments are associated with this issue
No comments are associated with this issue

Italics 2. Pregnant people' Abortion is a critical part of the spectrum of reproductive health care. Since the Supreme Court permitted states to criminalize abortion in [Italics] Dobbs v. Jackson Women's Health Organization[] there have been reports of people experiencing pregnancy complications necessitating abortion but being unable to access care. [Footnote 1]: Feibel Carrie. "Because of Texas Abortion Law Her Wanted Pregnancy Became a Medical Nightmare." NPR JE 11, y 2022 https://www.npr.org/sections/health-shots/2022/07/26/1111280165/because-of-texas-abortion-law-her-wanted-pregnancy-became-a-medical-nightmare[Following the [Italics] Dobbs] decision individuals — especially people of color people with low incomes immigrants young people people with disabilities and LGBTQ people — are facing numerous logistical and legal barriers to accessing care with an increased threat of arrest and prosecution as states seek to criminalize abortion care. The consequences of the Dobbs decision will fall especially heavily on those who experience intersectional discrimination.
No comments are associated with this issue
No comments are associated with this issue
No comments are associated with this issue
No comments are associated with this issue
No comments are associated with this issue
No comments are associated with this issue

I strongly support the proposed rule from the Department of Health & Human Services (HHS) to prevent harmful discrimination in health care. It is critically important that HHS restore and expand protections under section 1557 of the Affordable Care Act because no one should be denied health care or insurance coverage for the care simply because of who they are. This rule is especially important for members of the LGBTQ community who all too often face mistreatment in health care settings.

My name is **FULL NAME** and I am from Fountain Colorado. I am writing in regard to the Department of Health and Human Services comprehensive review of section 1557 of the Affordable Care Act and a Notice of Proposed Rulemaking for Nondiscrimination in Health Programs and Activities. RIN 0945-AA17 [ADD PERSONAL MESSAGE about why you support nondiscrimination protections for LGBTQ people in healthcare and health insurance]

I support the proposed rule because it provides protections for LGBTQ+ people in health care settings and that is very important to my family. Additionally the mission of HHS is to ensure the health and well being of ALL Americans.
No one should be denied health care or health insurance coverage simply because they are cisbian gay bisexual transgender or queer. It is very important that the Department of Health & Human Services (HHS) adopt this proposed rule implementing section 1557 of the Affordable Care Act so that it is clear to everyone that federal law barring discrimination in health care based on sex protects LGBTQ people.
Because members of the LGBTQ community too often face mistreatment in health care settings I strongly support the proposed rule from the Department of Health & Human Services (HHS) implementing section 1557 of the Affordable Care Act. It is essential that HHS restore and expand protections under section 1557 because no one should be denied health care or insurance coverage for their care simply because of who they are.

The mission of HHS is to ensure the health and well-being of ALL Americans. My child is transgender and it was obvious at 11 years old. It was not a choice. It was just a child trying to make sense of how he felt and who he was amidst the sea of ignorance and bad information out there in the media. In the end we are all just people trying to make it trying to be happy and finding our place. This is not possible if you do not have access to medical care. If you can't feel comfortable with the most basic human needs it becomes increasingly difficult to live a happy meaningful life. This is not politics. It is just human decency and giving everyone a chance. Please enact Section 1557 of the ACA.

Gay and trans people are fearful of rejection in health settings and this is wrong! HHS is supposed to be providing health care for everyone. We need teeth to enforce our rules and make sure this discrimination stops happening.
I am writing to oppose the Health and Human Services (HHS) proposed rule change to ObamaCare Section 1557. This rule would change the definition of discrimination on the basis of sex to include "sexual orientation and gender identity." The effects of this would be dramatic and would greatly infringe upon the First Amendment rights of many people of faith. This rule change is a threat to our fundamental right to religious liberty. It is misguided punitive and unconstitutional.

I oppose the proposed HHS rule Nondiscrimination in Health Programs and Activities" (RIN 0945-AA17). Adding pregnancy terminations as a pregnancy related condition under the definition of sex discrimination is malfeasance not only to health professionals who seek to provide lifesaving and life giving care to all their patients it is an attack on innocent babies of women and children born and unborn. The conscience rights of health care professionals and insurers are at stake as they should not be coerced to perform or cover abortions. Additionally abortion is NOT healthcare is harmful to women and takes the life another human being. Therefore pregnancy termination does not constitute sex discrimination and should not be covered under sex discrimination nor forced to be covered by taxpayer dollars which a majority of Americans agree with. The provisions of the proposed rule which protect abortion is a direct violation of moral conscience and religious objections of health care professional and taxpaying Americans and likely violates people religious freedoms and conscience rights protection under existing federal protections. For the reasons stated above oppose the abortion related provisions of the proposed rule.
No comments are associated with this issue
No comments are associated with this issue

Section 1557 of the Affordable Care Act is a groundbreaking anti-discrimination provision that prohibits discrimination in health care on the basis of race color national origin age disability and sex including pregnancy gender identity and sex stereotyping. Health insurers hospitals clinics and any other entities that receive federal funds are covered by this law. Importantly Section 1557's prohibition on discrimination on the basis of sex protects women people who are pregnant people who have had abortions are transgender and those who are gender expansive from discrimination when accessing the health care they need. Section 1557 is unique as it acknowledges people often experience varying forms of oppression around their identities and allows for patients to bring claims based on multiple and intersecting forms of discrimination. For example Section 1557 is designed to add protection for someone who is experiencing discrimination because they are both pregnant and transgender or someone who is both Black and an immigrant. It recognizes that experiencing oppression at the intersection of multiple historically rooted identities can shape an individual's life course.

(b)(5)

The Leadership Conference on Civil and Human Rights

Physicians for Reproductive Health

(b)(5)

s background Section 1557 of the Affordable Care Act (ACA) prohibits
iscrimination on the basis of race color national origin sex age or disability under
ny health program or activity that receives federal financial assistance. In 2016
he U S Department of Health and Human Services (HHS) finalized a regulation
hat defined "on the basis of sex" to include sex stereotyping gender identity and
erminations of pregnancy. However in 2020 HHS removed gender identity and
exual orientation from the Section 1557 regulation. This proposed rule among
ther modifications to non discrimination policies proposes to revert back to the
016 definition of "on the basis of sex" effectively rescinding the 2020
o cy.ACEP supports the rescission of the 2020 regulation. In 2019 ACEP and the
mergency Medicine Residents' Association (EMRA) issued a statement opposing
he initial purpose to revoke the regulation. ACEP stated that we strongly believe
hat discrimination in any form should be prohibited in health care. Both by law
nd by oath emergency physicians must care for all patients seeking emergency
edical treatment [Footnote 1: 42 U.S. Code § 1395dd. Examination and
reatment for emergency medical conditions and women in labor.] Denial of
mergency care or delay in providing emergency services on the basis of race
eligion sexual orientation gender identity ethnic background social status type of
ayer or ability to pay is unethical. Under our Code of Ethics as emergency
hysicians [Footnote 2: ACEP Code of Ethics for Emergency Physicians. Approved
n 2017. https://www.acep.org/patient-care/policy-statements/code-of-ethics-
r-emergency-physicians/].

he Department incorrectly interprets the U.S. Supreme Court's holding in
ostock v. Clayton County 140 S. Ct. 1731 [2020] and improperly expands the
cope of Section 1557 of the Affordable Care Act based on that incorrect
nterpretation. With the threat of losing federal healthcare funding the
epartment attempts to coerce the states into adopting a federal policy that is
ontrary to their own laws and policy.

ection 1557 prohibits discrimination on the basis of race color national origin sex
ge or disability under any health program or activity that receives federal
inancial assistance or under any program or activity that is administered by an
xecutive agency or by any entity established under Title I of the ACA (e.g. Health
surance Marketplaces). After the Department issued its second Section 1557
ule in June 2020 the AHA commented stated "Hospitals and health systems value
very individual we have the privilege of serving regardless of race religion
ational origin sexual orientation or gender identity. That is why we urged the
dministration to not move forward with changes to non discrimination
rotections. We are deeply disappointed that this rule weakens important
rotections for patients and could limit coverage. Treating all with dignity and
espect will continue to guide us. In everything we do."

process and consistently advocated for strong enforcement of Section 1557 since
he law was enacted in 2010. We opposed the prior Administration's 2020
ection 1557 rule which undermined enforcement by rescinding substantial
ortions of the 2016 final rule [Footnote 2: 84 FR 27846.] [Footnote 3: 81 FR
31375]. APA is pleased to see that the current NPRM addresses concerns APA
dentified and documented in comments submitted to the Department of Health
nd Human Services [HHS] in 2019 [Footnote 4: APA. (2019 August 13). Comment
ubmitted to the U.S. Department of Health and Human Services Office for Civil
ights on Attention: Section 1557 NPRM RIN 0495-AA11. Concerns documented
included limiting scope of coverage/applicability; eliminating regulatory
rovisions defining the prohibition on discrimination based on sex to include
ender identity sex stereotypes and pregnancy status; eliminating the provision
requiring health insurers from varying benefits in ways that discriminate against
ertain groups; eliminating specific health insurance coverage protections for
ransgender individuals; weakening protections that provide access to
nterpretation and translation services for individuals with limited English
roficiency; deleting or weakening sections of the current regulations prohibiting
iscrimination against people with disabilities; and adopting extremely broad
eligious freedom and conscience exemptions for health care providers]. The new
roposed rule strengthens civil rights protections for patients and consumers in
ederally funded health programs and HHS programs. It affirms protections
gainst discrimination on the basis of sex including sexual orientation and gender
dentity consistent with the U.S. Supreme Court's holding in Bostock v. Clayton
ounty and reiterates protections from discrimination for seeking reproductive
ealth care services. It requires covered entities to train staff in providing
anguage assistance services for individuals with limited English proficiency (LEP)
nd effective communication and reasonable modifications to policies and

ions Section 1557 Discrimination on the Basis of Sex Section 92.101 Purpose and
ond discrimination on in Public Programs] DHCS as the single state Medicaid agency
or California submitted comments in response to the 2019 Proposed Rule (84
ed. Reg. 27846) which was finalized without substantive change in the 2020
nal Rule (85 Fed. Reg. 37160). To summarize DHCS and its partners expressed
oncern with the roll back of federal nondiscrimination safeguards for historically
aring racialized and underserved populations including those who are transgender
hose with limited English proficiency (LEP) those with disabilities and those
eeking access to reproductive health care. Of particular concern was the narrow
efinition of discrimination on the basis of sex that excluded gender identity and
exual orientation and the removal of the tagline and language access
equirements for LEP individuals. This overly narrow framework presented
everal consequences for California's health care system and programs including
he potential for widescale impediments to accessing care for some of our most
ulnerable residents; the chilling effect on beneficiaries seeking and health care
rofessionals providing or referring for essential health care services particularly
hose of a sensitive nature like reproductive health; and the negative fiscal
mpacts borne by states and the state's system as a result of health complications
esulting from delayed or foregone care the increased costs and reliance on
tate-funded programs to fill in and mitigate such gaps and the potential
ccelerating of sizable federal financial participation where states exceeded these
laims in a manner that could be interpreted to conflict with federal law.
ctually in addition to the harms highlighted above the 2019 and 2020 rulemaking
resented serious legal flaws in the manner in which they were promulgated
nder the Administrative Procedure Act and their departure from and
nconsistency with the underlying federal statutes being implemented.
pecifically these rulemakings evince an exceedingly narrow interpretation
nited to the physical act of sexual intercourse between male and female in contravention of

olor national origin disability and age in any program or activity receiving federal
inancial assistance (or in entities offering credits subsidies or contracts of insurance) or in
ny health program or activity administered by an executive agency or entity.
While the interpretation of Section 1557 has been highly contested over the
ears at the heart of the issue is the ACA which is built upon the core goal of
roviding access to high quality affordable health care to all individuals.
ongress's intent to utilize Section 1557 to eliminate unlawful discrimination in
very facet of health care is clear when it incorporated existing civil rights
rotections into Section 1557. These protections include antidiscrimination
rotections in Title VI the Age Discrimination Act and Section 504 as they apply to
ealth care activities and programs and extending the sex discrimination
rotections of Title IX to health care [Footnote 1: 42 U.S.C. §
8116] Implementing regulations issued by HHS in 2016 further reinforced the
mportance of Section 1557 in carrying out one of the main goals of the ACA
nsuring access to high quality affordable health care for all individuals without
he threat of discrimination which can often discourage enrolling coverage
eading to poor and inadequate health outcomes while exacerbating existing
ealth disparities in underserved communities [Footnote 2: 81 Fed. Reg. 31375
ay 18 2016)].The 2016 rule codified important nondiscrimination protections
ncluding a broad definition of "on the basis of sex" prohibiting discrimination
rotecting individuals from having their health insurance canceled or limited
olely based on their race color national origin sex [including pregnancy gender
dentity and sex stereotyping) age or disability. Further this rule protected
ransgender individuals from having their coverage denied or limited based on
he fact that they are transgender. The 2016 rule also codified protections for
imited English proficient individuals as well as individuals that suffer from
isabilities by providing them with appropriate aids and access to auxiliaries and

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American College of Emergency Physicians

Arkansas Department of Human Services

American Hospital Association

(b)(5)

American Psychological Association

California Department of Health Care Services

Covered California

(b)(5)

|Bod: Sexual Orientation and Gender Identity|The comment period for the Department of Education's proposed Title IX rule concluded on September 12. The Heritage Foundation submitted a number of comments in response to this rule. Given the abnormally high response rate in opposition to the department's plan, many are still waiting on the response to the comments. More importantly, no final rule has been released yet concerning Title IX's redefinition of sex, pregnancy, and abortion. Since the proposed Title IX regulations redefine discrimination "on the basis of sex" to include "sex stereotypes, sex characteristics, pregnancy or related conditions, sexual orientation, and gender identity" in federally funded education programs and activities, it is worth noting that this proposed rule has not been finalized nor implemented. |Footnote 5: 87 Federal Register 41390|Nonetheless, the department alleges that because "Title VII and Title IX's prohibitions against sex discrimination, like Bostock's reasoning, applies to Title IX and by extension to Section 1557." Thus, Section 1557 also prohibits discrimination based on "sexual orientation and gender identity."" |Footnote 6: Rachel Morrison "HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandates on Health Care," The Federalist Society, September 8, 2022, https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-in-health-care-1|As we will see, however, this is an incorrect reading of the Bostock decision and thereby removes the main precedent HHS provides for its redefinition of sex, pregnancy, and abortion. Moreover, Title IX's own proposed rule lies upon this faulty reading of Bostock and its final rule has yet to be released.

ensure that health services are broadly available in the United States and address significant barriers to healthcare access caused by inadequate and discriminatory health insurance coverage. |Footnote 4: Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified at 42 U.S.C. §§ 18001-18122).) To reduce these barriers, the ACA "added Section 1557, which broadly prohibits all health programs and activities receiving federal financial assistance, including medical providers, health systems, and health insurers, from discriminating against individuals on the basis of race, color, national origin, sex, age, or disability. |Footnote 5: Specifically, Section 1557 prohibits discrimination on the basis of any protected classification covered under Title VI of the Civil Rights Act (race, color, and national origin), Section 504 of the Rehabilitation Act of 1973 (disability), Title IX of the Education Amendments (sex), and the Age Discrimination Act of 1975 (age).) In 2016, when HHS first issued a final rule implementing Section 1557, it recognized that discrimination within the healthcare system contributes to poor coverage and inadequate health outcomes, exacerbates existing health disparities, undermines communities, and leads to ineffective distribution of healthcare resources. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376, 31444 (May 18, 2016) (codified at 45 C.F.R. pt. 92) (the "2016 Rule"). To prevent statutorily prohibited discriminatory treatment and coverage in healthcare and its specific impact on historically marginalized populations, in particular transgender people, women, and others seeking reproductive healthcare or with pregnancy-related conditions, individuals with LEP, and people with disabilities—the 2016 Rule adopted several key provisions, including: (a) clarifying that Section 1557 broadly applies to all health providers and insurers that receive federal financial assistance, Id. at 31467 (codified at 45 C.F.R. § 92.4), (b) clarifying that Section 1557's prohibition on discrimination on the basis of sex included discrimination based on gender identity, sex stereotypes, s

We write in support of HHS' proposed rule, Nondiscrimination in Health Programs and Activities (Docket HHS-OS-2022-0012), and to urge HHS to explicitly clarify nondiscrimination protections for LGBTQI+ individuals seeking assisted reproduction (AR) services. When Congress passed the Affordable Care Act (ACA) in 2010, it included strong antidiscrimination protections. Section 1557, including a prohibition on discrimination on the basis of sex. Discrimination on the basis of sex includes discrimination on the basis of sexual orientation, gender identity, and sex characteristics as well as sex stereotypes and pregnancy or related conditions. By explicitly clarifying that prohibited sex discrimination includes these categories, the proposed rule affirms Congress' intent in passing Section 1557 to prohibit all forms of sex discrimination. This is also consistent with case law, including the Supreme Court's 2020 decision in Bostock v. Clayton County. While Section 1557 and the proposed rule, as it stands, would extend to LGBTQI+ individuals and couples who wish to have children, including via AR, we believe that the proposed rule could be further improved by specifying that health programs and activities should not discriminate against LGBTQI+ individuals by placing conditions on coverage that are centered around different-sex couples. Although this letter focuses on the discrimination LGBTQ + individuals face in particular, the same 1557 protections should apply to other individuals who also face discrimination in accessing AR services.

We write as Chairs of House committees with primary jurisdiction over the Patient Protection and Affordable Care Act (ACA) in support of the Department of Health and Human Services's (HHS) proposed rule, Nondiscrimination in Health Programs and Activities.| Footnote 1: Department of Health and Human Services, Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824 (Aug. 4, 2022) (proposed rule).| The rule effectuates statutory text and congressional intent in enacting Section 1557 of the ACA to ensure that individuals' civil rights are protected when receiving health care services. Similar to previously the proposal rectifies key gaps in prior iterations of the rule that were inconsistent with the ACA's statutory mandate and undermined the purpose of the law. The proposed rule reflects evolving, judicial precedent, technological developments affecting patient access to care, and is particularly imperative given the continually growing threats to reproductive health and LGBTQI+ health. We strongly support the proposed rule and urge HHS to swiftly finalize the rule following the public comment period.

Under your leadership, the Department and this Administration are poised to commit unconstitutional attempts to reinterpret nondiscrimination law, yet you seek to disregard those judgments against you in proposing this Rule. Women from both sides of the political spectrum beg you to reconsider your ill-advised attempts. Decisions such as [Tallies Religious Sisters of Mercy, et al. v. Becerra, et al., Franciscan Alliance, Inc. v. Becerra, or Christian Employers Alliance v. U.S. Equal Employment Opportunity Commission, et al.] should compel you to listen to most Americans and work to protect our unique identity as women instead of segregating our concerns. In order to appease some small, radical supporters, thumbing your nose at the courts only underscores this Rule's nothing short of an executive power grab, like the illegal, late 2016 Rule regarding Section 1557 of the Affordable Care Act (ACA). The Department is "reading" its preferred language into the meaning of "sex" that has never been authorized by Congress or approved by the Supreme Court. The Biden Administration's loss in [Tallies, West Virginia v. EPA] should have caused you to reevaluate this illegal legislative rulemaking. It is reckless and irresponsible to disregard women's dignity and safety concerns and the directive of courts, including the Supreme Court, merely because a decision does not fit your policy preferences. The U.S. Department of Education's reinterpretation of Title IX which was promulgated outside of the legal requirements of the Administrative Procedures Act was thrown out in federal court. It cannot be relied upon to justify this Rule.

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The Heritage Foundation

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Attorneys General of California, New York, Massachusetts, and nineteen other States

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Congressman Mike Quigley

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U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Concerned Women for America

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In the 2016 Rule HHS recognized "that a fundamental purpose of the ACA is to ensure that health services are available broadly on a nondiscriminatory basis to individuals throughout the country" and that "[e]quitable access for all individuals without discrimination is essential to achieving this goal." 81 Fed. Reg. 31379, 31444. HHS explicitly acknowledged the seriousness of continuing discrimination against LGBTQ individuals and the health care disparities caused by discrimination. Id. at 31460. According to the 2016 Rule, prohibited the blanket exclusion of transition-related healthcare services, the denial or limitation of coverage of services used for gender transition when those services would normally be covered when treating a non-transition related health condition; and the refusal to cover treatment that is typically associated with a particular gender because an individual identifies with another gender or is listed as having another gender in their medical records. Id. at 31471–72. Further, if an insurance company covers a particular treatment for any condition, the carrier could not refuse to cover the same treatment because it is requested by a transgender or gender-nonconforming individual or because it is being utilized in a manner consistent with the gender identity. Id. at 31445. The 2020 Rule attempted to eviscerate these needed reforms. It stripped HHS's Section 1557 regulations of the express protections against discrimination based on gender identity, sex stereotypes and pregnancy-related conditions. These changes ignored nearly 200000 comments to the 2020 Rule many opposing the stark retreat from the 2016 Rule's protections that could result in LGBTQ individuals facing unreasonable barriers in obtaining appropriate medical care. In New York several States sought to enjoin the 2020 Rule due to harms to their public health systems. Courts promptly enjoined elements of the 2020 Rule. [Footnote 14: See Whitman-Walker Clinic, 485 F. Supp. 3d at 42–43 (D.D.C.); Walker, 480 F. Supp. 3d at 429–30.]

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[Bold: I. The Proposed Rule Addresses Discriminatory Conduct that Disproportionately Impacts Communities at the Intersection of Multiple Protected Identities] Federal law has prohibited race discrimination in health care since the passage of Title VI of the Civil Rights Act of 1964. However, Title VI does not apply to all health care-related activities and programs nor does it apply to all forms of discrimination in health care. Section 1557 therefore fills in a critical gap by extending anti-discrimination protections to patients at the intersection of multiple identities. We appreciate that the department has outlined the types of discrimination prohibited in Section 92.101 of the proposed rule. We strongly support the intersectional nature of Section 1557 and urge the department to identify other ways to address intersectional discrimination in the regulatory provisions of the 2022 proposed rule itself, such as including a specific recognition of intersectional discrimination in Section 92.101 as well as in other sections throughout the proposed rule. The proposed rule proscribes many forms of discrimination that amplify the impacts of racism and other forms of bias in health care. For example, the proposed rule seeks to eliminate discrimination against Limited English Proficient (LEP) individuals and people living with disabilities — groups that are largely comprised of people of color. Likewise, Section 1557 proscribes sex discrimination in health care and we welcome that the department explicitly expand upon what constitutes discrimination on the basis of sex in the final rule. As discussed further below, the proposed rule restricts discriminatory conduct against these groups which will improve health care access and outcomes for people with multiple systemically marginalized identities.

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These youth report a greater incidence of mental health issues and suicidal behaviors, suffer bullying and victimization to a greater extent than heterosexual youth and have difficulty addressing concerns with their medical providers. [Footnote 25: Hudaisa Hafeez et al., Health Care Disparities Among Lesbian, Gay, Bisexual and Transgender Youth: A Literature Review, Cureus (Apr. 23, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478216.] One study found that 56% of transgender youth reported a previous suicide attempt and 86% reported suicidal thoughts. [Footnote 26: Ashley Austin et al., Suicidality Among Transgender Youth: Elucidating the Role of Interpersonal Risk Factors, 37 J. of Interpersonal Violence 2696 (2022), https://pubmed.ncbi.nlm.nih.gov/32349313.] The Centers for Disease Control and Prevention found that transgender students are more likely to report feeling unsafe at or going to and from school, being bullied, threatened or injured with a weapon at school, being forced to have sex and experiencing physical and sexual dating violence. [Footnote 27: See Michelle M. Johns et al., U.S. Ctrs. for Disease Control & Prevention, Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicidal Risk and Sexual Risk Behaviors Among High School Students, 68 Morbidity Mortality Weekly Report 67, 69 (2019), http://dx.doi.org/10.15585/mmwr.mm6803a3.] Undergoing puberty that does not align with one's gender identity and developing permanent undesired secondary sex characteristics is "often a source of significant distress" for transgender adolescents. [Footnote 28: Rinera Lopez et al., Statement on Gender-Affirmative Approach to Care from the Pediatric Endocrine Society Special Interest Group on Transgender Health, 29 Current Op. Pediatrics 475, 480 (2017), https://pubmed.ncbi.nlm.nih.gov/28562420.] Access to gender affirming care improves health outcomes for transgender youth. Transgender teens with access to such support and gender-affirming healthcare experience mental health outcomes equivalent to their cisgender peers. [Footnote 29: Dominici

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of sex" under Section 1557 is arbitrary and capricious and contrary to law. "Statutory language, logic, and medical history support the view that "sex" means "biological sex" under Title IX and by extension Section 1557 not "gender identity."] [Bold: A. Sex Under Section 1557 means biological sex.] Section 1557 guarantees that no individual can be denied benefits in a federally run or federally funded health program or activity based "on the grounds prohibited under" and the enforcement mechanisms from four existing federal civil rights laws: Title VI of the Civil Rights Act of 1964 (race, color, national origin), Title IX of the Education Amendments of 1972 (sex), the Age Discrimination Act of 1975 (age), and Section 504 of the Rehabilitation Act of 1973 (disability). [Footnote 33: 42 U.S.C. § 18116.] As now FPPC President Ryan Anderson and now FPPC Senior Fellow Roger Severino noted in 2016, "Section 1557 of the ACA does not create special privileges for new classes of people or require insurers and physicians to cover or provide specific procedures or treatments." [Footnote 34: Roger Severino & Ryan T. Anderson, Proposed Obamacare Gender Identity Mandate Threatens Freedom of Conscience and the Independence of Physicians, Heritage Found. Backgrounder No. 3089, 2 (Jan. 8, 2016), https://www.heritage.org/health-care-reform/report/proposed-obamacare-gender-identity-mandate-threatens-freedom-conscience.] Looking to the statutory text and congressional intent it is clear that Section 1557 did not extend to sexual orientation or gender identity. Regarding sexual orientation, the ACA makes one reference to the term in a provision related to grant programs. [Footnote 35: See 42 U.S.C. § 294e-1(b)(2) ("participation in the institutions' programs of individuals and groups from different racial, ethnic, cultural, geographic, religious, linguistic, and class backgrounds and different genders and sexual orientations").] If Congress wanted to prohibit LGBTQ discrimination it would have used the term as it did here. Regarding gender identity, the ACA was passed by Congress in March 2010 and at

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American College of Emergency Physicians

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Arkansas Department of Human Services

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American Hospital Association

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exhand sex discrimination is based upon an erroneous application of the Bostock ruling and a failure to protect doctors and patients alike from compelled speech and action. In what seems to be an ideologically motivated move the Department also fails to acknowledge the controversy surrounding and the harms caused by so-called gender transition. Instead of providing clarity the Department muddies the waters by simultaneously failing to define sex while expanding its meaning to include non-observable subjective preferences that obscure its regulation the sexbased difference that is the basis for Title IX itself. All people deserve to be treated with dignity and respect. Contrary to its express goal this proposed rule would greatly multiply discrimination and harm within federally funded educational programs and activities and beyond. The Department cites the Supreme Court's decision in [Italics] Bostock v. Clayton County[] as justification for its expansion of sex discrimination to include sexual orientation gender identity and other categories. As we have argued before the administration's application of [Italics] Bostock[] which exclusively focused on employment discrimination to Title IX is erroneous. In [Italics] Bostock v. Clayton County[] the Supreme Court's ruling proceeded "on the assumption that 'sex' signified what the employers suggest referring only to biological distinctions between male and female." [Footnote 7] Bostock v. Clayton County 590 U.S. 1403, Ct. 1731 (2020)[] The ruling dealt with discrimination on the basis of sex in matters of employment according to Title VII of the Civil Rights Act. It did not redefine sex to include gender identity and sexual orientation. It also did not apply its ruling to any other part of the Civil Rights Act beyond Title VII.Notably the Bostock court used the term "transgender status" [Italics: not] "sexual orientation and gender identity" as HHS erroneously posits. Bostock is limited to employment nondiscrimination and "did not adopt gender identity as a protected basis." [Footnote 8] Morrison "HHS's Proposed Rule on Discrimination on the Basis of Sex Transgender Mandates & Health Care."

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disease defined by the failure to achieve a successful pregnancy after 12 months or more of appropriate timed unprotected intercourse or therapeutic donor insemination." Many health plan policies for AR coverage are based on this definition. Others use a definition of infertility based solely on failure to achieve a pregnancy after a period of unprotected heterosexual intercourse. Both of these definitions used in this context place an undue burden on non-heterosexual individuals and couples who wish to reproduce. Health plans using these definitions often impose significant extra costs or complete exclusions of coverage of fertility treatments for LGBTQI+ people. We believe these pervasive policies that focus on cisgender heterosexual couples are inherently discriminatory and HHS should clarify in the Final Rule that AR coverage if offered must be offered without regard to sexual orientation or gender identity sex characteristics [including intersex traits] or any other factors protected by Section 1557. AR includes several methods for facilitating reproduction in the case of medical or social infertility. These include intrauterine insemination (IUI) in vitro fertilization (IVF) and surrogacy. Denying such services based on an individual or couple's inability to have unprotected procreative sexual intercourse is inherently discriminatory against LGBTQI+ individuals and couples particularly for the vast majority of samesex couples for whom sexual intercourse cannot lead to pregnancy. For example it is discriminatory to deny IUI to a couple composed of two cisgender women based on their inability to engage in procreative sexual intercourse with each other. In [Italics] Bostock[] the Supreme Court considered whether LGBTQ+ workers who were fired from their jobs for their sexual orientation or gender identity were discriminated against on the basis of sex. The Court held that the Civil Rights Act's protection against employment discrimination on the basis of sex applied and that a plain reading of the protection extends to discrimination based on sexual orientation or gender

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Congressman Mike Quigley

The passing of the Affordable Care Act (ACA) and Section 1557 went a long way toward addressing pervasive discrimination in healthcare against the LGBTQ+ community. Section 1557 prohibits discrimination by federally funded health programs on the basis of race color national origin age disability or sex in covered healthcare programs and activities [Footnote 7: Medina Caroline Mahowald Lindsay "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities." Center for American Progress 15 Oct. 2020 www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/ The Obama Administration's final rule implementing Section 1557 helped many LGBTQI+ individuals gain access to healthcare and insurance with its nondiscrimination protections on the basis of gender identity and sex stereotyping. While the Obama's Section 1557 rule was a big step forward in advancing LGBTQI+ health equity the Trump Administration's 2020 Section 1557 rule undermined that progress and caused confusion and fear around accessing healthcare for the LGBTQI+ community. The Trump Section 1557 rule not only removed protections for LGBTQI+ patients from Obama's Section 1557 rule but also eliminated sexual orientation and gender identity nondiscrimination protections in several CMS programs. This included many programs that disproportionately benefit LGBTQI+ individuals such as insurance enrollment qualified health plans and the Program of All-Inclusive Care for the Elderly (PACE). Removal of these critical nondiscrimination protections has left LGBTQI+ patients confused and fearful of accessing necessary healthcare which is especially concerning given the recent COVID-19 pandemic as well as the surge of anti-LGBTQI+ legislation sweeping the nation.

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Howard Brown Health

rights norms and obligations. A. International human rights law prohibits discrimination on the basis of sex including discrimination based on termination of pregnancy sexual orientation and gender identity. We support the Administration's efforts to advance access to nondiscriminatory healthcare which will bring U.S. policy closer into compliance with international human rights law. Human rights are based on the principles of universality and nondiscrimination as set forth in the Universal Declaration of Human Rights (UDHR): "All human beings are born free and equal in dignity and rights." [Footnote 83: Universal Declaration of Human Rights adopted Dec. 10 1948 art. 1 2 G.A. Res. 217A (III) U.N. Doc. A/810 at 71 (1948).] Equality and nondiscrimination are core principles of international human rights law and nondiscrimination is a crucial obligation for all core human rights treaties including the International Covenant on Civil and Political Rights (ICCPR). [Footnote 81: International Covenant on Civil and Political Rights adopted Dec. 16 1966 art. 2 26 G.A. Res. 2200A (XX) U.N. GAOR 21st Sess. Supp. No. 16 U.N. Doc. A/6316 (1966) 999 U.N.T.S. 171 (entered into force Mar. 23 1976) [hereinafter ICCPR]. Article 26 of the CCPR establishes equality before the law and forbids discrimination "on any ground such as race colour sex language religion political or other opinion national or social origin property birth or other status." This list is deliberately not exhaustive and the Human Rights Committee and other bodies have affirmed that "other status" encompasses sexual orientation and gender identity. United Nations High Commissioner for Human Rights Discriminatory Laws and Practices and Acts of Violence Against Individuals Based on Their Sexual Orientation and Gender Identity para. 7 U.N. Doc. A/HRC/19/41 (Nov. 17 2011) [hereinafter UNHCHR Discriminatory Laws and Practices]. [which the United States ratified in 1992 [Footnote 82: CHCHR Status of Ratification Interactive Dashboard http://indicators.ohchr.org/ (last visited Sept. 30 2022).] and the Covenant on

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health care personnel's refusals to provide health care on grounds of religious or moral objection do not jeopardize access to reproductive health care. [International human rights law holds that the right of religious freedom by one individual cannot justify infringement on the human rights of others including women and LGBTQI individuals. [Footnote 101: Ahmed Shaheed Special Rapporteur on Freedom of Religion or Belief, Interim Rep. of The Special Rapporteur on Freedom of Religion or Belief para. 46 U.N. Doc. A/72/365 (Aug 28 2017).] Incorporation of federal refusal laws would encourage more provider discrimination contrary to human rights norms. [Footnote 102: See Human Rights Council Report of the Working Group on the issue of discrimination against women in law and practice para. 95 U.N. Doc. A/HRC/32/44 (Apr. 8 2016) [concluding that "inadequately regulated conscientious objection may constitute a barrier for women when exercising their right to have access to reproductive and sexual health services. The Jurisprudence of human rights treaty bodies states that where conscientious objections is permitted States still have an obligation to ensure that women's access to reproductive health services is not limited and that conscientious objection is a personal not an institutional practice."][The World Health Organization's 2022 Abortion Care Guideline reiterates that "the human rights obligation to ensure conscientious objection does not hinder access to quality abortion care." [Footnote 118: WORLD HEALTH ORGANIZATION ABORTION CARE GUIDELINE 60 [Mar. 8 2022] (https://www.who.int/publications/i/item/9789240039483.] The Guideline also states that "[If it proves impossible to regulate conscientious objection in a way that respects patients and fulfils abortion seekers' rights conscientious objection [abortion provision may become indefensible." [Footnote 104: Id.]. Further the UN Special Rapporteur on Freedom of Religion or Belief has specifically mentioned "the denial of access to reproductive health services" as an example

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prevent a retrogression of rights. [Retrogression is a backwards step in law or policy that impedes or restricts the enjoyment of a right. The principle against retrogression is premised on the obligation of governments to ensure constant forward progress in realizing rights. [Footnote 110: International Covenant on Economic Social and Cultural Rights adopted Dec. 16 1966 art. 2 para. 1 G.A. Res. 2200A (XXI) U.N. GAOR 21st Sess. Supp. No. 16 U.N. Doc. A/6316 (1966) 993 U.N.T.S. 3 [entered into force Jan. 3 1976].] In the context of sexual and reproductive health in particular the Committee on Economic Social and Cultural Rights ("CESCR") – the Committee overseeing implementation of International Covenant on Economic Social and Cultural Rights ("ICESCR") – has provided some examples of measures which would be retrogressive. [Footnote 111: Committee on Economic Social and Cultural Rights General Comment No. 22 (2016) on the right to sexual and reproductive health [article 12 of the International Covenant on Economic Social and Cultural Rights) para. 38 U.N. Doc. E/C.12/GC/22 (2016).] These include "legal and policy changes that reduce oversight by States of the obligation of private actors to respect the right of individuals to access sexual and reproductive health services." [Footnote 112: Id. Other examples of retrogressive measures include the removal of sexual and reproductive health medications from national drug registries; laws or policies revoking public health funding for sexual and reproductive health services; [imposition of barriers to information on goods and services relating to sexual and reproductive health, and enacting laws criminalizing certain sexual and reproductive health conduct and decisions. [The United States is currently experiencing a retrogression of reproductive rights of which the overturn of Roe] is just the latest and most extreme example. Over the past decade states across the country have engaged in a retrogression of abortion rights. This has occurred with in the context of a retrogression of civil rights overall including

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Underline: This Rule is not defensible|Nothing in Congressional statute or statutory interpretation by the U.S. Supreme Court has changed the meaning of sex discrimination under Title IX Title VII of the ACA. The Department has no legitimate authority to override federal civil rights law to redefine the immutable characteristic of sex to mean "gender identity." Bostock established that "transgender status" was protected under Title VII's hiring and firing [transgender status" was based on the declared persona of an adult self identifying as the opposite sex. The court went no further than recognizing this status under Title VII to extend certain workplace protections. It did not impose other social and financial obligations or an employer other employees or a health care plan. There was no "right" to accommodation beyond securing or retaining a job. Using the "reasoning" of [Italics: Bostock] to create an undefined unlimited and ever evolving class of "gender identity" is an injection of politics and policy desires not adherence to settled lawful statute. This is legislative rule making at its worst. HHS is trying to do exactly what the Department of Education is seeking to do under Title IX – creating an artificial undefinable and unenforceable right to demand accommodation for a self declared identity. This is a seismic change to the objective classifications of civil rights laws.

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Concerned Women for America

Sec. VIII. The proposed rule restores the proper scope of Section 1557's nondiscrimination protections. We support the proposed rule's restoration of the scope of application of Sec. 1557's nondiscrimination protections which were severely curtailed by the 2020 rule. The 2020 Rule narrowed its scope of application of nondiscrimination protections to the narrowest possible set of entities falling short of its statutory authority in its interpretation of Sec. 1557 and jeopardizing patient access to care. The Department should restore application of Sec. 1557's nondiscrimination protections to its original scope ensuring that a greater number of patients will be able to benefit from Section 1557's nondiscrimination protections.

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[Italics: Legal scholars argue Title IX should not be a positive mandate for abortion.][The Harvard Journal of Law and Gender published an academic article in 2020 entitled "Reproducing Inequality Under Title IX." The article begins by highlighting the insufficient attention given to Title IX's intersection with pregnancy and reproduction" [172]. It goes on to frame pregnancy and maternity as "significant obstacles" to educational attainment [173]. The authors criticize Title IX for only addressing pregnancy and reproduction after it has occurred and threatened academic or athletic pursuits. Instead they argue for a proactive approach. At length the authors argue that the abortion neutrality mandate undermines Title IX's potential as it does not require universities to provide abortion services for students. In short they believe Title IX should shift from a negative abortion provision [protecting a woman from discrimination should she receive an abortion] to a positive abortion provision. This positive provision would take the form of requiring "educational institutions to provide any support for students seeking or having an abortion such as referrals to abortion providers education about abortion as an option or access to abortion care as part of a student health" [173].

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The prior rule undermined these protections by limiting the applicability of Section 1557 including limiting the number of federal health programs subject to 1557 and narrowing the applicability of 1557's protections. This created uncertainty and confusion regarding the responsibilities of providers and the rights of persons who experience discrimination and inconsistencies with other regulatory requirements that entities are subject to. For [e.g. the Americans with Disabilities Act] and Section 504 of the Rehabilitation Act]

National Alliance on Mental Illness

[Italics: There is no need for regulatory action.] EO 12866 section 1(b) establishes the principles of regulation including that "Each agency shall identify the problem that it intends to address (including where applicable the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem." To justify rapacious current regulations including the 2020 Rule HHS must provide specific evidence as to how those regulations are causing harms or burdens and how the Proposed Rule would remedy the alleged defects [italics: whether] causing equal or greater harms and burdens. [Footnote 6: Michigan v. EPA 135 S. Ct. 2699 (2015).] [regulation is rational if it disregards the relationship between its costs and benefits]. Telecomm. v. FCC 836 F.2d 551 561 (D.C. Cir. 1988) ["a regulation perfectly reasonable and appropriate in the face of a given problem is highly capricious if that problem does not exist"] | HHS has failed to meet that exacting standard in every respect.

Ethics & Public Policy Center

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(b)(5) Concerned Women for America

(b)(5) Attorneys General of California, New York, Massachusetts, and nineteen other States

(b)(5) Center for American Progress

(b)(5) Advocates for Intersex Youth

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|Bold. 7 Application of Section 1557 to all HHS Administered Health Programs and Activities|The States also support the Proposed Rule's inclusion of all HHS-administered health programs and activities in the scope of coverage. 87 Fed Reg. at 47838. |Footnote 30: The States concur with HHS that clarifying that Section 1557 applies to Federally administered health programs and activities appropriately conforms to the purpose and intent of Section 1557. See 87 Fed Reg. at 47838.| The 2020 Rule restricted the scope of covered federal programs to those "administered by [HHS] under Title I" of the Affordable Care Act. 45 C.F.R. § 92.4(a)(2). But this restriction contravened the language and intent of Section 1557 which states that it applies to programs and activities that are "administered by an Executive Agency or any entity established under [Title I of the ACA]." 42 U.S.C. § 18116(a) (emphasis added). The States concur with HHS that to the extent Section 1557's text leaves any ambiguity a better and more reasonable reading of this language is in line with Congress' intent to cover a broad swath of activities means that it should apply to all HHS-administered programs. See 87 Fed. Reg. at 47829. |Footnote 11: Although the Proposed Rule only covers [HHS-administered health programs and activities the States encourage other Federal agencies to adopt conforming regulations mirroring the Proposed Rule to clarify Section 1557's application to Federal health programs and activities administered by other Federal agencies.| As with HHS's proposed changes regarding the definition of entities receiving Federal financial assistance the States support this broader scope of coverage for HHS-administered programs and activities because it will reduce confusion and prevent discrimination reducing costs of adverse health outcomes that might otherwise be borne by the States' public health systems.

|Italics Preemption of state and local laws:| The HHS proposed rule also creates conflicts between state and local laws and HHS regulations. HHS states that its "proposed regulation attempts to balance State autonomy with the necessity to create a Federal benchmark that will provide a uniform level of nondiscrimination protection across the country" (47907). But the proposed rule goes much further than previous HHS rules and many state laws that recognize the biological difference between the sexes and protect the value of unborn life. It is overly broad language seems explicitly designed to nullify recently enacted state laws that protect minors from destructive sex reassignment procedures and surgeries and that protect unborn babies from the brutality of abortion. The proposed rule purports to override these laws' legitimate basis in the various state legislatures and undermine the democratic process across the country.

Comments associated with this issue are included in the subsections below.

The Proposed Rule Clarifies Its Obligations Pursuant to Other Federal Nondiscrimination Laws

We applaud the Department's recognition of the many ways people often experience discrimination based on their intersecting race national origin sex age disability and other protected categories. The preamble of the proposed rule highlights the serious health consequences of discrimination on the basis of pregnancy or related conditions especially for Black and Latino women |Footnote 19: 87 Fed. Reg. at 47832.| The preamble also notes the prevalence of discrimination against people who experience transphobia and racism and discrimination against women with disabilities |Footnote 20: Id. at 47820.| To better ensure that Section 1557 applies to intersectional discrimination we urge the Department to include a clear reference to discrimination based on a combination of protected categories in the relevant provisions of the proposed rule.

Department recognizes in the preamble to the NPRM that people may experience discrimination in health care on more than one basis. It would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. We propose the following change to section 92.101(a)(1): "Except as provided in Title I of the ACA an individual may not on the basis of race color national origin sex age or disability "[Bold] or any combination thereof[] be excluded from participation be denied the benefits of or otherwise be subjected to discrimination under any health program or activity operated by a covered entity." This language should also be added to sections 92.207(a) |b)(1) and |b)(2). This addition is incredibly important as similar to the importance of understanding the intersectionality of race and sexuality with comprehensive sex education factoring for intersectional discrimination within the various forms of discrimination that LGBTQIA+ youth can experience within the medical system is necessary. According to Rockefeller Institute of Government of SUNY |embedded hyperlink text |https://rockinst.org/blog/understanding-and-addressing-the-challenges-faced-by-lgbtq-people-of-color-poc-in-accessing-mental-health-care/)| LGTBQAI+ youth of color are vulnerable to risk of suicide and poor mental health due to mistrust of mental health providers and fear of discrimination. We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law for ruling |Italics Price Waterhouse v Hopkins| and |Italics Bostock v. Clayton County| makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity including transgender status. It is essential that this rule tracks those decisions to provide assurance to participants beneficiaries and enrollees and not cause covered entities that these bases are unequivocally included. We also support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex-based.

concerned that the proposed rule does not adequately address or reflect the unique political relationship between AI/ANs and the federal government. As stated above the United States has a federal trust responsibility to provide health care services to AI/AN individuals. Like any other Executive Department Agency the U.S. Department of Health and Human Services [the "Department"] has a duty and responsibility to ensure that the laws it administers are implemented in a manner that respects Congress' authority to enact Indian-specific legislation that fulfills this responsibility. Existing CMS regulations also recognize that Indian health programs are entitled to provide services to Indian people and are exempt from the prohibition on discrimination on the basis of race color or national origin in Title VI of the Civil Rights Act. |Footnote 1. 45 C.F.R. § 80.3(d).| In order to fulfill that trust responsibility Congress has the authority to enact Indian-specific laws and "to take Indian-specific provisions out of general laws. [Footnote 2: See e.g. Indian Health Care Improvement Act 25 U.S.C. § 1601 et seq.; Indian Self Determination and Education Assistance Act 25 U.S.C. §450 et seq., Indian Federal or Act 20 U.S.C. §7401 et seq. Tribally Controlled Schools Act 25 U.S.C. §2501 et seq., Tribally Controlled College or University Assistance Act 25 U.S.C. §1801 et seq., Native American Housing Assistance and Self-Determination Act 25 U.S.C. §4101 et seq.; Indian Child Welfare Act 25 U.S.C. §1901 et seq.; Indian Child Protection and Family Violence Prevention Act 25 U.S.C. §3201 et seq., Indian Employment Training and Related Services Demonstration Act 25 U.S.C. §3401 et seq. |These Indian-specific laws and provisions are based on political rather than racial distinctions and do not violate prohibitions on racial discrimination. In Morton v. Mancari | the U.S. Supreme Court recognized that "[t]he plenary power of Congress to deal with the special problems of Indians is drawn both explicitly and implicitly from the Constitution itself." |Footnote 3: 417 U.S. 535, 551, 52 |1974).|The Indian Health Service/Tribal/Urban Indian Organization |I/T/U|

1) Discrimination and Health Equity: APA strongly supports more robust enforcement of Section 1557 as outlined in this NPRM because doing so would advance population health approach to treatment and improve health equity. |Footnote 5: APA. (2022). Psychology's Role in Advancing Population Health.| Discrimination in health care settings is closely tied to behavioral health disparities observed in diverse populations. Individuals seeking either behavioral or physical health care experience discrimination throughout the system. From obtaining insurance coverage to receiving a proper diagnosis and treatment. Even the perception of discrimination in healthcare settings has been shown to contribute to higher unmet needs for health care utilization poor health and health disparities among racial and ethnic minorities |Footnote 6: Lee C. Ayers S. L. & Kronenfeld J. J. (2010). The association between perceived provider discrimination healthcare utilization and health status in racial and ethnic minorities. Ethnicity & disease 19(3) 330–337. An increase in discrimination will exacerbate existing disparities and harm the mental health and well-being of historically marginalized individuals and communities.

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Attorneys General of California, New York, Massachusetts, and nineteen other States

American Association of Christian Schools

Senate Democrats

SIECUS: Sex Ed for Social Change

Tribal Technical Advisory Group to CMS (TTAG)

American Psychological Association

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The Proposed Rule addresses racial health disparities by improving disability access Improving health care access for people living with disabilities is critical to reducing racial health disparities Black people are more likely to have a disability relative to White people in every age group and according to the CDC three in 10 American Indian/Alaskan Native people and one in four Black people live with disabilities In addition people of color with disabilities are more likely to face various forms of violence including police brutality and sexual violence particularly Black disabled Americans And while there are statistically fewer disabled Asian Americans and Latinx people in the U S compared to White people they struggle with racial discrimination language barriers and other intersectional boundaries to equity.

As discussed previously we appreciate HHS's recognition of intersectional discrimination and its unique harm for e g older adults of color and "individuals who experience both transphobia and racism." [Footnote 57: 87 Fed. Reg. at 47870.] In addition to explicitly stating that Sec. 1557 prohibits intersectional discrimination under § 92 301 we urge HHS to recognize intersectional causes of action in the rule itself The rule would be a stronger tool against intersectional discrimination if it clarifies that the multiple grounds on which individuals are protected against discrimination under Sec. 1557 are overlapping and additive and are not to be considered in isolation from each other.
No comments are associated with this issue

We strongly support Proposed Rule Section 1557 of the Affordable Care Act.John Clarke increasingly cares for residents of the LGBTQ community and want to ensure that supports are strengthened to provide health and living services in a safe welcoming environment LGBTQ+ elders many of whom have experienced stigma and discrimination throughout their lives face multiple and serious obstacles to healthy aging At John Clarke Senior Living we wish to ensure that barriers to an open hospitable care environment are eliminated Codifying protections against discrimination on the basis of sex including discrimination on the basis of sexual orientation and gender identity under the Proposed Rule Section 1557 will go a long way in supporting our efforts to provide that setting.Please ensure that all of our Elders are protected from discrimination.

As discussed previously we appreciate HHS's recognition of intersectional discrimination and its unique harm for e g older adults of color and "individuals who experience both transphobia and racism." [Footnote 57: 87 Fed. Reg. at 47870.] In addition to explicitly stating that Sec. 1557 prohibits intersectional discrimination under § 92 301 we urge HHS to recognize intersectional causes of action in the rule itself The rule would be a stronger tool against intersectional discrimination if it clarifies that the multiple grounds on which individuals are protected against discrimination under Sec. 1557 are overlapping and additive and are not to be considered in isolation from each other

Applying the Age Act procedures to all claims involving age discrimination puts older adults at a disadvantage because the Age Act procedures require a claimant to exhaust administrative remedies before they may file a civil action [Footnote 58: 45 C F R § 91 50(a)] The administrative exhaust requirement imposes significant hurdles on an individual's ability to seek recourse for discrimination based on age they must file an administrative complaint within 180 days of the event complained of or lose their right to relief: [Footnote 60: 45 C.F.R. § 91 42(a)] In addition to legally sufficient they must refrain facts in the complaint that can be difficult to ascertain'. [Footnote 61: 45 C F R 91 42(b)] and then they must wait 180 days for HHS to investigate before they can proceed with a claim in court. [Footnote 62: 45 C.F.R. § 91.50(a).' No other cause of action under Sec 1557 imposes such a requirement. Title VI procedures do not [Footnote 63: 28 C F R. § 42 101 et seq.] providing Title VI administrative procedures without any exhaustion requirement) ; Lack of consistency in administrative procedural requirements will only undermine enforcement of intersectional claims and stymies the statute's intent to fight discrimination in healthcare For example an older adult who experiences transphobia racism and ageism should not be forced to either forgo the ageism claim or proceed through one of HHS administrative exhaustion to seek a remedy in court for the intersectional discrimination they experienced .

practices There is [Hyperlink physician bias, https://www.downtoutstruts.com/episodes/season-2-physicians-healthcare-access- isabiezzoni, with 82 percent of clinicians believing that patients with disabilities have a lower quality of life than patients without disabilities even though many whole lives with severe disabilities have a "good quality of life." Only 56 5 percent of physicians strongly welcome patients with disabilities into their practices and 40 7 percent of clinicians are "very confident" that they can "provide the same quality of care" to patients with disabilities Biased [Hyperlink clinicians' assumptions: https://ncd.gov/sites/default/files/NCD_COVID-19_Progress_Report_508.pdf; contribute to decisions about treatment with deadly results During the early months of the coronavirus pandemic patients with IDD were discriminated against They were deprioritized relative to other patients in terms of access to ventilator support and critical care beds. Some were denied the help of their caregivers or personal support personnel during hospitalization which many need to effectively communicate their needs Informal and formal Crisis Standards of Care documents which related to rationing of healthcare denied care to patients with specific disabilities. [Hyperlink Coronavirus; https://news.syr.edu/blog/2022/08/13/covid-was-deadlier-for-those-with-intellectual-disabilities-according-to-new-research/#:~:text=COVID%20was%20deadlier%20for%20those%20with%20intellectual%20disabilities%2C%20according%20to%20new%20research-Tuesday%2C%20September%2013&text=Authors%20of%20a%20new%20peer-reviewed%20study%20on%20COVID-19%20and%20people%20with%20intellectual%20and%20developmental%20disabilities%20(IDD)%20-%202020.' was more lethal for people with intellectual disability A though the [Hyperlink Americans with Disabilities Act: https://www.statnews.com/2022/11/13/doctors-confused-accommodations-people-disability/] [ADA] mandates that people with disabilities receive equal care and accommodations so they can get proper care problems with

Services [HHS] proposed rule to strengthen Nondiscrimination in Health Care and to express our support for continued action from HHS to clarify specific guidelines physicians' and health care providers' ability to prescribe life-saving medications to people specifically people with disabilities and to ensure protections for providers who provide emergency abortions for people with disabilities [Footnote 1. In this letter we want to clarify "protections" to mean clarifying the ability to provide emergency abortions for people with disabilities]. We ask that the protections in this letter be clearly outlined in the final rule to implement Section 1557 of the Affordable Care Act [ACA] (Section 1557) [Footnote 2: Centers for Medicare and Medicaid Services. Office for Civil Rights (OCR) Office of the Secretary HHS proposed rule on Section 1557 of the Affordable Care Act (ACA) [Section 1557) [2022) Document link Section 1557 Notice of Proposed Rulemaking (hhs.gov)]. The Supreme Court's decision to overturn Roe v. Wade has created confusion for health care providers who often do not have clear guidance on when a pregnant person's life is sufficiently at risk to warrant an exception to an abortion ban. Clinicians have already reported that they are having to put patients' lives in danger while they wait on ethics consults around medically necessary procedures [Footnote 3: Goldhill O 2022 'A story time': Fear of prosecution forces doctors to choose between protecting themselves or their patients [or ink]' STAT Available at: https://www.statnews.com/2022/07/05/a-story-time-fear-of-prosecution-forces-doctors-to-choose-between-protecting-themselves-or-their-patients/?utm_source=STAT+Newsletters&utm_campaign=3d84507be9-Daily_Recap&utm_medium=email&utm_term=0_1bab3d7961-3d84507be9-148644513+ [Accessed 14 July 2022]' Meanwhile patients with disabilities have reported being denied medications that can be used for medication abortion despite relying or their to treat other conditions [Footnote 4: Sharp S. 2022 Pu [Underline: Is gender dysphoria a disability under this Rule?]Does the Department agree or disagree that "gender dysphoria" constitutes a disability under the Americans with Disabilities Act as a Fourth Circuit Court of Appeals panel recently concluded in [Italics 'Williams v. Kincaid]? If so how does that assertion impact obligation and liability under this Rule? This question cannot be ignored as it is central to the responsibilities of recipients and providers of services required under this Rule

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Alliance of Multicultural Physicians

Justice in Aging

John Clarke Senior Living

Justice in Aging

Justice in Aging

Institute for Exceptional Care

Senator Kirsten Gillibrand

Concerned Women for America

(b)(5)

access to FDA approved medical ons we req ues additional and im mediate clarification that health care providers must continue to be able to im plement life-saving measures to people especially those with disabilities and urge the Department to p ori ze its issuance People with disabil es experience discrimination in the provis on of health care services and as such we also encourage HHS under your stewardsh p to pursue interim steps to clarify emphasize and enforce existing disab ty and c scrimination require ments in hea th care especially after the recent Supreme Court decision to overturn Roe v Wade [Footnote 13: DOBBS STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH ET AL v JACKSON WOMEN'S HEALTH ORGAN ZAT ON ET AL [2022] 597 U S 19 1 142 S Ct 2228 213 L Ed 2d 545 2022 U S LEXIS 3057 90 USLW 4785 22 Cal Daily Op Serv 5029 2022 Daily Journal D A R 6199 70 Fla L Weekly Fed S 1 1392 Dobbs v Jackson Women's Health Organization 10/24/2022] [supremecourt.gov] which overturned Roe v Wade removing the constitutional right to a abortion services]. Accessibility of hea th care settings w l become increasingly important as people with disabil es will be traveling to unfamiliar locations to access medications and providers and will depend on facilities being accessible upon arrival [Footnote 14: Rosman K (2022) For a Woman in a Wheelchair Abortion Access Was One More Cha enge Retrieved 25 July 2022 from https://www.nytimes.com/2022/07/14/style/abortion-access-ability-planned-parenthood.html] HHS is poised to address the ongoing discrimination against those with disabilities in the delivery of health care services as outlined in the Section 504 RFI through the Office of Civil Rights (OCR) [Footnote 15: HHS has the jurisdiction to treat discrimination cases as outlined through the Office for Civil Rights (OCR) through this department. DEPARTMENT OF HEALTH AND HUMAN SERVICES n th D scr minat on on the Basis of Disability in Critica Health and Human Service Programs or Activities. Office for Civil Rights (OCR) Office of the Secretary HHS 90 J-2] We strongly support HHS Secretary Becerra issuing

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Senator Kristen Gillibrand

turing the recent pandemic provides a timely and urgent reminder of why broader and deeper awareness of civil rights is needed among healthcare entities. Family members friends and paid caregivers who provide the personal care assistance needed by people with a range of disabilities were treated as ordinary "visitors" and turned away by security personnel nurses and other healthcare providers. The result placed people with disabilities at risk of having their communication and health care needs ignored or misunderstood left unaided equally be held from health care services or be ng forced to undergo additional invasive procedures such as restraints or the insertion of a feeding tube. The COVID-19 public health emergency only highlighted how hospitals and health care facilities of various sizes have long failed to fully integrate and operationalize civil rights laws leaving people with disabilities their advocates and their family members with few or no effective options to obtain the effective communication and policy modifications necessary for good health outcomes. For example DRM represented a 42 year old woman diagnosed with Mitochondrial Encephalopathy Lactic Acidosis and Stroke-like Episodes (MELAS) a rare congenital condition. The nursing home where her guardian placed her refused to allow her family to visit during the beginning of the pandemic even though family visits greatly improved her well being. Meanwhile nursing home staff were free to come and go. We referred the nursing home administrators to DOJ guidances and an OCR guidance about how civil rights laws were still in effect. It made no difference to the administrators. DRM also had clients with developmental disabilities and Autism who required hospitalizations and whose family members were not allowed to visit them. These individuals had communication issues that the treating professionals were not aware of and did not know how to accommodate. The treatment for these individuals suffered. As an organization that works with people with disabilities seeking healthcare we have seen healthcare providers

Disability Rights Maine

6. Highlight Unique experiences of intersectionality. Many individuals identify as an intersection that alone may hold identities in a particular gender identity while also having a lived experience of disability. Each intersection of an individual's identity needs to be included in a nondiscriminatory manner.

The Arc of Pennsylvania

The proposed rule addresses racial health disparities by improving disability access improving health care access for people living with disabilities is critical to ameliorating racial health disparities. Black people are more likely to have a disability relative to White people in every age group and according to the CDC three in Ten American Indian/Alaska Native people and one in four Black people live with disabilities. In addition people of color with disabilities are more likely to face various forms of violence including police brutality and sexual violence particularly Black disabled Americans. And while there are statistically fewer disabled Asian Americans and Latinx people in the U S compared to White people they struggle with racial discrimination language barriers and other intersectional boundaries to equity.

Alliance of Multicultural Physicians

The Americans with Disabilities Act and the Rehabilitation Act both prohibit discrimination against people with disabilities though Section 1557 strengthens these anti discriminatory protections

The Leadership Conference on Civil and Human Rights

Comments associated with this issue are requested in the questions below.

HHS claims that the 2020 Rule "hinder[s] the Department's mission of pursuing health equity and protecting public health." [Footnote 9: 87 Fed Reg. 47829.] Indeed on September 30 2022 Vice President Harris stated in an interview about disparities" and climate events her belief that "our lowest income communities and our communities of color [] are the most impacted by these extreme conditions . . . so we have to address this in a way that is about [italics] giving resources based on equity[]" and "making sure that the policies say a piece of what they do that's directly harming [those] communities in terms of their health and well being." [Footnote 10 Priyanka Cheopra Jonas Interview of Kamala Harris before the Democratic National Committee's Women's Leadership Forum in Washington D.C. (Sept. 30 2022) https://youtu.be/d8bUaVB/9Hk] But the mission of HHS is to "enhance the health and well being of [] Americans by providing for effective health and human services and by fostering sound sustained advances in the sciences underlying medicine public health and social services." [Footnote 11: U S Dep't Health & Human Servs. Introduction About HHS https://www.hhs.gov/about/strategic-plan/2022-2026/introduction/index.html#mission. [emphasis added]] There is nothing in HHS's mission statement about "health equity." [Footnote 12 For example several states employed discriminatory racial set asides for their federally funded COVID-19 vaccine distribution to promote "health equity." EPPC along with Boyden Gray & Associates filed a complaint on behalf of a New Hampshire resident whom the state prohibited from receiving a COVID-19 vaccine solely because of his race. EPPC and Boyden Gray & Associates Demand HHS Hold New Hampshire Accountable for Unlawful Racial Set-Asides in COVID-19 Vaccine Distribution https://eppc.org/news/eppc-and-boyden-gray-associates-demand-hhs-hold-new-hampshire-accountable-for-unlawful- racial set asides in covid 19 vaccine distribution/. Despite the clear violations of Sec on 1557 and Title VI of the Civil There is no evidence that the 2020 Rule has or will cause any harm or burden necessitating the need for this rulemaking. To justify replacing the 2020 Rule HHS must provide specific evidence as to how that Rule is causing harms or burdens. Footnote 13: See EO 12866 § 1(b) (establishing the principles of regulation including that "Each agency shall identify the problem that it intends to address including where applicable the failures of private markets or public institutions that warrant new agency action as well as assess the significance of that problem".]

Ethics & Public Policy Center

HHS also claims that the 2020 Rule "caused confusion in complying by failing to provide clear procedural requirements." [Footnote 14: 87 Fed Reg. 47830.] This is mere speculation. HHS fails to cite to any entity complaint or enforcement action that demonstrates such confusion exists. Making such a claim without substantial concrete evidence is arbitrary and capricious.

Ethics & Public Policy Center

color national origin disability and age in any program or activity receiving federal financial assistance including credits subsidies or contracts of insurance or in any health program or activity administered by an executive agency or entity. While the interpretation of Section 1557 has been highly contested over the years at the heart of the issue is the ACA which is built upon the core goal of providing access to high quality affordable health care to all individuals. Congress's intent to incorporate Section 1557 to eliminate unlawful discrimination in every facet of health care is clear when it incorporated existing civil rights protections into Section 1557. These protections include antidiscrimination protections in Title VI the Age Discrimination Act and Section 504 as they apply to health care activities and programs and extending the sex discrimination protections of Title IX to health care [Footnote 1: 42 U.S.C. § 18116]. Implementing regulations issued by HHS in 2016 further reinforced the importance of Section 1557 in carrying out one of the main goals of the ACA ensuring access to high quality affordable health care for all individuals without the threat of discrimination which can often discourage enrolling in coverage leading to poor and inadequate health outcomes while exacerbating existing health disparities in underserved communities [Footnote 2: 81 Fed.Reg. 31375 (July 18 2016)]. The 2016 rule codified important nondiscrimination protections including a broad definition of "on the basis of sex" prohibiting discrimination by protecting individuals from having their health insurance canceled or limited solely based on their race color national origin sex (including pregnancy gender identity and sex stereotyping) age or disability. Further this rule protected transgender individuals from having the coverage denied or limited based on the fact that they are transgender. The 2016 rule also codified protections for limited English proficient individuals as well as individuals that suffer from disabilities by providing them with appropriate aids and access to build rage and

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Covered California

CalHHS believes this NPRM largely alleviates our prior concerns over equity and increasing access to care by restoring these crucial and more inclusive protections. The NPRM is vastly more consistent with the language and intent of ACA Section 1557 as well as other underlying federal statutes (including ACA Section 1554) and related legal precedents. The proposed rule once finalized will avoid previous concerns with public confusion over differences between the federal and state standards and mitigate the various chilling effects associated with beneficiaries seeking and providers rendering care. The proposed rule will also restore fiscal certainty for states like California that chose to go beyond the 2020 Final Rule and avoided the prospect of jeopardizing federal financial support in vital health programs and activities. Moreover the reinstatement of the 2016 regulatory framework will assure meaningful access to all individuals as intended by Congress and reflective of the diversity of populations served by covered entities in both California and nationwide. The physical economic and emotional health concerns associated with the COVID-19 pandemic have revealed that our society's inability to erase discrimination and resolve equity issues continues to hamper our collective efforts to fight the pandemic and address other public health challenges and more generally improve the health and well-being of all individuals. CalHHS is committed to prioritizing and increasing efforts to reduce inequities of our health care systems and ensuring equitable and effective access to health care free from discrimination for all.

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California Department of Health Care Services

MNACHC agrees with HHS' judgement that the statutory text of Section 1557 is clear: Congress intended that the law apply to these entities and address these issues. [Bold: Thus MNACHC strongly supports HHS' restoration of and improvements to § 92.207 including its inclusion of specific forms of prohibited discrimination.

Minnesota Association of Community Health Centers

• Consistent Regulatory Requirements. BLBSA urges that Medicare Advantage and Part D plans be deemed compliant if they are following the standards set forth in their Section 1557 rules including the use of the CMS model Multi-Language Insert (MLI). We strongly urge maximum possible consistency so that the same language legal template could be used for both MA/Part D and the commercial businesses.

Blue Cross Blue Shield Association

No comments are associated with this issue.

Many children face discrimination in health care systems and settings that can impede their ability to access the services they need for healthy development. Such limited access to comprehensive developmentally appropriate care poses a barrier for children to thrive throughout their lives. For example the impact of discrimination in childhood years has been linked to toxic stress which compounded over time predisposes them to a higher likelihood of chronic disease in adulthood and other long-term negative health outcomes. [Footnote 1: https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/discrimination#5]. We strongly support the proposed rule's nondiscrimination protections in all federally funded supported and conducted health programs and activities. Discrimination in health coverage and care prevents many individuals from getting the care they need to stay healthy and directly contributes to healthcare disparities in our communities. We strongly support the rule's prohibition on discrimination on the basis of race color national origin (including immigration status and language) sex (including sex stereotyping and gender identity) disability and age. While we strongly support the provisions in the proposed rule we want to highlight that without addressing financial and other resource constraints that are placed on practices by the proposed rule there will be limitations to implementation of the proposed standards if finalized. We detail several of these barriers to implementation in our comments below.

American Academy of Pediatrics

AMCP applauds the Administration's goal of ensuring that everyone regardless of their race color national origin sex age or disability has access to quality health care coverage without being subject to discrimination. Discrimination in health care contributes adversely to adverse health outcomes for a variety of populations including women LGBTQIA+ individuals and individuals with limited English proficiency [Footnote 1: See e.g. https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-019-0729-2]. [Footnote 2: https://aspe.hhs.gov/sites/default/files/2021-07/gpt-health-ib.pdf. https://www.medicalnewstoday.com/articles/gender-bias-in-healthcare#examples]. [Footnote 3: https://journalethics.ama-assn.org/article/language-based-inequity-health-care-who-poor-hsturiary/2017-04]. It is important to note that "health disparities do not exist in isolation but are part of a reciprocal and complex web of problems associated with inequality and inequity" [Footnote 4: https://nam.edu/health-inequities-social-determinants-and-intersectionality/]. Addressing health disparities is by necessity also complex and requires thoughtful well-devised action [Footnote 5: Because of the complexity of health disparities use of a common terminology promotes understanding when engaging in meaningful dialogue and identifying concrete actions our profession can take. To that end AMCP has compiled a glossary of terms meant to serve as a resource for improving communications among providers patients and caregivers (https://www.amcp.org/sites/default/files/2022-05/DEIGlossary_May2022.pdf).

Academy of Managed Care Pharmacy (AMCP)

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American Academy of Child and Adolescent Psychiatry

Health Care For All

NAACP Legal Defense and Education Fund, Inc

Center for Reproductive Rights

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The Leadership Conference on Civil and Human Rights

Alliance of Multicultural Physicians

The Leadership Conference on Civil and Human Rights

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At SIECUS we advocate for the right of young people to have access to accurate and non-stigmatizing sexual and reproductive health education. This education includes instruction on where and how to access necessary sexual and reproductive health services. This is critically important when we are working to address the poor mental health outcomes disproportionately which is compounded by the fact that 81% of LGBTQAI+ youth [embedded hyperlink text [https://pathtoengagement.that.com/news/us-mental-healthcare-access-trails-other-nations-due-to-cost] were not able to access mental health care because of the cost. Beyond cost LGBTQAI+ youth may feel hesitant or even unsafe with parental involvement and require confidential access to low-cost services. This is also compounded by the fact that LGBTQAI+ youth are disproportionately likely to be homeless and/or live in poverty which has many implications on their health and access to medical care. Lastly many LGBTQAI+ youth face stigma and discrimination [embedded hyperlink text: https://files.kff.org/attachment/issue-brief-health-and-access-to-care-and-coverage-for-lgbt-individuals-in-the-us-2] within the healthcare system that prevent them from accessing healthcare services. Ultimately without the inclusion of comprehensive sex education we know that LGBTQIA+ students may continue to experience discrimination in their school settings but by eliminating discrimination in the healthcare system some of the health inequities experienced by the LGBTQIA+ community can be alleviated.

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SIECUS: Sexuality Information and Education Council of the United States

[Bold: II. The Proposed Rule Addresses Various Forms of Systemic Discrimination in Health Care and Methods of Prevention] The department properly notes that health disparities in the United States are directly attributable to persistent bias in the health care system. Both explicit and implicit discrimination serve as barriers to care, lead to lower quality care and drive worse health outcomes for communities. Discrimination in health care is often systemic — deeply embedded within the policies, procedures and practices of covered entities. The proposed rule addresses several major drivers of systemic discrimination, including anti-discrimination policies and procedures and algorithmic discrimination. The proposed rule takes a critical step toward addressing the ways in which discrimination manifests systemically in health care.

The Leadership Conference on Civil and Human Rights

[Discrimination is a significant problem for people with mental illness and other marginalized populations and has a negative impact on mental health. People with serious mental illness often experience discrimination in accessing and receiving health care services.[Footnote 1: Graham Thornicroft, Diana Rose and Aarti Kassam, "Discrimination in Health Care Against People with Mental Illness," International Review of Psychiatry 19(2) 113-122 2009 https://www.tandfonline.com/doi/abs/10.1080/09540260701278937,] leading to disparities in health outcomes. People who perceive more discrimination directed at themselves or other members of their racial or ethnic group are at greater risk for reduced mental health status.[Footnote 11: Y. Paradies, "A systematic review of empirical research on self-reported racism and health," International Journal of Epidemiology 35(4):888–901 2006 https://academic.oup.com/ije/article/35/4/888/688369,] and are more likely to underutilize mental health care.[Footnote 111: Diana Burgess et al. "The Association Between Perceived Discrimination and Underutilization of Needed Medical and Mental Health Care in a Multi-Ethnic Community Sample," Journal of Health Care for the Poor and Underserved 19(3):894-911 2008 https://muse.jhu.edu/article/242580/summary,] And when people with higher levels of perceived discrimination and lower English proficiency use services they are less likely to use appropriate medical care. [Footnote 1v: Michael Spencer et al. "Discrimination and Mental Health-Related Service Use in a National Study of Asian Americans," American Journal of Public Health 100(12) 2410-2417 2010 https://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2009.176321.] Many people in LGBTQI communities face discrimination, prejudice, denial of civil and human rights, harassment, and family rejection—all of which can lead to new or worsened symptoms, particularly for those with intersecting racial or socioeconomic identities. Section 1557 hopes to mitigate these negative effects by

National Alliance on Mental Illness

Overall the LGBTQIA+ community experiences many challenges when interacting with healthcare providers and health insurers according to a report [embedded hyperlink text (https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtq-communities/)] by Center for American Progress. Key findings from the report include: • 23 percent of LGBTQIA+ respondents including 27 percent of LGBTQIA+ respondents of color reported that in the past year they postponed or avoided getting needed medical care when sick or injured due to disrespectful or discriminatory treatment from doctors or other health care providers. • Overall 15 percent of LGBQ respondents including 25 percent of LGBQ respondents of color reported experiencing some form of care refusal by a doctor or other health care provider in the year prior. • Overall 57 percent of transgender or nonbinary respondents including 48 percent of transgender or nonbinary respondents of color reported that they experienced at least one kind of care refusal by a health care provider in the past year; • 55 percent of intersex respondents reported that in the past year a health care provider refused to see them because of their sex characteristics or intersex variation. • Overall 30 percent of transgender or nonbinary respondents including 47 percent of transgender or nonbinary respondents of color reported experiencing one form of denial by a health insurance company in the past year; • 28 percent of transgender or nonbinary respondents including 39 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender-affirming hormone therapy in the year prior; and • 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender affirming surgery in the year prior.

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SIECUS: Sexuality Information and Education Council of the United States

[Italics: Intersectional Discrimination][Often the discrimination that older adults experience in health care and HCBS is at the intersection of their identities as an older person and as a person with a disability, a person of color, a person with LEP, an LGBTQ+ person, and/or as a woman. For example, during focus groups Black and Latinx Medicare enrollees age 65 and older reported experiencing discrimination based on their multiple identities including their age like being both Black and a woman or being Latino and having LEP or an accent.[Footnote 15: The Commonwealth Fund, What an Ideal Health Care System Might Look Like: Perspectives from Older Black and Latinx Adults (Jul. 21 2021) www.commonwealthfund.org/publications/2021/jul-/what-ideal-health-care-system-might-look-like.] Many of the examples we share below and throughout this comment illustrate this intersection. Discrimination based on intersectional identities was not understood or considered or even ignored by the drafters of most civil rights laws including Title VI Section 504, Title IX, and the Age Act. So, after discrimination in both the administrative context and the courts has been viewed through the lens of one marginalized group. However, this is not the case for Sec. 1557. There is a reason Congress enacted a new Health Care Rights Law that is to bring these anti-discrimination protections under one enforceable authority. As health care civil rights experts have observed: "If Congress believed that Title VI already provided adequate protections against health care discrimination, the analogous part of Section 1557 would have proven unnecessary. Rather, Sec. 1557 provides an independent basis for protections from discrimination based on race, color, national origin, age, disability, and sex." [Footnote 16: Jamila Taylor, Fleta Wilson-Brooks, & Katie Keith, ACA Sec. 1557 As A Tool For Anti-Racist Health Care, Health Affairs (Dec. 8 2021) https://www.healthaffairs.org/do/10.1377/forefront.20211207.962085/full/,]

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Center on Aging

We also support strong enforcement of Section 1557 and the Department's reinterpretation in the preamble that the law protects people who experience intersectional discrimination. This encompasses individuals who experience health care discrimination at the intersection of two or more protected characteristics (for example some combination of sexism (e.g. people who are pregnant or capable of pregnancy or LGBTQIA+) racism xenophobia (e.g. people with limited English proficiency (LEP)) ableism or ageism. We urge the Department to provide greater clarity in the final rule regarding the protections and enforcement mechanisms available for intersectional discrimination under Section 1557. For example the Department should amend the proposed regulatory text at § 92.101(a)(1) to clarify that intersectional discrimination is prohibited. Specifically we recommend this provision to be amended as follows: [a] [1] [i] [A] General. "[1] Except as provided in Title I of the ACA an individual must not on the basis of race color national origin sex age disability or any combination thereof be excluded from participation in be denied the benefits of or otherwise be subjected to discrimination under any health program or activity operated by a covered entity. In addition §92.301 should ensure that the Department will have clear and accessible procedures for individuals to file and the agency to investigate and remediate discrimination complaints including intersectional discrimination complaints. The Department should also make clear throughout the final rule that Section 1557 creates a health specific anti-discrimination cause of action that is subject to a single standard regardless of a plaintiff's protected class or classes.

The preamble of the NPRM HHS recognizes that Sec. 1557 is its own statute enforceable by private right of action in the courts and is intended to address intersectional discrimination. We strongly urge HHS to identify ways to address intersectional discrimination in the regulatory provisions of the rule itself. [Id.] Specifically we recommend making an explicit reference to intersectional discrimination in the regulatory text of § 92.101. We propose amending § 131(a)(1) as follows: "Except as provided in Title I of the ACA an individual must not on the basis of race color national origin sex age or disability [underlined] or any combination thereof[]"

To better understand these disparities and challenges faced by the LGBTQIA+ community it is critical that we continue to strengthen non-discrimination policies such as Section 1557 that expand access to health insurance coverage. Under the Affordable Care Act. This is increasingly important in the current sociopolitical climate as states move to impose various restrictions on LGBTQIA+ individuals seeking access to sexual and reproductive health services. One such case is in Texas Braidwood Management Inc. v. Xavier Becerra et al. [Embedded Hyperlink #1 https://storage.courtlistener.com/recap/gov.uscourts.txnd.330361/gov.uscourts.txnd.330381.1.0.pdf] where a federal judge has ruled in favor. [Embedded Hyperlink text (https://www.texastribune.org/2022/09/07/texas HIV ACA wa. 1/1] of employers refusing to provide coverage for contraception and life saving antiretroviral drugs for HIV prevention also known as PrEP because doing so is against their religious beliefs. This decision comes after a 2020 federal mandate to require that this drug be provided free of charge. Moreover the plaintiffs of the case blatantly admitted that their reasoning was grounded in anti-LGBTQIA prejudice. Given that LGBTQIA communities have been disproportionately impacted by HIV/AIDS restricting access to PrEP inequitably impacts their health and well-being. This ruling highlights the necessity for non-discrimination clauses within health insurance coverage policies to protect these individuals from employers health insurers and providers who may refuse LGBTQIA affirming healthcare.

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Center for Reproductive Rights

Justice in Aging

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Covered California appreciates HHS's prioritization of equity as a foundational element in this proposed rule and its programs more broadly. Since its inception addressing health equity and disparities in health care has been integral to the mission of Covered California and central to its benefit design and LHP issuer counterability efforts. More recently Covered California has been working with Medi-Cal California's Medicaid health care program and the California Public Employees' Retirement System (CalPERS) the state's public employee health benefits purchaser to design our work on quality and equity. Covered California has also had longstanding contractual requirements for LHP issuers on demographic data collection. Our experiences may prove helpful for both federal and state efforts in this area.

IECHS Sex Ed for Social Change

Covered California

No comments are associated with this issue

Although a number of federal laws prohibit several forms of discrimination Section 1557 extends these protections to any health program or activity that receives federal funding any health program or activity that HHS administers the health insurance exchanges and all plans offered by insurers that participate in those marketplaces. This Proposed Rule not only clarifies the broad civil rights protections extended in Section 1557 but most importantly provides concrete tools to combat racism and other forms of discrimination in health care. First the Proposed Rule addresses various forms of discrimination that disproportionately affect communities of color including on the basis of disability status national origin and sex. Second the Proposed Rule addresses systemic discriminatory underlying policies and practices that harm people of color. Finally the Proposed Rule calls for vast enforcement authority across all segments of the health care system and related activities ensuring Section 1557's prohibition against race discrimination is adhered to across the country.

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Alliance of Multicultural Physicians

Black LGBTQ+ people also experience additional health care barriers due to their gender identity and/or transgender status. As noted in a recent report by the Center for American Progress Black LGBTQ+ people face high rates of discrimination from medical providers. [Footnote 33 Lindsay Mahowald Black LGBTQ Individuals Experience Heightened Levels of Discrimination CENTER FOR AM. PROGRESS (Jul. 13 2021) https://www.americanprogress.org/article/black-lgbtq-individuals-experience-heightened-levels-discrimination/.] Transgender people of color experience denial of care and medical abuse more frequently than white transgender people [Footnote 34 Care. Ne Medi-Ked et al. Protecting and Advancing Health Care for Transgender Adult Communities CENTER FOR AM. PROGRESS (Aug. 18 2021) https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/.] including for conditions such as asthma or diabetes. [Footnote 35 Id.]

NAACP Legal Defense and Education Fund, Inc.

Abortion restrictions further imperil Black American's health and deny their dignity. In Dobbs a conservative majority of the United States Supreme Court reversed nearly a half a century of legal precedent and stripped the constitutional right to bodily autonomy from over a hundred million people. [Footnote 37 Dobbs 597 U.S.] The proliferation of abortion restrictions after Dobbs will only exacerbate health inequities for Black Americans. Historically Black Americans have been denied control over their bodies their reproduction and their fertility. Howard University School of Law's Illuminate and Civil Rights Clinic contributed in its brief in Dobbs "During slavery Black women were denied all bodily autonomy; they were expressly endorsed the notion that they lacked humanity and could be 'bred' for their owner's profit." [Footnote 38 Br. for Howard U. Sch. of L. Hum. & Civ. Rts. Clinic Dobbs v. Jackson Women's Health 597 U.S. (2022) [No. 19-1392] at 3 available at https://reproductiverights.org/wp-content/uploads/2021/09/Black-Women-Protective-Liberty-Amicus-Brief.pdf.] Birth control gave Black people control over their health and their lives. [Footnote 39 Id. at 15.] "The ability to control whether to give birth is a fundamental component of freedom for all women. But for Black women whose procreation has been forced monetized and controlled since they arrived on American shores access to birth control represented a unique form of liberty." [.]

NAACP Legal Defense and Education Fund, Inc.

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when and how to become parents. For example women of color report that "some physicians brush off their fertility concerns assuming they can get pregnant easily emphasize birth control over procreation and may dissuade them from having children." [Footnote 40 ETHICS COMM. OF THE AM. SOC. FOR REPRODUCTIVE MEDICINE DISPARITIES IN ACCESS TO EFFECTIVE TREATMENT FOR INFERTILITY IN THE UNITED STATES: AN ETHICS COMMITTEE OPINION (2021) https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/disparities in access to effective treatment for infertility in the us-pdfmembers.pdf.] Additionally Black women are more likely to live in "contraceptive deserts" where pharmacies make it more difficult to purchase contraception [Footnote 41 Jennifer Barber et al. Contraceptive Deserts? Black-white differences in characteristics of nearby pharmacies J. RACIAL ETHNIC HEALTH DISPARITIES (August 2019) at /19 available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6660992/pdf/nihms1037159.pdf.] or to struggle to afford birth control. [Footnote 42 Clarrita Bellamy Black women are underserved when it comes to birth control access: The Roe decision could make that worse NBC NEWS (June 30 2022 3:50 AM) https://www.nbcnews.com/news/nbcblk/black-women-are-underserved-comes-birth-control-access-roe-decision-rcna35924; Planned Parenthood Who's Most Impacted by Attacks on Birth Control https://www.plannedparenthoodaction.org/fight-for-birth-control/facts/whos-most-impacted-by-attacks-on-birth-control (last visited Sept. 23 2022).] Moreover even before Dobbs existing abortion restrictions in many states which had caused numerous barriers to care forced people to travel further for abortion care. [Footnote 43 Bellamy supra note 42.] Because Black people are less likely to have health insurance that covers abortion and are often less able to cover the [illegible] communities. As of August 16 2022 most abortions are now banned in 13 states and five more states are expected to do so by no later abortion imminently. Footnote 45 Caroline Kitchener et al. Abortion is banned in these states. Mapping abortion law changes by state. Wash. Post https://www.washingtonpost.com/politics/2022/06/24/abortion-state-laws-timeline-roe/ (last visited Sept. 23 2022).] Accordingly an estimated ten million Black women of childbearing age now face restrictions on abortion. Footnote 46 Tayo Holmason & Kelsey Butler Black Women Are Hardest Hit by Abortion Restrictions Sweeping the Deep South BLOOMBERG (Aug. 23 2022 7:00 AM ET) https://www.bloomberg.com/news/articles/2022-08-23/black-women-are-hardest-hit-by-abortion-restrictions-sweeping-the-deep-south?leadSource=uverify%20wall [Delays and denials of abortion care hurt Black American's health. Since Dobbs there have been several reports of people experiencing pregnancy complications necessitating abortion but being unable to access care. [Footnote 47 Carrie Feibel Because of Texas Abortion Law Her Wanted Pregnancy Became a Medical Nightmare NPR (Jul. 26 2022) https://www.npr.org/sections/health-shots/2022/07/26/1111280165/because-of-texas-abortion-law-her-wanted-pregnancy-became-a-medical-nightmare] Without adequate access to abortion care more people are likely to die from pregnancy related complications. For example at some hospitals in Texas short on care for patients with ectopic pregnancies a dangerous and life-threatening condition which occurs when a fertilized egg attaches outside of the uterus is being delayed to avoid violating the state's law that was triggered after the Dobbs decision. [Footnote 48 Associated Press Texas Hospitals Delaying Care Over Violating Abortion Law PBS NEWS HOUR (July 13 2022) https://www.pbs.org/newshour/nation/texas-hospitals-delaying-care-over-violating-abortion-law.] A 2021 study by the University of Colorado estimated

Bench C. Discrimination On The Basis Of Pregnancy-Related Conditions And the Impact of [Italics: Dobbs]] In the Proposed Rule HHS correctly recognizes that discrimination on the basis of pregnancy or its related conditions is a form of sex discrimination that impacts healthcare access. 87 Fed. Reg. at 47832. Where patients are denied medication treatment or even information these actions can result in serious health consequences. Id. As HHS recognizes access to healthcare is unique particularly for those who experience intersectional discrimination such as people of color and those with disabilities. Id.

While the proposed rule does not have specific provisions related to discrimination based on race and color we'd like to emphasize the importance of protecting individuals from this discrimination and the compounding impact race and color can have on intersectional discrimination. We're encouraged the agency to acknowledge this intersectional nature of discrimination in the final rule. Discriminatory health care systems and policies play an outsized role in the ability of people of color to access quality health care in the United States. Given the deep legacy of racism and other forms of discrimination in health systems and health policy Section 1557 of the Affordable Care Act is a significant step towards rectifying centuries of policies and practices that have created worse health outcomes for underserved groups. We would encourage language in the final rule be crafted in a way to prohibit discrimination that worsens or creates racial health disparities while not limiting affirmative actions that may be needed to fully and sufficiently address our current existing racial health disparities [illegible] has on our patients and the communities we care for overall. But we must also acknowledge the role providers have played in perpetuating discrimination. There is a growing body of research that demonstrates the negative health consequences of discrimination on an individual's overall health and well-being [embedded hyperlink text https://www.aoa.org/news/press/releases/stress/2015/impact]. For example experiences of racism and discrimination has been shown to cause psychological distress including depression and increased anxiety hypertension and adverse cardiovascular events [embedded hyperlink text https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6557496/)] and poor maternal health outcomes particularly for Black women [embedded hyperlink text https://www.nhlbi.nih.gov/news/2021/systemic-racism-key-risk-factor-maternal-health-and-illness]. The continued presence of discrimination in our health care systems also interferes with the trust necessary for the patient-provider relationship. Instances of discrimination discourage people from seeking essential care and can have long-term consequences harming the health and well-being of individuals families and communities. Discrimination in health care is an ongoing problem. For example according to research conducted by the Commonwealth Fund [embedded hyperlink text https://www.commonwealthfund.org/publications/issue-briefs/2022/apr/how-discrimination-in-health-care-affects-older-americans]] Black people were most likely to report racial discrimination in a health care setting with 44 percent of Black people reporting this happens often or very often [embedded hyperlink text https://patientengagementhit.com/news/one-quarter-of-adults-report-social-discrimination-in-healthcare]. Regardless of gender it is also well documented that structural racism and discrimination in our health care settings contributes to increased maternal mortality with Black women three to four times more likely

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NAACP Legal Defense and Education Fund, Inc

NAACP Legal Defense and Education Fund, Inc

Attorneys General of California, New York, Massachusetts, and nineteen other States

American Academy of Pediatrics

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Physicians for Reproductive Health

American Progress "reveal that LGBTQ+ communities encounter discrimination and other challenges when interacting with health care providers and health insurers underscoring the importance of strengthening nondiscrimination protections through Section 1557 of the Affordable Care Act." [Hyperlink: https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/] Key findings from the report include: - 23 percent of LGBTQI+ respondents including 27 percent of LGBTQI+ respondents of color reported that in the past year they postponed or avoided getting needed medical care when sick or injured due to disrespect or discrimination from doctors or other health care providers: - Overall 15 percent of LGBQ respondents including 23 percent of LGBQ respondents of color reported experiencing some form of care refusal by a doctor or other health care provider in the year prior; - Overall 32 percent of transgender or nonbinary respondents including 46 percent of transgender or nonbinary respondents of color reported that they experienced at least one kind of care refusal by a health care provider in the past year; - 55 percent of intersex respondents reported that in the past year a health care provider refused to see them because of their sex characteristics or intersex variations; - Overall 30 percent of transgender or nonbinary respondents including 47 percent of transgender or nonbinary respondents of color reported experiencing one form of denial by a health insurance company in the past year; - 28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender-affirming hormone therapy in the year prior; and - 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender-affirming surgery in the year prior Our youth face increased

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Colorist

It is also important to note that Americans of color continue to face significant structural barriers to healthcare access Our 2022 report Our Collective Future: The Economic Impact of Unequal Life Expectancy [embedded hyperlink text https://www.aarp.org/content/dam/aarp/research/surveys_statistics/econ/2022/longevity-economy-disparities-life-expectancy.doi.10.26419-2Fint.00042.008.pdf] found that people of color disproportionately live in communities with inadequate health care dealing with bias in encounters with healthcare providers and receive poorer quality care in nursing homes. These disparities rob individuals of what they need to maintain good health and live longer healthier lives by decreasing overall mortality and they stifle the overall economy causing all Americans to suffer as a result. Our findings project 5.8 million premature deaths and an overall annual economic cost that may exceed $1 trillion by 2050 due to these inequities in health care access

AARP

Italics Dobbs] We expect a stark increase in prosecutions for self-managed abortion; [key other pregnancy outcomes such as miscarriage will also be the subject of prosecution. [Footnote 25: There have been over 60 documented cases of people being criminally arrested or investigated for self managing abortion or assisting someone else obtain an abortion. Laura Huss Self-Managed Abortion is Not Illegal in Most of the Country but Criminalized on Weapons Anyway [If/When/How (Aug. 9 2022)] https://www.ifwhenhow.org/abortion-criminalization-new-research/; Robert Ballow Losing a Pregnancy Could Land You in Jail in Post Roe America NPR [Jul. 5 2022] https://www.npr.org/2022/07/03/1103015302/abortion-prosecuting-pregnancy-loss [interviewing legal experts from If/When/How and the National Advocates for Pregnant Women]; If/WHEN/HOW FULFILLING ROE'S PROMISE 2019 UPDATE [2019] https://www.fwhenhow.org/resources/roes-unfinished-promise-2019-update/; Jeong Paltrow & Flavin Arrests of and Forced Interventions on Pregnant Women in the United States 1973 2005 Implications for Women's Legal Status and Public Health 38 J. Health Politics Policy & Law 299 [2013]; Sandhya Dorle Criminalization of Pregnancy has Already Been Happening to the Poor and Women of Color NPR [Aug. 3 2022] https://www.npr.org/2022/08/03/1114381477/criminalization-of-pregnancy-has-already-been-happening-to-the-poor-and-women-of [including expert accounts of the intersection of criminalization and pregnancy outcomes for people of color] With at least thirteen states where abortion is already illegal criminalization pregnant people are under increased surveillance and treated with heightened suspicion [Footnote 26: This has already occurred while the protections of Roe were in effect. Pregnant people have been investigated penalized and even incarcerated where there's a suspicion that a person was responsible for the termination of their pregnancy. See Brief for If/When/How: Lawyering for

Center for Reproductive Rights

of disaggregated demographic data supports the department's enforcement efforts. We commend the department for recognizing the critically important role demographic data plays in addressing discrimination and health disparities. Footnote 18: Fed. Reg. at 47896 7] However we are concerned the department does not at minimum require covered entities to collect disaggregated demographic data. Better national standards and uniform data collection practices could have an outsized impact on efforts to narrow health disparities. HHS must require demographic data collection based on multiple demographic variables including sex race ethnicity primary language age gender identity sexual orientation and disability status. At the community and population levels these variables both individually and in combination can reveal health disparities. For example racial and ethnic minority women receive poorer quality care than racial and ethnic minority men who receive poorer care than White men. [Footnote 19: Rosaly Correa de Araujo et al. Gender differences across racial and ethnic groups in the quality of care for acute myocardial infarction and heart failure associated co-morbidities Women's Health Issues 44 [2006]; Ann F. Chou et al. Gender and racial disparities in the management of diabetes mellitus among Medicare patients Women's Health Issues 150 [2007].] Spanish-speaking Hispanics experience poorer quality care than English-speaking Hispanics who experience poorer care than non-Hispanic Whites. [Footnote 20: Eric M. Cheng Alex Chen & William Cunningham Primary language and receipt of recommended health care among Hispanics in the United States J. General Internal Medicine 288 [2007]; C. Arnette Dubbard & Ziya Gize Language spoken and differences in health status access to care and receipt of preventive services among U.S. Hispanics Am. J. Public Health 2021 (2008).] Compared to women without disabilities women with disabilities are more likely not to have regular mammograms or Pap tests. Footnote 21: Marguerite L. Diab & Mark V. Johnston Relationships between level of educational peoples of color are [bold/underlined] half as likely to be diagnosed] or receive eating disorders treatment than their white counterparts. Specifically the Trevor Project's [underlined/bold] new report found] indigenous and multiracial LGBTQI+ youth report the highest rates of eating disorder diagnosis at 32% and 30% respectively with an additional one third of each group suspecting they had an eating disorder. Further Black LGBTQI+ youth are diagnosed at half the rate of white LGBTQI+ youth despite sharing similar rates of eating disorder suspicion

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The Leadership Conference on Civil and Human Rights

Eating Disorders Coalition for Research Policy & Action

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Overall the LGBTQIA+ community experiences many challenges when interacting with healthcare providers and health insurers according to a report [embedded hyperlink text (https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtq-communities/)] by Center for American Progress. Key findings from the report include - 23 percent of LGBTQ+ respondents including 27 percent of LGBTQIA+ respondents of color reported that in the past year they postponed or avoided getting needed medical care when sick or injured due to disrespect or discrimination from doctors or other health care providers,- Overall 15 percent of LGBQ respondents including 23 percent of LGBQ respondents of color reported experiencing some form of care refusal by a doctor or other health care provider in the year prior; Overall 32 percent of transgender or nonbinary respondents including 46 percent of transgender or nonbinary respondents of color reported that they experienced at least one kind of care refusal by a health care provider in the past year;- 55 percent of intersex respondents reported that in the past year a health care provider refused to see them because of their sex characteristics or intersex variation. Overall 30 percent of transgender or nonbinary respondents including 47 percent of transgender or nonbinary respondents of color reported experiencing one form of denial by a health insurance company in the past year;- 28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender-affirming hormone therapy in the year prior, and - 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender affirming surgery in the year prior.

These problems persist in 2022. Data in a [bold/underlined; new report] from the Center for American Progress "reveal that LGBTQIA+ communities encounter discrimination and other challenges when interacting with healthcare providers and health insurers underscoring the importance of strengthening nondiscrimination protections through Section 1557 of the Affordable Care Act." Key findings from the report include - 23 percent of LGBTQIA+ respondents including 27 percent of LGBTQIA+ respondents of color reported that in the past year they postponed or avoided getting needed medical care when sick or injured due to disrespect or discrimination from doctors or other health care providers, Overall 15 percent of LGBQ respondents including 23 percent of LGBQ respondents of color reported experiencing some form of care refusal by a doctor or other health care provider in the year prior;-Overall 32 percent of transgender or nonbinary respondents including 46 percent of transgender or nonbinary respondents of color reported that they experienced at least one kind of care refusal by a health care provider in the past year;55 percent of intersex respondents reported that in the past year a health care provider refused to see them because of their sex characteristics or intersex variation -Overall 30 percent of transgender or nonbinary respondents including 47 percent of transgender or nonbinary respondents of color reported experiencing one form of denial by a health insurance company in the past year, 28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender-affirming hormone therapy in the year prior; and 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender affirming surgery in the year prior.

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health care is well documented [Footnote 28: Jamille Fields Allsbrook & Katie Keith ACA Section 1557 As A Tool for Anti-Racist Health Care Health Affairs (Dec. 8 2021) https://www.healthaffairs.org/do/10.1377/forefront.20211207.962085/full/] and older adults are harmed by it in multiple ways. Analysis of Medicare enrollee shows that compared to white enrollees people of color are more likely to report being in relatively poor health more likely to have certain chronic conditions such as hypertension and diabetes less likely to have one or more doctor visit but have higher rates of hospital admissions and emergency department visits [Footnote 29: Kaiser Family Found. Racial and Ethnic Health Inequities and Medicare (Feb. 16 2021) https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.]Racism that leads to disparate care in testing and treatment for certain conditions such as heart disease [Footnote 30: Amber Johnson Understanding Why Black Patients Have Worse Coronary Heart Disease Outcomes: Does the Answer Lie in Knowing Where Patients Seek Care? Journal of the American Heart Association (Nov. 30 2019) https://www.ahajournals.org/doi/10.1161/JAHA.119.014278] and end-stage renal disease [ESRD] [Footnote 31: CDC Chronic Kidney Disease Surveillance System] disproportionately harms older adults who are at higher risk for such conditions. As one example Blacks and Latinos with ESRD are less likely than their white counterparts to have timely referral to nephrologists pre-dialysis nephrology care adequate dialysis education and planned dialysis initiation. They are also less likely to receive home dialysis. [Footnote 32: Natasha Persaud Racial Disparities in Home Dialysis Use Documented Renal & Urology News (Apr. 20 2022) https://www.renalandurologynews.com/home/news/nephrology/chronic-kidney-disease-ckd/racial-disparities-home-dialysis-less-likely-in-black-and-hispanic-vs-white-patients/.]

Another form of harm is when victims of racial discrimination experience poorer health outcomes in old age. For example studies have shown that Black and Latino people who experience racial discrimination have higher rates of cognitive decline. [Footnote 33: Univ. of Tx at Austin Cognitive Impairment in Hispanic Adults linked to Discrimination Experiences (Sept. 19 2022) https://news.utexas.edu/2022/09/19/cognitive-impairment-in-hispanic-adults-linked-to-discrimination-experiences/] This helps explain why Black and Latino older adults have higher rates of Alzheimer's and related dementias compared to non-Hispanic white older adults. Discrimination throughout the lifetime also causes "weathering" [Footnote 34: Arah Sandow "Weathering": What are the health effects of stress and discrimination? (Feb. 26 2021)https://www.medicalnewstoday.com/articles/weathering-what-are-the-health-effects-of-stress-and-discrimination] and a lower life-expectancy. Recent plunges in overall life expectancy were most severe among people of color. They have died at younger ages during the COVID-19 pandemic than white Americans due to structural racism that pervades our healthcare social support and economic systems. One shocking example is the drop in life expectancy for Native American/Alaska Native people which fell by 6.6 years from 2019 to 2021 [Footnote 35: CDC Life Expectancy in the U.S. Dropped for the Second Year in a Row in 2021 (Aug. 2022) https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/20220831.htm]

Other biases result in disparate harm to older adults of color. For example many providers do not accept or limit their intake of patients with Medicaid [Footnote 36: Kayla Hodgeson & Martha Heberlein Physician Acceptance Of New Medicaid Patients: What Matters And What Doesn't Health Affairs (Apr. 10 2019) https://www.healthaffairs.org/doi/10.1377/hblog20190401.878580/full/. MACPAC Physician Acceptance of New Medicaid Patients: Findings from the National Electronic Health Records Survey (June 2021) https://www.macpac.gov/wp-content/uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf ;" In 2017 (the most recent year available) physicians were significantly less likely to accept new patients insured by Medicaid (74.3 percent) than those with Medicare (87.8 percent) or private insurance (96.1 percent) "] which impacts access to care for older adults of color the most as these communities are disproportionately dually eligible for Medicaid and Medicare. [Footnote 37: Kaiser Family Foundation Racial and Ethnic Health Inequities and Medicare (Feb 16 2021) https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/] Even providers who accept Medicare may refuse to see someone who is dually enrolled in Medicaid because Medicaid billing may present some additional administrative burdens and providers do not want to forgo the co-insurance that the individual is not required to pay and that the state usually does not pay due to the "lesser of" policy

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[bold/underlined: LGBTQI+ individuals] experience higher levels of stigma and that shame concealment of one's sexual identity and discrimination leads to an increased rate of eating disorders. For LGBTQI+ youth the research is even more bleak. LGBTQI+ youth report [add/underlined: higher levels] of sexual minority specific distress and depressive symptoms and suicidality compared to their heterosexual peers. It is estimated that LGBTQI+ youth that are diagnosed with an eating disorder are [bold/underlined: four times more likely to attempt suicide] than LGBTQI+ youth who never had or suspected they had an eating disorder.

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system. Black Americans have long confronted inequities in health care access, treatment and outcomes. These disparities are particularly acute for Black pregnant and LGBTQI+ people and weaken society as a whole. Redlining and other discriminatory practices have fostered ongoing residential segregation that has kept Black Americans in under-resourced neighborhoods, left generations of Black communities disproportionately exposed to health hazards and denied them equal access to health care. [Footnote 11 See generally ELIZ SHAPIRO ET AL., LOCATHURGOOD MARSHALL INSTITUTE, NYU SCHOOL OF LAW, BRENNAN CENTER FOR JUSTICE AT NYU SCHOOL OF LAW, THE BLACK-WHITE RACIAL WEALTH GAP [2019], https://thurgoodmarshall.nyu.edu/wp-content/uploads/2019/11/FINAL-RWG-Brief-v1.pdf.] Because redlined neighborhoods were often chosen as the sites for new factories or highways, people of color are more likely to live in polluted areas and bear environmental hazards. [Footnote 12 Laura Wamsley, Even many decades after redlining, areas see higher levels of air pollution, NPR (Mar. 30, 2022), https://www.npr.org/2022/03/30/1085882933/redlining-pollution-race-gap; Darrell Cusick, Past Racist "Redlining" Practices Increased Climate Burden on Minority Neighborhoods, SCIENTIFIC AM. (Jan. 27, 2020), https://www.scientificamerican.com/article/past-racist-redlining-practices-increased-climate-burden-on-minority-neighborhoods/; SHAPIRO ET AL., supra note 11, at 13.] Furthermore, until the 1960s, hospitals were rigidly segregated and unequal. [Footnote 13 David Barton Smith, The Politics of Racial Disparities: Desegregating the Hospitals in Jackson, Mississippi, M. LEBANK Q., Jan. 2005, at 24, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690142/.] While hospitals are now integrated, Black Americans still do not have equal access to health care facilities. Predominantly Black racially-isolated neighborhoods are more likely to be in primary care deserts and "offer fewer ambulatory facilities, more limited access to physicians and a lower supply of surgeons." [Footnote 14 Mariana L.

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are due to racial bias. A 2003 literature review by the National Academy of Medicine found that people of color were less likely than white people to receive appropriate cardiac care; kidney dialysis or transplants; and are often also denied the most successful treatments for stroke, cancer, or AIDS. [Footnote 17 H. Jack Geiger, Racial and Ethnic Disparities in Diagnosis and Treatment: A Review of the Evidence and a Consideration of Causes, INSTITUTE OF MEDICINE COMMITTEE ON UNDERSTANDING AND ELIMINATING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE, UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE, WASHINGTON (DC): NATIONAL ACADEMIES PRESS, [Brian D. Smedley et al. eds., 2003], available at https://www.ncbi.nlm.nih.gov/books/NBK220037/.] The literature review further concludes that "provider and institutional bias are significant contributors" to health inequities. [Footnote 18 Id.] A 2016 study similarly found that some medical students and medical residents hold false beliefs about biological differences between Black people and white people, leading them to discount Black patients' pain and make less accurate treatment recommendations. [Footnote 19 Kelly M. Hoffman et al., Racial Bias in Pain Assessment and Treatment Recommendations, and False Beliefs About Biological Differences Between Blacks and Whites, 113 PROC. OF THE NAT'L ACAD. OF SCI. 4296, 4301 (2016), https://www.pnas.org/doi/10.1073/pnas.1516047113.] These disparities persist today, as noted in the NIH's 2021 National Health Care Quality and Disparities Report which found that Black people received worse care than white people across 45 percent of 139 quality measures. [Footnote 20 U.S. DEP'T OF HEALTH & HUMAN SERVS., AGENCY FOR HEALTHCARE RES. & QUALITY, 2021 NATIONAL HEALTHCARE QUALITY & DISPARITIES REPORT EXECUTIVE SUMMARY, 2020) at ES-3 0-3-0-51, https://www.ahrq.gov/sites/default/files/wysiwyg/research/

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This disparate treatment by medical providers as well as systemic disparities in health care needs and access are often reproduced by the clinical algorithms providers increasingly rely on to help diagnose and treat patients. For example, although Black Americans are four times more likely to have kidney failure, the standard algorithm used around the country to determine transplant list placement explicitly uses race as a factor and puts Black patients lower on the chart than white patients even when all other factors remain identical. [Footnote 21 Rae Ellen Bichell & Cara Anthony, Kidney Experts Say It's Time to Remove Race From Medical Algorithms, Doing So Is Complicated, HEALTH AFFAIRS, (June 8, 2021), https://khn.org/news/article/black-kidney-patients-racial-health-disparities/?utm_campaign=KHN%3A+Daily+Health+Policy+Report&utm_medium=email&_hsmi=135948885&_hsenc=p2ANqtz-8ODaaeKPHQSQeAfiCeyLxAbaGTNgUloFyX4KUJptvaQDUyan8RyLCujUa8kMR623a6e7lV0KBUtZgGVacR1yNbzQ_Tts4lcRnHP2vMJLzeQ&utm_content=132394588&utm_source=hs_email.' Many doctors now believe that the data that led the algorithm's developers to incorporate race coefficient is actually a reflection of both systemic health disparities and discrimination by providers, and that the continued use of the algorithm leads to worse outcomes for Black patients. [Footnote 22 Id.] A 2013 study similarly found that algorithms used to identify sicker patients who would benefit from additional care led to Black patients receiving less quality care than their non-Black counterparts. [Footnote 23 Starre Vartan, Racial Bias Found in a Major Health Care Risk Algorithm, SCI. AM. (Oct. 24, 2013), https://www.scientificamerican.com/article/racial-bias-found-in-a-major-health-care-risk-algorithm/.]

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Disproportionate exposure to health hazards and discrimination by health care providers, including through the use of clinical algorithms, create vast disparities in health outcomes for Black people. Black people have higher rates of diabetes, hypertension, and heart disease than other groups. [Footnote 24 Rina Lavizzo-Mourey & David Williams, Being Black Is Bad for Your Health, U.S. NEWS, (Apr. 14, 2016), https://www.usnews.com/opinion/blogs/policy-dose/articles/2016-04-14/theres-a-huge-health-inequity-gap-between-white-and-black-americans.] Black infants die at a rate 2.3 times higher than white infants. [Footnote 25 U.S. Dep't of Health & Human Svcs., Office of Minority Health, Infant Mortality and African Americans, https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=23#:~:text=Non%2DHispanic%20Black%2FAfrican%20American%20to%20non%2Dhispanic%20white%20infants (last visited Sept. 23, 2022).] And Black children have a 500% higher death rate from asthma compared with white children. [Footnote 26 Lavizzo-Mourey & Williams, supra note 24.] Black people and other people of color were also more likely to be hospitalized and die due to COVID-19. [Footnote 27 Centers for Disease Control, Risk for COVID-19 Infection, Hospitalization, and Death By Race/Ethnicity, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html (last visited Sept. 23, 2022).] As a result, even before the pandemic, Black Americans' life expectancy was four years lower than that of white Americans. [Footnote 28 Centers for Disease Control, Life expectancy at birth, age 65, and age 75, by sex, race, and Hispanic origin: United States, selected years 1900–2018 (2019), https://www.cdc.gov/nchs/data/hus/2019/004-508.pdf.]

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Improving health care access for people with disabilities can also help reducing health disparities which are often compounded by pervasive ableism and intersecting systems of discrimination. For example, Black people are more likely to have a disability relative to White people in every age group and, according to the Centers for Disease Control and Prevention, three in 10 American Indian/Alaska Native people and one in four Black people live with disabilities. [Footnote 6 "Adults with Disabilities: Ethnicity and Race," Centers for Disease Control and Prevention, 16 Sept. 2020, https://www.cdc.gov/ncbddd/disabilityandhealth/materials/infographic-disabilities-ethnicity-race.html.] Additionally, older adults with disabilities often experience discrimination based on both ageism and ableism.

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Black Americans confront particularly stark disparities in maternal health outcomes. Pregnant women of color are often subjected to discrimination throughout pregnancy and the postpartum period including mistreatment during labor and delivery. [Footnote 29 Saraswathi Vedam et al. The Giving Voice to Mothers study: inequity and mistreatment during pregnancy and childbirth in the United States. Reproductive Health (June 2019) https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-019-0729-2.] People of color are also more likely to experience certain birth risks and adverse birth outcomes. [Footnote 30 Samantha Artiga et al. What are the implications of the Overturning of Roe v. Wade for Racial Disparities? Kaiser Family Foundation (July 19 2022) https://www.kff.org/racial-equity-and-health-policy-issue-brief/what-are-the-implications-of-the-overturning-of-roe-v-wade-for-racial-disparities/.] As a result Black women are three-to-four times more likely to die from pregnancy-related complications than white women. [Footnote 31 Donna L. Hoyert Centers for Disease Control Maternal Mortality Rates in the United States 2020 https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm.] According to a recent study by the CDC many of these deaths are preventable. [Footnote 32 Nada Hassanein 'Staggering' and 'sobering': More than 80% of US maternal deaths are preventable CDC study shows USA TODAY (Sept. 19 2022 1:53 PM) https://www.usatoday.com/story/news/health/2022/09/13/cdc-us-maternal-deaths-preventable/10412527002/.]

between individuals and the health care system. The denial of adequate language services to LEP individuals constitutes discrimination based on national origin. The lack of communicating in a person's preferred language leads to people who are otherwise eligible not enrolling in programs and/or not receiving timely or comprehensive health care. CCJ provides assistance to applicants and beneficiaries in enrolling and maintaining Medicaid coverage and works closely with the Spanish-speaking community. Despite the fact that Medicaid applicants can indicate their preferred language in the MI Bridges system applicants and beneficiaries routinely do not receive notices in their preferred language. In 2021 CCJ sent MDHHS a Freedom of Information Act (FOIA) request asking for any MDHHS forms notices or letters that were translated into Spanish. In response MDHHS sent several generic documents that were intended to be used for Spanish-speaking applicants. Notably only the non-discrimination section was translated into Spanish. The action taken in the case including whether an individual was approved or denied a benefit was not translated. In addition the individual's hearing rights were not translated. In its response MDHHS noted that "The documents are primarily in English. When a Spanish is selected in Bridges as the primary language the only change is an additional page is added in Spanish. Case actions for Medicaid are produced on a DHS 1606 that the ALDHS 3605 [are] are not provided in Spanish." That same year CCJ filed a complaint with the Office of Civil Rights. That investigation is ongoing. CCJ requested an update on its complaint in 2021 and was told that MDHHS agreed to translate the Appointment Notice Verification Checklist Notice of Case Action and Medicaid Notice of Case Action in Spanish and Arabic by February 2022. CCJ followed up on the status in 2022 and was told that OCR was still getting information on about the implementation of the translation of documents from MDHHS. CCJ recently assisted Spanish-speaking individuals and noted that they received these notices according to data from the Department of Labor's 2020 National Agricultural Workers Survey approximately 55% of U.S. farmworkers reported limited English proficiency. [Footnote 1: U.S. Department of Labor Findings from the National Agricultural Workers Survey 2018 2020 (NAWS) published January 2022 available at https://www.dol.gov/sites/dolgov/files/ETA/naws/pdfs/NAWS%20Research%20Report%2016.pdf] About two-thirds of farmworkers are most comfortable conversing in Spanish a growing number are from indigenous communities who may be limited Spanish proficient. [Footnote 2. IBID] Farmworkers often identify language access as a primary barrier to health care. During the COVID-19 pandemic the lack of culturally and linguistically appropriate information impacted farmworker vaccination rates and COVID-19 treatment. We therefore focus our comments on the language access provisions of the 2022 proposed rule.

Every day our organizations hear from consumers across the state who face challenges accessing equitable affordable high quality health coverage and care. We hear from people for whom English is not their primary language seeking culturally and linguistically competent health care services. We hear heart-wrenching stories from people who need access to timely and compassionate abortion services. We hear from people of various genders including transgender people who already have trouble finding the gender affirming coverage and care they seek. We hear from people with disabilities who face overwhelming obstacles to find all the services they need to remain in the community. These are real people who already encounter barriers to accessing the health care services and supports they need. HLA and HLA believe in the critical importance of ensuring that all people can obtain equitable high quality affordable health care without facing discriminatory barriers. The nondiscrimination requirements of the Affordable Care Act (§ 1557 are critical to ensuring the health and well-being of our communities. We support the administration in strengthening this provision of the ACA and make the below recommendations to further guarantee the robust implementation of the law.

Although a number of federal laws prohibit several forms of discrimination Section 1557 extends these protections to any health program or activity that receives federal funding any health program or activity that HHS administers and health insurance exchanges and all plans offered by insurers that participate in those marketplaces. This Proposed Rule not only clarifies the broad civil rights protections extended in Section 1557 but most importantly provides concrete tools to combat racism and other forms of discrimination in health care. First the Proposed Rule addresses various forms of discrimination that disproportionately affect communities of color including on the basis of disability status national origin and sex. Second the Proposed Rule addresses systemic discrimination including policies and practices that harm people of color. Finally the Proposed Rule calls for vast enforcement authority across all segments of the health care system and related activities ensuring Section 1557's prohibition against race discrimination is adhered to across the country.

Children with immigrant parents groups that face persistent discrimination in accessing health care represent the fastest growing segment of the US population. One in every four children in the United States approximately 18 million children lives in an immigrant family. [Footnotes xxvi and xxvii: Julie M. Linton Andrea Green COUNCIL ON COMMUNITY PEDIATRICS Lance A. Chilton James H. Duffee Kimberley J. Dilley J. Raul Gutierrez Virginia A. Keane Scott D. Krugman Carla D. McKelvey Jacqueline L. Nelson. Providing Care for Children in Immigrant Families. Pediatrics September 2019; 144 (3): e20192077 10.1542/peds.2019-2077; https://datacenter.kidscount.org/data/tables/115-children-in-immigrant-families?loc=1&loct=1&selected/1/any/false/1729/3787,1870,573,869,436,868,868,713,any/4454,6] Children in immigrant families are less likely to be insured compared to children of nonimmigrant families. Further the chilling effect from the former Administration's public charge rule has contributed to increased fear among immigrant families about participating in programs and seeking services including health coverage and care. This chilling effect continues despite new rules published by the Biden Administration. Even when immigrant children and families can access health care providers they face further obstacles when language barriers prevent effective communication between pediatricians children and families on medical issues. Although many immigrant children speak English their parents may not creating a barrier that can prevent families from accessing needed health services and/or causing inadequate communication with health care providers. In fact parental limited English proficiency is associated with worse health care access and quality for children. [Footnote xxviii: Julie M. Linton Andrea Green COUNCIL ON COMMUNITY PEDIATRICS Lance A. Chilton James H. Duffee Kimberley J. Dilley J. Raul Gutierrez Virginia A. Keane Scott D. Krugman Carla D. McKelvey Jacqueline L. Nelson: Providing Care for Children in

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Genesee County Legal Aid Society dba Center for Civil Justice

Farmworker Justice

Health Care For All

Alliance of Multicultural Physicians

American Academy of Pediatrics

|Bold: D Protections for Individuals with Limited English Proficiencies|Over 67 million people in the United States speak a language other than English at home and of those approximately 25 million may be considered LEP. Footnote 54: See Karen Ziegler & Steven A. Camarota Center for Immigration Studies 62 3 Million in the United States Spoke a Foreign Language at Home in 2018 at 2 |2019| https://cis.org/Report/673- Million-United-States-Spoke-Foreign-Language-Home-2018.' The States have an interest in ensuring that our populations of LEP individuals have meaningful access to health programs and activities despite language related barriers. Footnote 54: Several of the undersigned States are among the states with the highest share of populations speaking a foreign language at home including California |45 percent| New Mexico |34 percent| New Jersey |32 percent| New York and Nevada |each 31 percent| Hawaii |28 percent| and Massachusetts |24 percent| Id at 5. Several other States have experienced dramatic increases in the number of LEP individuals in their States including Nevada (up 108 percent) North Carolina (up 102 percent) Washington (up 432 percent) and Oregon (up 383 percent| Id at 6.] Indeed it is well-known that language related barriers can severely limit an individual's opportunity to access healthcare services assess options express choices follow medical instructions ask questions and seek assistance |Footnote 55: Nat l Health Law Program & Access Project Language Services Action Kit at 40 |2004) https://www.commonwealthfund.org/sites/default/files/documents/media_files_publications_fund_report_2002_may_providing_language_interpretation_services_in_health_care_settings_examples_from_the_field_ny_action_kit_report_3204_pdf.pdf |

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includes a determination based on the linguistic characteristics of a national origin group." 81 Fed Reg at 31467 470 71. HHS emphasized that Congress intended through Section 1557 to have effective ways to eliminate disparities in healthcare including through the use of language services |Footnote 56: Rose Chu et al. U S Dep't of Health & Human Servs ASPE Research Brief: The Affordable Care Act and Asian American and Pacific Islanders at 1 (May 1 2014) https://aspe.hhs.gov/sites/default/files/private/pdf/92346/rb.pdf. U.S. Dep't of Health & Human Servs. HHS Action Plan to Reduce Racial and Ethnic Health Disparities at 15 17 19-20 |2015| https://aspe.hhs.gov/reports/hhs-action-plan-reduce-racial-ethnic-health-disparities-implementation-progress-report-2011-2014-0.' Therefore in order to "ensure that [health programs and activities] aimed at the American public do not leave some behind simply because they face challenges communicating in English" Id at 31410 HHS provided specific protections to guarantee meaningful access to healthcare for LEP individuals. Id at 31431 31. Footnote 57: In connection with the 2016 Rule HHS credited substantial evidence submitted to the agency that LEP individuals with access to adequate language assistance services "experience treatment related benefits such as enhanced understanding of physician instruction shared decision-making provision of informed consent adherence with medical orders preventive testing appointment attendance and follow up compliance" and that providers also benefit by the ability to "more confidently make diagnoses prescribe medications reach treatment decisions and ensure that treatment plans are understood by patients" 81 Fed Reg at 31459 | Yet the 2020 Rule gutted the 2016 Rule's robust language access provisions In particular the 2020 Rule eliminated the notice and tagline requirements removed a requirement that interpreters be "qualified" and reiterated the "meaningful access" requirement In doing so HHS cited the financial and administrative burden associated with

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proficiency |LEP| Linguistic access has long received legal protection. Since 1964 Title VI of the Civil Rights Act has guaranteed that no one may be discriminated against in federal programs based on their race color or national origin More recently additional civil rights protections have been implemented including Executive Order 13166 which aimed to improve access to federal programs and federally assisted activities for persons who as a result of national origin have limited English proficiency Section 1557 extends earlier civil rights protections to any health program or activity receiving federal financial assistance or any program or activity administered by an Executive Agency or any entity established under the ACA More than 25 million Americans speak [Hyperlink: https://data.census.gov/cedsci/table?q=language&tid=ACSST1Y2019.S1601] English less than "very well" including over 16 million Spanish speakers Language access in health care will only grow more important over time Between 1990 and 2013 the LEP population grew [Hyperlink: https://www.migrationpolicy.org/article/limited-english-proficient-population-united-states-2013] IIDs If people with LEP are limited in their ability to benefit from federally funded health programs the effect is to discriminate based on national origin in violation of Section 1557 In 2019 16 1% of Latinos and 13 4% of Asian Americans and Pacific Islanders spoke little or no English compared to 0 6% of non-Hispanic Whites. [Footnote : Our DOJUS analysis of 2019 American Community Survey data accessed through IPUMS USA University of Minnesota www.ipums.org] Inadequate language services contribute to poorer care and outcomes for patients with LEP While it can vary by condition or reason for admission individuals with LEP often experience longer hospital stays and are more likely [Hyperlink: https://cdn.ymdedge.com/files/sdfs public/pdfs/journals/0158_fta.pdf] to be readmitted than English speaking patients. In fact one study found that patients with LEP who do not receive

DOJUS

of disaggregated demographic data supports the department's enforcement efforts. We commend the department for recognizing the critically important role demographic data plays in addressing discrimination and health disparities Footnote 18: Fed Reg at 47856-7] However we are concerned the department does not at minimum require covered entities to collect disaggregated demographic data. Better national standards and uniform data collection practices could have an outsized impact on efforts to narrow health disparities. HHS must require demographic data collection based on multiple demographic variables including sex race ethnicity primary language age gender identity sexual orientation and disability status. At the community and population levels these variables both individually and in combination can reveal health disparities For example racial and ethnic minority women receive poorer quality care than racial and ethnic minority men who receive poorer care than White men [Footnote 19 Rosely Correa-de-Araujo et al Gender differences across racial and ethnic groups in the quality of care for acute myocardial infarct or and heart failure associated co morbidities Women's Health Issues 44 |2006]; Arn K. Chou et al Gender and racial disparities in the management of diabetes mellitus among Medicare patients Women's Health Issues 150 |2007|] Spanish-speaking Hispanics experience poorer quality care than English-speaking Hispanics who experience poorer care than non-Hispanic Whites [Footnote 20 Eric M Cheng Alex Chen & William Cunningham Primary language and receipt of recommended health care among Hispanics in the United States J General Internal Medicine 283 |2007| C Annette DuBard & Ziya Gizlice Language spoken and differences in health status access to care and receipt of preventive services among U S Hispanics Am J Public Health 2021 (2008).' Compared to women without disabilities women with disabilities are more likely not to have regular mammograms or Pap tests. Footnote 21 Marguerite F Dlab & Mark V Johnston Relationships between level

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National Immigration Law Center

InterACT: Advocates for Intersex Youth

AARP

Advocates for Youth

SIECUS: Sex Ed for Social Change

experience discrimination in healthcare. Based on a recent survey by the Center for American Progress (CAP) in the past year alone 15% of LGBQ respondents including 23% of LGBQ people of color experienced care refusal by a provider [Footnote 1 Medina Caroline Mahowald Lindsay. "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities." Center for American Progress 15 Oct. 2020 www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtq-communities/] For trans and non-binary [TNB] individuals 32% reported that they experienced care refusal by a health care provider in the past year. Rates of discrimination were even higher for TNB people of color with 46% reporting care refusal. [Footnote 2: Ibid.]. The CAP survey also showed that 39% of intersex respondents reported a health care provider refused to see them because of their sex characteristics or intersex variation [Footnote 3 Ibid.]. For TNB patients having their insurance cover necessary and affirming medical care has become an ever increasing obstacle with states all across the country introducing bills to ban gender affirming care for TNB people. In the past year 30% of TNB patients including 47% of TNB patients of color reported at least one form of denial by a health insurance company including denials for necessary gender-affirming hormone therapy or gender-affirming surgery [Footnote 4: Ibid].Delaying or avoiding healthcare due to discrimination contributes to poorer health outcomes for LGBTQI+ individuals including higher rates of chronic disease like heart disease certain cancers asthma and strokes [Footnote 5 Fredriksen-Goldsen Karen I et al. "Chronic Health Conditions and Key Health Indicators among Lesbian Gay and Bisexual Older US Adults 2013-2014." American Journal of Public Health American Public Health Association Aug. 2017 www.ncbi.nlm.nih.gov/pmc/articles/PMC5508188/]. Discrimination also takes a toll on mental health with LGBTQ+ patients having higher rates of mental health distress and suicidality. [Footnote 6 Ibid].

Although a number of federal laws prohibit several forms of discrimination Section 1557 extends these protections to any health program or activity that receives federal funding any health program or activity that HHS administers the health insurance exchanges and all plans offered by insurers that participate in those marketplaces. This Proposed Rule not only clarifies the broad civil rights protections extended in Section 1557 but most importantly provides concrete tools to combat racism and other forms of discrimination in health care. First the Proposed Rule addresses various forms of discrimination that disproportionately affect communities of color including on the basis of disability status national origin and sex. Second the Proposed Rule addresses systemic discrimination including policies and practices that harm people of color. Finally the Proposed Rule lays out vast enforcement authority across all segments of the health care system and related activities — ensuring Section 1557's prohibition against race discrimination is adhered to across the country.

Howard Brown Health

Abortion restrictions further imperil Black Americans' health and deny their dignity. In Dobbs a conservative majority of the United States Supreme Court reversed nearly a half a century of legal precedent and stripped the constitutional right to bodily autonomy from over a hundred million people. [Footnote 37 Dobbs 597 U.S.]. The proliferation of abortion restrictions after Dobbs will only exacerbate health inequities for Black Americans. Historically Black Americans have been denied control over their bodies their reproduction and their fertility. As Howard University School of Law's Human and Civil Rights Clinic noted in its brief in Dobbs "During slavery Black women were denied all bodily autonomy; the law expressly endorsed the rape that they lacked humanity and could be 'bred' for their owner's profit." [Footnote 38 Br. for Howard U. Sch. of L. Hum. & Liv. Res. Clinic Dobbs v. Jackson Women's Health 597 U.S. (2022) [No. 19-1392] at 3 available at https://reproductiverights.org/wp-content/uploads/2021/09/Black-Womens-Procreative-Liberty-Amicus-Brief.pdf] Birth control gave Black people control over their health and their lives. [Footnote 39 Id. at 18] "The ability to control whether to give birth is a fundamental component of freedom for all women. But for Black women whose procreation has been forced monitored and tortured since they arrived on American shores access to birth control represented a unique form of liberty." [ ]

Alliance of Multicultural Physicians

when and how to become parents. For example women of color report that "some physicians brush off their fertility concerns assume they can get pregnant easily emphasize birth control over procreation and may dissuade them from having children." [Footnote 40 ETHICS COMMITTEE OF THE AM. SOC. FOR REPRODUCTIVE MEDICINE DISPARITIES IN ACCESS TO EFFECTIVE TREATMENT FOR INFERTILITY IN THE UNITED STATES: AN ETHICS COMMITTEE OPINION (2021) https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/disparities_in_access_to_effective_treatment_for_infertility_in_the_us.pdfmembers.pdf] Additionally Black women are more likely to live in "contraceptive deserts" where pharmacies make it more difficult to purchase contraception [Footnote 41 Jennifer Barber et al. Contraceptive Deserts? Black-white differences in characteristics of nearby pharmacies J. RACIAL ETHNIC HEALTH DISPARITIES (August 2019) at 719 available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6601993/pdf/nihms1017159.pdf] or to struggle to afford birth control. [Footnote 42 Claretta Bellamy Black women are underserved when it comes to birth control access. The Roe decision could make that worse NBC NEWS (June 30 2022 3:50 AM) https://www.nbcnews.com/news/nbcblk/black-women-are-underserved-comes-birth-control-access-roe-decision-rcna35974. Planned Parenthood Who's Most Impacted by Attacks on Birth Control https://www.plannedparenthoodaction.org/fight-for-birth-control/facts/whos-most-impacted-by-attacks-on-birth-control (last visited Sept. 23 2022)] Moreover even before Dobbs existing abortion restrictions in many states which had caused numerous patients to be forced people to travel further for abortion care. [Footnote 43 Bellamy supra note 42] Because Black people are less likely to have health insurance that covers abortion and are oftentimes unable to cover the

NAACP Legal Defense and Education Fund, Inc.

communities. As of August 18 2022 most abortions are now banned in 13 states and five more states are expected to quickly ban abortion imminently. [Footnote 45 Caroline Kitchener et al. Abortion is banned in these states: Mapping abortion law changes by state Wash. Post https://www.washingtonpost.com/politics/2022/jul/24/abortion-state-laws-timeline-roe/] (last updated Sept. 23 2022).] Accordingly an estimated ten million Black women of childbearing age now face restrictions on abortion [Footnote 46 Taylor Johnson & Kelsey Butler Black Women Are Hardest Hit by Abortion Restrictions Sweeping the Deep South BLOOMBERG (Aug. 23 2022 7:00 AM ET) https://www.bloomberg.com/news/articles/2022-08-24/black-women-are-hardest-hit-by-abortion-restrictions-sweeping-the-deep-south?leadSource=uverify%20wall] Delays and denials of abortion care are hurting Black American's health. Since Dobbs there have been several reports of people experiencing pregnancy complications necessitating abortion not being unable to access care. [Footnote 47 Carrie Feibel Because of Texas Abortion Law Her Wanted Pregnancy Became a Medical Nightmare NPR (Jul. 26 2022) https://www.npr.org/sections/health-shots/2022/07/26/1111280165/because-of-texas-abortion-law-her-wanted-pregnancy-became-a-medical-nightmare] Without adequate access to abortion care more people are likely to die from pregnancy related complications. For example at some hospitals in Texas abortion care for patients with ectopic pregnancies a dangerous and life threatening condition which occurs when a fertilized egg attaches outside of the uterus is being delayed to avoid violating the state's law that was triggered after the Dobbs decision. [Footnote 48 Associated Press Texas Hospitals Delaying Care Over Violating Abortion Law PBS NEWS HOUR (Jul. 15 2022) https://www.pbs.org/newshour/nation/texas-hospitals-delaying-care-over-violating-abortion-law] A 2021 study by the University of Colorado estimated

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[Bold: C. Discrimination On The Basis Of Pregnancy-Related Conditions And the Impact of [Italics: Dobbs]] In the Proposed Rule HHS correctly recognizes that discrimination on the basis of pregnancy or its related conditions is a form of sex discrimination that impacts healthcare access. 87 Fed. Reg. at 47832. Where patients are denied medication treatment or even information these actions can result in serious health consequences. Id. As HHS recognizes access to healthcare is crucial particularly for those who experience intersectional discrimination such as people of color and those with disabilities. Id.

Attorneys General of California, New York, Massachusetts, and nineteen other States

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According to the National Center for Transgender Equality (NCTE) Report of the 2015 U.S. Transgender Survey | Hyperlink https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf, for example transgender people experience a high level of mistreatment and discrimination by healthcare providers. One third (33 percent) of respondents report that in the past year they had at least one negative experience with a healthcare provider with higher rates for people of color and those with disabilities. These experiences include outright refusal of care verbal and physical abuse and sexual assault. Due to a justified fear of violence and discrimination 23 percent of respondents reported in the past year that they had not sought care when they have needed to.Similarly recent surveys of LGBTQI+ Americans by the Center for American Progress found 69 percent of intersex respondents [Hyperlink: https://www.americanprogress.org/article/key-issues-facing-people-intersex-traits/] reported discriminatory experiences in healthcare in the prior year and 50 percent of intersex respondents [Hyperlink: https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtq-communities/] postponed or did not seek needed medical care due to disrespect or discrimination from providers. A national survey by the Trevor Project [Hyperlink: https://www.thetrevorproject.org/research-briefs/the-mental-health-and-well-being-of-lgbtq-youth-who-are-intersex-dec-2021/] found that youth who both had intersex traits and identified as LGBTQ reported a healthcare provider trying to change their sexual orientation or gender identity at twice the rate of their non-intersex LGBTQ peers. The changes that the Department has included in the proposed rule will have a substantial impact in combating this current reality

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of disaggregated demographic data supports the department's enforcement efforts. We commend the department for recognizing the critically important role demographic data plays in addressing discrimination and health disparities. Footnote 13, Fed. Reg. at 47856-7] However we are concerned the department does not at minimum require covered entities to collect disaggregated demographic data. Better national standards and uniform data collection practices could have an outsized impact on efforts to narrow health disparities. HHS must require demographic data collection based on multiple demographic variables including sex race ethnicity primary language age gender identity sexual orientation and disability status. At the community and population levels these variables both individually and in combination can reveal health disparities. For example racial and ethnic minority women receive poorer quality care than racial and ethnic minority men who receive poorer care than White men. [Footnote 14 Rosaly Correa-de-Araujo et al. Gender differences across racial and ethnic groups in the quality of care for acute myocardial infarction and heart failure associated co-morbidities Women's Health Issues 44 (2006): Ann F. Chou et al. Gender and racial disparities in the management of diabetes mellitus among Medicare patients Women's Health Issues 150 (2007)] Spanish-speaking Hispanics experience poorer quality care than English-speaking Hispanics who experience poorer care than non-Hispanic Whites. [Footnote 23 Eric M. Cheng Alex Chen & William Cunningham Primary language and receipt of recommended health care among Hispanics in the United States J. General Internal Medicine 288 (2007): C. Arnethe DuBard & Ziya Gizlice Language spoken and differences in health status access to care and receipt of preventive services among U.S. Hispanics Am. J. Public Health 2021 (2008).] Compared to women without disabilities women with disabilities are more likely not to have regular mammograms or Pap tests

Footnote 23: Marguerite L. Diab & Mark V. Johnston Relationships between level of unmet need and quality of life after stroke: psychological factors contribute to variance in unmet needs and life satisfaction Int J Rehabil Res. 2013 Mar;36(1):66-73. doi: 10.1097/MRR.0b013e32835a1f6e. [Italics Dobbs v. Jackson Women's Health Organization] It is essential for the Administration's Proposed Rule to robustly protect patients from discrimination relative to pregnancy including for having or seeking abortion care. Even before the fall of [Italics Roe v. Wade] many patients were unable to access abortion care because of medically unnecessary barriers imposed by anti-abortion politicians. Now with states moving quickly to ban abortion and the consequences of these state abortion bans ripping across the country people of color people with low incomes people who are immigrants young people people with disabilities and LGBTQI+ people are facing numerous logistical and legal barriers to accessing care with an increased threat of arrest and prosecution in places where abortion is illegal. It is critical that the Administration's Proposed Rule clearly and consistently includes abortion care as part of the prohibition on discrimination based on pregnancy or related conditions throughout the final rule

Overall the LGBTQIA+ community experiences many challenges when interacting with healthcare providers and health insurers according to a report [embedded hyperlink here (https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtq-communities/)] by Center for American Progress. Key findings from the report include - 23 percent of LGBTQ+ respondents including 27 percent of LGBTQI+ respondents of color reported that in the past year they postponed or avoided getting needed medical care when ill or injured due to disrespect or discrimination from doctors or other health care providers; - Overall 15 percent of LGBQ respondents including 23 percent of LGBQ respondents of color reported experiencing some form of care refusal by a doctor or other health care provider in the year prior; - Overall 54 percent of transgender or nonbinary respondents including 46 percent of transgender or nonbinary respondents of color reported that they experienced at least one kind of care refusal by a health care provider in the past year; - 55 percent of intersex respondents reported that in the past year a health care provider refused to see them because of their sex characteristics or intersex variation. - Overall 30 percent of transgender or nonbinary respondents including 47 percent of transgender or nonbinary respondents of color reported experiencing some form of denial by a health insurance company in the past year; - 28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender-affirming hormone therapy in the year prior, and - 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender-affirming surgery in the year prior. WPHCA is numerously supportive of this expansive definition of discrimination under this rule as this will protect LGBTQ patients experiencing discrimination in health care settings especially in certain states where access to essential services is threatened. Many states lack explicit LGBTQ discriminatory protections in health care and WPHCA appreciates the Administration's intention to return 1557 protections back to language in the 2016 rule and in many instances expand upon those protections

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IECUS: Sex Ed for Social Change

Wisconsin Primary Health Care Association

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|Italics LGBTQIA Justice in Aging strongly supports the proposal to clarify that under Sec. 1557 discrimination "on the basis of sex" includes but is not limited to discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions; sexual orientation, and gender identity." |Footnote 17: 87 Fed. Reg. 47824 47911 (§ 92.101(a)(2)).| We agree with HHS that Supreme Court case law including |Italics Price Waterhouse v. Hopkins and Bostock v. Clayton County| makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity including transgender status. We appreciate HHS's discussion and definitions of these terms, including the pervasiveness of discrimination against transgender individuals in health care. The terms "gender identity" and "transgender status" are often used interchangeably and courts have construed the term "gender identity" to encompass "transgender identity." However some have sought to justify a termination against transgender people by distinguishing it from gender identity. |Bold| We therefore urge HHS to amend § 92.101(a)(2) to explicitly include "transgender status" in addition to the other bases listed. |These specific protections are necessary to help reduce the pronounced health disparities and higher poverty rates LGBTQ+ older adults experience compared to their heterosexual and cisgender peers. |Footnote 18: SAGE & National Resource Center on LGBT Aging: Facts on LGBT Aging https://www.lgbtagingcenter.org/resources/pdfs/SAGE_LGBT_Aging_Final_R2.pdf]. Discrimination in health care contributes to these disparities. LGBTQIA+ older adults have been denied care provided inadequate care and have been afraid to seek necessary care for fear of mistreatment. |Footnote 19: Mary Beth Foglia & Karen L. Fredriksen Goldsen Health Disparities among LGBT Older Adults and the Role of Nonconscious Bias Hastings Cent Rep. |Mar 2015| https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365932/#!po=6.

These problems persist. In 2022 Data in Build/Expanded: new report| From the Center for American Progress "reveal that LGBTQI+ communities encounter discrimination and other challenges when interacting with health care providers and health insurers underscoring the importance of strengthening nondiscrimination protections through Section 1557 of the Affordable Care Act." Key findings from the report include: 23 percent of LGBTQI+ respondents including 27 percent of LGBTQI+ respondents of color reported that in the past year they postponed or avoided getting needed medical care when sick or injured due to disrespect or discrimination from doctors or other health care providers. Overall 15 percent of LGBQ respondents including 23 percent of LGBQ respondents of color reported experiencing some form of care refusal by a doctor or other health care provider in the year prior; Overall 12 percent of transgender or nonbinary respondents including 18 percent of transgender or nonbinary respondents of color reported that they experienced at least one kind of care refusal by a health care provider. In the past year, 15 percent of "intersex" respondents reported that in the past year a health care provider refused to see them because of their sex characteristics or intersex variation. Overall 33 percent of transgender or nonbinary respondents including 47 percent of transgender or nonbinary respondents of color reported experiencing one form of denial by a health insurance company in the past year,-28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender affirming hormone therapy in the year prior and 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender affirming surgery in the year prior.

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System Black Americans have long confronted inequities in health care access treatment and outcomes. These disparities are particularly acute for Black pregnant and LGTBQ+ people and weaken society as a whole.Redlining and other discriminatory practices have fostered ongoing residential segregation that has kept Black Americans in under resource neighborhoods oft generations of Black communities disproportionately exposed to health hazards and denied them equal access to health care. |Footnote 11 See generally TOMI SHAPIRO ET AL. LDF THURGOOD MARSHALL INST. & INST. ON ASSETS AND SOC. POL'Y AT BRANDEIS UNIV. THE BLACK WHITE RACIAL WEALTH GAP |2019| https://iminstitute.org/wp-content/uploads/2019/11/FINAL-RWG-Brief.pdf | Because redlined neighborhoods were often chosen as the sites for new factories or highways people of color are more likely to live in polluted areas and near environmental hazards. |Footnote 12 Laura Warmsley Every many decades later redlined areas see higher levels of air pollution NPR (Mar. 30 2022) https://www.npr.org/2022/03/30/1089283953/redlining-pollution-race-air. Daniel Cusick Past Racist "Redlining" Practices Increased Climate Burdens on Minority Neighborhoods SCIENTIFIC AM. (Jan. 21 2020) https://www.scientificamerican.com/article/past-racist-redlining-practices increased-climate-burden-on-minority-neighborhoods/. SHAPIRO ET AL. supra note 11 at 13 | Furthermore until the 1960s hospitals were rigidly segregated and unequal |Footnote 13 David Barton Smith The Politics of Racial Disparities Desegregating the Hospitals in Jackson Mississippi M. LBANK Q. Jul. 2005 at 247 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690144/| While hospitals are now integrated Black Americans still do not have equal access to health care facilities. Predominantly Black racially-isolated neighborhoods are more likely to be in primary care deserts and suffer fewer ambulatory facilities more limited access to physicians and a lower supply of surgeons." |Footnote 14 Mariana C

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The Department's proposal to once again recognize Section 1557's application to private insurance continues the chain of properly implementing Congress' intent when drafting Section 1557 to encompass all forms of health care access. According to data in a new report from the Center for American Progress |Hyperlink: https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtq-communities/| transgender and nonbinary people at large experience significant discrimination when seeking insurance coverage for medical care. Key findings include that in the past year,• 30 percent of transgender or nonbinary respondents, including 47 percent of transgender or nonbinary respondents of color reported experiencing one form of denial by a health insurance company;• 28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported a denial of coverage for gender affirming hormone therapy, and• 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported a denial of coverage for gender-affirming surgery.

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Black Americans confront particularly stark disparities in maternal health outcomes. Pregnant women of color are often subjected to discrimination throughout pregnancy and the postpartum period including mistreatment during labor and delivery. |Footnote 29 Saraswathi Vedam et al. The Giving Voice to Mothers study inequity and mistreatment during pregnancy and childbirth in the United States Reproductive Health (June 2019) https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-019-0729-2.| People of color are also more likely to experience certain birth risks and adverse birth outcomes. |Footnote 30 Samantha Artiga et al. What are the Implications of the Overturning of Roe v. Wade for Racial Disparities Kaiser Family Foundation (July 15 2022) https://www.kff.org/racial-equity-and-health-policy/issue-brief/what-are-the-implications-of-the-overturning-of-roe-v-wade-for-racial-disparities/.| As a result Black women are three- to four-times more likely to die from pregnancy related complications than white women. |Footnote 31 Donna L. Hoyert Centers for Disease Control Maternal Mortality Rates in the United States 2020 https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm | According to a recent study by the CDC many of these deaths are preventable. |Footnote 32 Nada Hassanein 'Staggering' and 'sobering': More than 80% of US maternal deaths are preventable CDC study shows USA TODAY (Sept. 19 2022 1:53 PM) https://www.usatoday.com/story/news/health/2022/09/19/cdc-us-maternal-deaths-preventable/10425171002/ |

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I support the proposed rule because it provides protections for LGBTQ+ people in health care settings and this is vital. Additionally the mission of HHS is to ensure the health and well-being of ALL Americans. I am a healthcare provider & have many patients in the LGBTQ+ community. I see the barriers that my patients face on a daily basis. Many of these patients are young & lack financial resources. Lack of Medicaid expansion in some states further restricts access to services. One example of a barrier includes patients who are unable to access PEP (post-exposure prophylaxis for HIV) because of insurance requirements for prior-authorization or a weekend. Obtaining prior auth or a weekend is impossible. Those medications (PEP) are time sensitive within 72 hours of possible HIV exposure and some patients are unable to access that care within the window. This is even when the ER prescribes & provides a first-dose if they cannot access clinic care elsewhere. Additionally not all clinics/urgent cares/PCPs prescribe PEP and PrEP. All of these factors puts patients at high risk of contracting HIV which could have been prevented except for an insurance/access barrier. This is

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during the patient has insurance which is yet another barrier. More patients are seeking PrEP and facing barriers like prior-authorizations for a preventative medication! This is heartbreaking as I also see newly diagnosed HIV patients who would have been good candidates for these medications if barriers were freed

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dual Healthcare Provider

I noted in the preamble to the NPRM, LGBTQI+ people face both health disparities and barriers to health care. The [underlined/bold: National Academies of Sciences, Engineering and Medicine] reports that discrimination against LGBTQI+ individuals in obtaining health insurance and in the terms of insurance coverage has long been a barrier to accessing health care which has contributed to significant health inequalities. LGBTQ+ people report poorer health overall and are at increased risk of numerous health conditions such as sexually transmitted infections, HIV, obesity, substance abuse, and mental health conditions including suicidality. They also are more likely than heterosexual individuals to acquire a disability at a young age. Much of this can be attributed to well-documented discrimination. According to a [bold/underlined: 2010 report] addressing health care discrimination against LGBT people and people living with HIV, more than half of all respondents reported at least one of the following types of discrimination in care: being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care professionals using harsh or abusive language; being blamed for their health care status; or health care professionals being physically rough or abusive. The same report found that many members of the LGBT community have a "high degree of anticipation and belief that they will face discriminatory care" which ultimately causes many people to not seek care

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how themselves to live freely and authentically in a country that supports them and protects them. As we like this would ensure their hope for an equitable and safe future for all people. As noted in the preamble to the NPRM, LGBTQI+ people face both health disparities and barriers to health care. The National Academies of Sciences, Engineering and Medicine reports that a combination of stigma against sexual and gender diverse persons in obtaining health insurance and in the terms of insurance coverage has long been a barrier to accessing health care which has contributed to significant health inequalities [Hyperlink https://nap.nationalacademies.org/catalog/25877/understanding-the-well-being-lgbtqi-populations]. LGBTQI people report poorer health overall and are at increased risk of numerous health conditions such as sexually transmitted infections, HIV, obesity, substance abuse, and mental health conditions including suicidality. They also are more likely than heterosexual individuals to acquire a disability at a young age. Much of this can be attributed to well-documented discrimination. According to a 2010 report addressing health care discrimination against LGBT people and people living with HIV, more than half of all respondents reported at least one of the following types of discrimination in care: being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care professionals using harsh or abusive language; being blamed for their health care status; or health care professionals being physically rough or abusive. The same report found that many members of the LGBT community have a "high degree of anticipation and belief that they will face discriminatory care" which ultimately causes many people to not seek care. Years later the situation has not much improved. The Department's Healthy People 2020 "[that we recognized that "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights." [Hyperlink: https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-

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experience discrimination in healthcare. Based on a recent survey by the Center for American Progress (CAP) in the past year, one in 15% of LGBQ respondents, including 23% of LGBQ people of color, experienced care refusal by a provider [footnote 1: Medina Caroline Mahowald Lindsay, "Advancing Health Care Discrimination Protections for LGBTQI+ Communities." Center for American Progress, 15 Oct. 2020, www.americanprogress.org/article/advancing-health-care-discrimination-protections-lgbtqi-communities/]. For trans and non-binary (TNB) individuals, 32% reported that they experienced care refusal by a health care provider in the past year. Rates of discrimination were even higher for TNB people of color with 46% reporting care refusal. [footnote 2: Ibid.]. The CAP survey also showed that 34% of intersex respondents reported a health care provider refused to see them because of their sex characteristics or intersex variation [footnote 3: Ibid.] For TNB patients having their insurance cover necessary and affirming medical care has become an ever-increasing obstacle with states all across the country introducing bills to ban gender affirming care for TNB people. In the past year, 30% of TNB patients including 42% of TNB patients of color reported at least one form of denial by a health insurance company, including denials for necessary gender-affirming hormone therapy or gender-affirming surgery. [Footnote 4: Ibid]. Delaying or avoiding healthcare due to discrimination contributes to poorer health outcomes for LGBTQI+ individuals, including higher rates of chronic disease like heart disease, certain cancers, asthma, and strokes. [footnote 5: Fredriksen-Goldsen, Karen I. et al. "Chronic Health Conditions and Key Health Indicators among Lesbian, Gay, and Bisexual Older US Adults, 2013-2014." American Journal of Public Health, American Public Health Association, Aug. 2017, www.ncbi.nlm.nih.gov/pmc/articles/PMC5551385/]. Discrimination also takes a toll on mental health with LGBTQI+ patients having higher rates of mental health

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stress and suicidality. [Footnote 6: Ibid.]

Black LGBTQI+ people also experience additional health care barriers due to their gender identity and/or transgender status. As noted in a recent report by the Center for American Progress, Black LGBTQI+ people face high rates of discrimination from medical providers. [footnote 44: Lindsay Mahowald, Black LGBTQ Individuals' Experiences Heightened Levels of Discrimination, CENTER FOR AMERICAN PROGRESS, (Jul. 13, 2021), https://www.americanprogress.org/article/black-lgbtq-individuals-experience-heightened-levels-discrimination/.] Transgender people of color experience denial of care and medical abuse more frequently than white transgender people. [Footnote 34: Caroline Medina et al., Protecting and Advancing Health Care for Transgender Adult Communities, CENTER FOR AMERICAN PROGRESS, (Aug. 18, 2021), https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/.] including for conditions such as asthma or diabetes. [footnote 35 Id.]

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Overall the LGBTQIA+ community experiences many challenges when interacting with healthcare providers and health insurers according to a report [embedded hyperlink text (https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtq-communities/)] by Center for American Progress. Key findings from the report include - 23 percent of LGBTQ+ respondents including 27 percent of LGBTQIA+ respondents of color reported that in the past year they postponed or avoided getting needed medical care when sick or injured due to disrespect or discriminat on from doctors or other health care providers,- Overall 15 percent of LGBQ respondents including 23 percent of LGBQ respondents of color reported experiencing some form of care refusal by a doctor or other health care provider in the year prior. Overall 52 percent of transgender or nonbinary respondents including 46 percent of transgender or nonbinary respondents of color reported that they experienced at least one kind of care refusal by a health care provider in the past year;- 55 percent of intersex respondents reported that in the past year a health care provider refused to see them because of their sex characteristics or intersex variation. Overall 30 percent of transgender or nonbinary respondents including 47 percent of transgender or nonbinary respondents of color reported experiencing one form of denial by a health insurance company in the past year;- 28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender affirming hormone therapy in the year prior, and 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender affirming surgery in the year prior.

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WPHCA is immensely supportive of this expansive definition of discrimination under this rule as this will protect LGBTQ patients experiencing discrimination in health care settings especially in certain states where access to essential services is threatened. Many states lack explicit LGBTQ discriminat on protections in health care and WPHCA appreciates the Administration's intention to return 1557 protections back to language in the 2016 rule and in many instances expand upon those protected ons

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SIECUS Sexuality Information and Education Council of the United States

Wisconsin Primary Health Care Association

[Italics] LGBTQIA Justice in Aging strongly supports the proposal to clarify that under Sec. 1557's discriminat on "on the basis of sex" includes but is not limited to discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions; sexual orientation, and gender identity." [Footnote 17: 87 Fed. Reg. 47824 47916 (to Be Codified at 45 C.F.R. pt. 92)] We agree with HHS that Supreme Court case law including [Italics] Price Waterhouse v. Hopkins and [Bostock v. Clayton County] makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity including transgender status. We appreciate HHS's discussion and definitions of these terms, noting the pervasiveness of discrimination against transgender individuals in health care. The terms "gender identity" and "transgender status" are often used interchangeably and courts have construed the term "gender identity" to encompass "transgender identity." However some have sought to justify discrimination against transgender people by distinguishing it from gender identity. [Bold] We therefore urge HHS to amend § 92.101(a)(2) to explicitly include "transgender status" in addition to the other bases listed [These specific protections are necessary to help reduce the pronounced health disparities and higher poverty rates LGBTQ+ older adults experience compared to the heterosexual and cisgender peers. [Footnote 18: SAGE & National Resource Center on LGBT Aging. Facts on LGBT Aging https://www.lgbtagingcenter.org/resources/pdfs/SAGE_LGBT_Aging_Final_R2.pdf.] Discrimination in health care contributes to these disparities: LGBTQI+ older adults have been denied care provided inadequate care and have been afraid to seek necessary care for fear of mistreatment. [Footnote 19: Mary Beth Foglia & Karen I. Fredriksen Goldsen Health Disparities among LGBT Older Adults and the Role of Nonconscious Bias Hastings Cent Rep. [Mar-Apr 2015] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365932/#s11title.]

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Older adults also experience discrimination based on their sexual orientation such as doctors making assumptions about the person sexual behavior forcing the older adult to disclose their sexual orientation. Others have been harassed and denied care. For example an older adult shared his story about visiting a urologist for a health concern not related to a sexually transmitted infection. He reported that when the doctor asked him if he was married and he said no and that he is gay the doctor replied " It's no wonder you're sick. What you people do is disgusting." The doctor refused to examine the man but he still had to pay for an office visit even though he didn't receive treatment. [Footnote 20: Story reported to SAGE and shared with permission.] Many older LGBTQI+ adults especially those age 80 and older express feelings of hesitation about disclosing their sexuality or gender identity to their health care provider or insurer because they fear being denied care or being dropped from their coverage. [Footnote 21: Mary Beth Foglia & Karen I. Fredriksen Goldsen Health Disparities among LGBT Older Adults and the Role of Nonconscious Bias Hastings Cent Rep. [Mar-Apr 2015] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365932/#s11title.] As one study found this "common fear suggests "shared decision-making during the clinical encounter is likely to be compromised thereby contributing to the perpetuation of health inequalities among LGBT older adults." [Footnote 22: Id.] Others report delaying care due to this fear.

Justice in Aging

In addition many LGBTQI+ older adults and their loved ones experience discrimination in long-term care facilities [Footnote 23: Justice in Aging et al. LGBT Older Adults in Long-Term Care Facilities: Stories from the Field. [updated June 2015] http://www.justiceinaging.org/wp-content/uploads/2015/06/Stories_from_the_Field.pdf.] Such as verbal and physical harassment denial of basic care [such as a shower] visiting restrictions, isolation improper discharge and refusal of admission. [Footnote 24: Noelle Feliciano] LGBTQ seniors fear discrimination when searching for housing PBS News Weekend [Oct. 10 2021] https://www.pbs.org/newshour/show/lgbtq-seniors-fear-discrimination-when-searching-for-housing. UCLA Williams Institute LGBT Aging: A Review of Research Findings Needs and Policy Implications [Aug. 2016] https://www.lgbtagingcenter.org/resources/pdfs/LGBT-Aging-A-Review.pdf.] For example a transgender older woman was discharged from the hospital to a rehabilitation facility after a procedure. When the aide who was assigned to her gave her a sponge bath the next day the aide discovered that she was transgender. The aide then brought in other nurses and made fun of the woman who was already in a vulnerable position being older and recovering from surgery. [Footnote 25: Story reported to SAGE and shared with permission.] Discrimination in LTSS settings can also be systemic. We have heard reports of privately operated group homes not accepting people living with HIV for example or making it clear that LGBTQI+ older adults are not welcome. The harms of this discrimination are compounded for older adults residing in smaller cities and rural areas—they are either forced to relocate themselves to get the care they need or delay or forgo services altogether.

Justice in Aging

LGBTQI+ older adults also fear discrimination in LTSS settings. For example a lesbian older adult who has witnessed discrimination against her own LGBTQI+ clients shared that she worries about who she will end up and whether it will be welcoming if she needs more assistance. Many choose not to receive home and community-based services hospice home health aides, or other assistance because they fear discrimination. This type of discrimination stings in a unique way because the services are often administered at home or elsewhere in the community where older adults should feel most comfortable and safe.

Justice in Aging

These problems persist. In 2022, Data in a [bold/underlined: new report] from the Center for American Progress "reveal that LGBTQI+ communities encounter discrimination and other challenges when interacting with health care providers and health insurers underscoring the importance of strengthening nondiscrimination protections through Section 1557 of the Affordable Care Act." Key findings from the report include: 23 percent of LGBTQI+ respondents including 27 percent of LGBTQI+ respondents of color reported that in the past year they postponed or avoided getting needed medical care when sick or injured due to disrespect or discrimination from doctors or other health care providers. Overall 15 percent of LGBQ respondents including 23 percent of LGBQ respondents of color reported experiencing some form of care refusal by a doctor or other health care provider in the year prior; Overall 32 percent of transgender or nonbinary respondents including 48 percent of transgender or nonbinary respondents of color reported that they experienced at least one kind of care refusal by a health care provider in the past year;55 percent of intersex respondents reported that in the past year a health care provider refused to see them because of their sex characteristics or intersex variation. Overall 50 percent of transgender or nonbinary respondents including 67 percent of transgender or nonbinary respondents of color reported experiencing some form of denial by a health insurance company in the past year,-28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender affirming hormone therapy in the year prior and 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender affirming surgery in the year prior.

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[bold/underlined: LGBTQI+ individuals] experience higher levels of stigma and that shame concealment of one's sexual identity and discrimination leads to an increased rate of eating disorders. For LGBTQI+ youth the research is even more clear. LGBTQI+ youth report [bold/underlined: higher levels] of sexual minority-specific victimization depressive symptoms and suicidality compared to their heterosexual peers. It is estimated that LGBTQI+ youth that are diagnosed with an eating disorder are [bold/underlined: four times more likely to attempt suicide] than LGBTQI+ youth who never had or suspected they had an eating disorder.

Eating Disorders Coalition for Research, Policy & Action

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Eating Disorders Coalition for Research, Policy & Action

system Black Americans have long confronted inequities in health care access treatment and outcomes. These disparities are particularly acute for Black pregnant and LGTBQ+ people and weaken society as a whole. Redlining and other discriminatory practices have fostered ongoing residential segregation that has kept Black Americans in under-resourced neighborhoods left generations of Black communities disproportionately exposed to health hazards and denied them equal access to health care. [Footnote 11 See generally TOM SHAPIRO ET AL. LDF HURGOOD MARSHALL INST. & INST. ON ASSETS AND SOC. POL'Y AT BRANDE S UNIV. THE BLACK-WHITE RACIAL WEALTH GAP (2019) (https://iminstitutefield.org/wp-content/uploads/2019/11/FINAL-RWG-Brief-1.pdf.) Because redlined neighborhoods were often chosen as the sites for new factories or highways people of color are more likely to live in polluted areas and bear environmental hazards. [Footnote 12 Laura Wamsley Even many decades later redlined areas see higher levels of air pollution NPR (Mar. 30 2022) (https://www.npr.org/2022/03/30/1089589294/redlining-pollution-racism; Danie Justice Past Racist "Redlining" Practices Increased Climate Burden on Minority Neighborhoods SCIENTIFIC AM. (Jan. 21 2020) (https://www.scientificamerican.com/article/past-racist-redlining-practices-increased-climate-burden-on-minority-neighborhoods/, SHAPIRO ET AL. supra note 11 at 13.] Furthermore until the 1960s hospitals were rigidly segregated and unequal. [Footnote 13 David Barton Smith The Politics of Racial Disparities Desegregating the Hospitals in Jackson Mississippi 94 M. I BANK Q. (n.s. 2005 at 242 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690142/.] While hospitals are now integrated Black Americans still do not have equal access to health care facilities. Predominantly Black racially isolated neighborhoods are more likely to be in primary care deserts and offer fewer ambulatory facilities more limited access to physicians and a lower supply of surgeons." [Footnote 14 Marshall C

NAACP Legal Defense and Education Fund, Inc

As noted in the preamble to the NPRM LGBTQI+ people face both health disparities and barriers to health care. The [underlined/bold: National Academies of Sciences Engineering and Medicine] reports that discrimination against LGBTQI+ individuals including health insurance and in the terms of insurance coverage has long been a barrier to accessing health care which has contributed to significant health inequities. LGBTQI+ people report poorer health overall and are at increased risk of numerous health conditions such as sexually transmitted infections HIV obesity substance abuse and mental health conditions including suicidality. They also are more likely than heterosexual individuals to acquire a disability at a young age. Much of this can be attributed to well-documented discrimination. According to a [bold/underlined: 2030 report] addressing health care discrimination against LGBT people and people living with HIV more than half of all respondents reported at least one of the following types of discrimination in care: being refused needed care, health care professionals refusing to touch them or using excessive precautions; health care professionals using harsh or abusive language; being blamed for the patient's health care status; or health care professionals being physically rough or abusive. The same report found that many members of the LGBT community have a "high degree of mistrust, isolation and belief that they will face discriminatory care" which ultimately causes many people to not seek care.

Eating Disorders Coalition for Research, Policy & Action

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Legislation has dramatically impacted both my quality of life and my sense of safety in this country. The legislation proposed has made me consider and reconsider the location I live in and worry constantly for both my safety and the potential for my lifesaving healthcare to be taken away." My security in the future has been compromised severely which is a feeling that impacts every moment of my life. There is a deep seated fear associated with not knowing how much longer you will have access to healthcare that I don't wish on anyone. These bills exist not to solve a problem in our society but to bully and further marginalize an already incredibly vulnerable population." "As a trans person and a mental health provider I find pronouns anti trans legislation deeply troubling. I believe that the negative impact of these legislation like this introduced. People including myself are fearful of what the future may bring and which rights will not be afforded to them and their families. Safety and access to healthcare are amongst the highest concerns." "My security in the future has been compromised severely which is a feeling that impacts every moment of my life. There is a deep seated fear associated with not knowing how much longer you will have access to care that I don't wish on anyone." "As someone involved in the medical care of gender affirming care the anti trans legislation specifically brings my future and the futures of individuals who wish to medically transition into question. It makes me concerned that I will not be able to practice in the state that I live in that I may not have access transition-related care myself and most importantly that my trans and nonbinary friends and patients will not be able to obtain life saving medical care." "I am incredibly proud to be trans in the field of education and I refuse to have to hide my identity or the identities of my students that they have to hide their identities because the government sees them as inferior or unworthy. My students deserve a future where they can be proud of their identities and they can access the gender-affirming care and communities they

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Development Foundation for Transgender Youth

allow themselves to live freely and authentically in a country that supports them and protects them. A rule like this would ensure their hope for an equitable and safe future for all people. As noted in the preamble to the NPRM, LGBTQ+ people face both health disparities and barriers to health care. The National Academies of Sciences, Engineering and Medicine reports that discrimination against sexual and gender diverse persons in obtaining health insurance and in the terms of insurance coverage has long been a barrier to accessing healthcare which has contributed to significant health inequalities [Hyperlink https://nap.nationalacademies.org/catalog/25877/understanding-the-well-being-of-lgbtqi-populations]. LGBTQI people report poorer health overall and are at increased risk of numerous health conditions such as sexually transmitted infections, HIV, obesity, substance abuse and mental health conditions including suicidality. They also are more likely than heterosexual individuals to acquire a disability at a young age. Much of this can be attributed to well documented discrimination. According to a 2030 report addressing health care discrimination against LGBT people and people living with HIV, more than half of all respondents reported at least one of the following types of discrimination in care: Being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care professionals using harsh or abusive language; being blamed for their health care status; or health care professionals being physically rough or abusive. The same report found that many members of the LGBT community have a "high degree of anticipation and belief that they will face discriminatory care" which ultimately causes many people to not seek care. Years later the situation has not much improved. The Department's Healthy People 2020 initiative recognized that "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights." [Hyperlink https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health] The Endocrine Society is the world's oldest and largest organization of clinicians devoted to hormone research and physicians who care for people with hormone-related conditions. Many of our 18000 members are recognized for their expertise in transgender research and medicine and we advocate to improve and promote access to care for transgender patients. [Bold: As such we are pleased that this proposed rule reverses the Section 1557 regulations implemented in 2020 which will clarify the protections for transgender patients and increase their access to the full spectrum of medical care including gender affirming care without fear of discrimination]

As well acknowledged, trans individuals experience higher rates of crime and trauma than many other populations and are unlikely to access healing and justice services. This is in no small part due to the discrimination and disrespect and even violence that trans people have experienced at the hands of health care professionals. Even one traumatic experience can cause a trans person to avoid accessing health care for years or even decades. Here are some of the stories FORGE has been told: [Italic: One [sexual] assault was in an Emergency Room at a hospital by a female doctor who I believe was angered by my appearance. I looked male and my hospital bracelet [sic] chart said "female."] We were verbally abused by both health care providers and police. The one doctor in ER could have refrained from severely harassing [sic] and raping me. Other providers could have tried harder to listen to what I was saying and dealing with my medical issue[s] instead of being so persistantly [sic] disrespected and [negative]ly focused on my gender expression/identity. Time spent in a doctor's office is always very limited and I would rather it be spent productively. And free of harassment ["What could my doctors have improved?] Not talked me "in". To tell me what they were going to do. Mean time wear a condom." In a public corridor as I am leaving the hospital after a rape. Called me the right pronoun. Health care practitioners are clueless about trans stuff around the issues that people born as women face in general and race...about class...about everything. I try never to deal with those people and ultimately other avenues for health care when possible. One Navy doctor abused me twice when a future site related to my sex reassignment surgery became infected. [Health care is but one part of human services systems but it is a critical part. Health care providers are frequently the most accessed professionals and bad treatment at their hands can affect individuals' willingness to access law enforcement, public benefits, educational institutions and much more.

Disparities and barriers to healthcare. The National Academies of Sciences Engineering and Medicine reports that discrimination against people of diverse genders and sexualities both in obtaining health insurance and in the terms of insurance coverage has long been a barrier to accessing healthcare which has contributed to significant health inequities. Because of this and other societal inequities, LGBTQI+ people report poorer health overall and increased risk factors for numerous health conditions such as sexually transmitted infections (STIs), HIV, substance misuse and mental health conditions including depression and suicidal ideation. They are also more likely than their cisgender and straight peers to acquire a disability or chronic illness at a younger age which necessitates further access to culturally humble healthcare. Much of this can be attributed to well documented discrimination. According to a 2030 report addressing health care discrimination against LGBT people and people living with HIV, more than half of all respondents reported at least one of the following types of discrimination in care: being refused needed care; healthcare professionals refusing to touch them or using excessive precautions; healthcare professionals using harsh or abusive language, being blamed for the healthcare status, or healthcare professionals being physically rough or abusive. The same report found that many members of the LGBT community have a "high degree of anticipation and belief that they will face discriminatory care" which ultimately causes many people to not seek care. More than a decade later the situation has not much improved. The Department's Healthy People 2020 initiative recognized that "LGBT individuals face health disparities linked to societal stigma, discrimination and denial of their civil and human rights." This surfaces in a wide variety of contexts, including physical and mental healthcare services. In a study published in Health Affairs researchers examined the intersection of gender identity, sexual orientation, race and economic factors in healthcare across. They conclude that discrimination as

Every day our organizations hear from consumers across the state who face challenges accessing equitable, affordable, high quality health coverage and care. We hear from people for whom English is not their primary language seeking culturally and linguistically competent health care services. We hear heart-wrenching stories from people who need access to timely and compassionate abortion services. We hear from people of various genders including transgender people who already have trouble finding the gender affirming coverage and care they seek. We hear from people with disabilities who face overwhelming obstacles to find and navigate all the services they need to remain in the community. These are real people who already encounter barriers to accessing the health care services and supports they need. HLA and HLA believe in the critical importance of ensuring that all people can obtain equitable, high quality, affordable health care without facing discriminatory barriers. The nondiscrimination requirements of the Affordable Care Act § 1557 are critical to ensuring the health and well-being of our communities. We support the administration in strengthening this provision of the ACA and make the below recommendations to further guarantee the robust implementation of this law.

Black LGBTQ+ people also experience additional health care barriers due to their gender identity and/or transgender status. As noted in a recent report by the Center for American Progress, Black LGBTQ+ people face high rates of discrimination from medical providers. [Footnote 34 Lindsay Mahowald, Black LGBTQ Individuals Experience Heightened Levels of Discrimination, CENTER FOR AM. PROGRESS, (Jul. 15, 2021), https://www.americanprogress.org/article/black-lgbtq-individuals-experience-heightened-levels-discrimination/] Transgender people of color experience denial of care and medical abuse more frequently than white transgender people. [Footnote 35 Care, Medicaid et al., Protecting and Advancing Health Care for Transgender and All Communities, CENTER FOR AM. PROGRESS (Aug. 18, 2021), https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-all-communities/] [including for conditions such as asthma or diabetes. [Footnote 35 Id.]

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Colorist

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Endocrine Society

FORGE, Inc

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Equitas Health

Health Care For All

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NAACP Legal Defense and Education Fund, Inc

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InterACT Advocates for Intersex Youth

Attorneys General of California, New York Massachusetts, and nineteen other States

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Eating Disorders Coalition for Research Policy & Action

Physicians for Reproductive Health

(b)(5)	American Progress "reveal that LGBTQ+ communities encounter discrimination and other challenges when interacting with health care providers and health insurers underscoring the importance of strengthening nondiscrimination protections through Section 1557 of the Affordable Care Act" [Hyperlink: https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtq-communities/] Key findings from the report include:- 23 percent of LGBTQI+ respondents including 27 percent of LGBTQI+ respondents of color reported that in the past year they postponed or avoided getting needed medical care when sick or injured due to disrespect or discrimination from doctors or other health care providers: Overall 33 percent of LGBQ respondents including 39 percent of LGBQ respondents of color reported experiencing some form of care refusal by a doctor or other health care provider in the year prior:- Overall 32 percent of transgender or nonbinary respondents including 46 percent of transgender or nonbinary respondents of color reported that they experienced at least one kind of care refusal by a health care provider in the past year, 55 percent of intersex respondents reported that in the past year a health care provider refused to see them because of their sex characteristics or intersex variation.- Overall 30 percent of transgender or nonbinary respondents including 47 percent of transgender or nonbinary respondents of color reported experiencing one form of denial by a health insurance company in the past year, 28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender-affirming hormone therapy in the year prior, and 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender-affirming surgery in the year prior Our youth face increased	(b)(5)	Color34
	Compared to the general population transgender individuals are at a greater risk for physical and mental health problems. They also face numerous barriers to improving their health and well being. It is challenging to find an appropriately trained healthcare professional because many U.S. clinicians are not formally taught how to care for transgender patients. Additionally medical treatment for gender dysphoria/gender incongruence is often considered elective by insurance companies which leave transgender individuals without coverage for physician-prescribed treatment. Finally many transgender individuals cannot access standard preventive services related to their sex assigned at birth (i.e. prostate cancer screening for a trans/nonbinary woman) due to insurance coverage limits. In our recent position statement on transgender health we make policy recommendations that would address these issues and improve transgender individuals' access to care. Our comments below focus on provisions in the proposed rule that we believe align with our position statement and will improve health outcomes for the transgender population and we urge that these provisions be finalized as proposed		Endocrine Society
	According to the National Center for Transgender Equality's [NCTE] Report of the 2015 U.S. Transgender Survey [Hyperlink: https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf, for example transgender people experience a high level of mistreatment and discrimination by healthcare providers. One third [33 percent] of respondents report that in the past year they had at least one negative experience with a healthcare provider with higher rates for people of color and those with disabilities. These experiences include outright refusal of care verbal and physical abuse and sexual assault. Due to a justified fear of violence and discrimination 23 percent of respondents reported in the past year that they had not sought care when they have needed to.Similarly recent surveys of LGBTQI+ Americans by the Center for American Progress found 69 percent of intersex respondents [Hyperlink: https://www.americanprogress.org/article/key-issues-facing-people-intersex-traits/] reported a stigmatizing experiences in healthcare in the prior year and 50 percent of intersex respondents [Hyperlink https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtq-communities/] postponed or did not seek needed medical care due to disrespect or discrimination from providers. A national survey by the Trevor Project [Hyperlink: https://www.thetrevorproject.org/research-briefs/the-mental-health-and-well-being-of-lgbtq-youth-who-are-intersex-oct-2021/] found that youth who both had intersex traits and identified as LGBTQ reported a healthcare provider trying to change their sexual orientation or gender identity at twice the rate of their non-intersex LGBTQ peers. The changes that the Department has included in the proposed rule will have a substantial impact in combating this current reality		38 Members of Congress
	Overall the LGBTQAI+ community experiences many challenges when interacting with healthcare providers and health insurers according to a report [embedded hyperlink text (https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtq-communities/)] by Center for American Progress. Key findings from the report include - 23 percent of LGBTQ+ respondents including 27 percent of LGBTQIA+ respondents of color reported that in the past year they postponed or avoided getting needed medical care when sick or injured due to disrespect or discrimination from doctors or other health care providers. Overall 33 percent of LGBQ respondents including 39 percent of LGBQ respondents of color reported experiencing some form of care refusal by a doctor or other health care provider in the year prior:- Overall 32 percent of transgender or nonbinary respondents including 46 percent of transgender or nonbinary respondents of color reported that they experienced at least one kind of care refusal by a health care provider in the past year, 55 percent of intersex respondents reported that in the past year a health care provider refused to see them because of their sex characteristics or intersex variation.- Overall 30 percent of transgender or nonbinary respondents including 47 percent of transgender or nonbinary respondents of color reported experiencing one form of denial by a health insurance company in the past year 28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender affirming hormone therapy in the year prior; and 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender-affirming surgery in the year prior		SIECUS Sex Ed for Social Change
	WPHCA is immensely supportive of this expansive definition of discrimination under this rule as this will protect LGBTQ patients experiencing discrimination in health care settings especially in certain States where access to essential services is threatened. Many states lack explicit LGBTQ discrimination protections in health care and WPHCA appreciates the Administration's intention to return 1557 protections back to language in the 2016 rule and in many instances expand upon those protections		Wisconsin Primary Health Care Association

gay bisexual transgender queer/questioning and intersex (LGBTQI+) individuals and urged President Biden to reinstate the 2016 protections upon taking office |Hyperlink
https://www.aafp.org/dam/AAFP/documents/advocacy/coverage/aca/LT-HHS-1557-OBD/19.pdf |Hyperlink
https://www.aafp.org/dam/AAFP/documents/advocacy/admin/transition/LT-WhiteHouse-HealthCareForAllRegulatoryRecommendations-012221.pdf] Access to gender-affirming care is critically important for the approximately 1.3 million individuals who identify as gender diverse (transgender nonbinary intersex etc.). Those who receive gender affirming care are less likely to attempt suicide have lower rates of depression and anxiety and use fewer illicit drugs |Footnote 1 Grant J M Mottet L A Tanis J Injustice at Every Turn: A Report of the National Transgender Discrimination Survey. Washington: National Center for Transgender Equality and National Gay and Lesbian Task Force. 2011;[May];1(2):198] |Footnote 2 American Medical Association. Issue brief: Health insurance coverage for gender affirming care of transgender patients. 2019;2(4)[May 2017]:1-5. https://www.ama-assn.org/system/files/2019-03/transgender-coverage-issue-brief.pdf] Yet gender diverse individuals continue to face disparities in access to health care services—nearly one in four transgender patients report avoiding needed medical care due to fear of stigma and discrimination leading to higher health care costs and poorer outcomes |Footnote 3 Seelman K L Colon-Diaz M LeCroy R H Xavier-Brier M & Kattari L. [2017] Transgender Noninclusive Healthcare and Delaying Care Because of Fear: Connections to General Health and Mental Health Among Transgender Adults. Transgender health 2(1) 17–28. https://doi.org/10.1089/trgh.2016.0024] The AAFP's policy on care for the transgender and gender nonbinary patient supports access to gender affirming care and the ability for physicians to refer patients if they are unable to provide

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|Italics LGBTQI+ Justice in Aging strongly supports the proposal to clarify that under Sec. 1557 discrimination on the basis of sex includes but is not limited to discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions; sexual orientation, and gender identity." |Footnote 17: 87 Fed. Reg. 47824 47911 (§ 92.101(a)(2)).] We agree with HHS that Supreme Court case law including |Italics Price Waterhouse v. Hopkins and Bostock v. Clayton County| makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity including transgender status. We appreciate HHS's discussion and definitions of these terms, including the pervasiveness of discrimination against transgender individuals in healthcare. The terms "gender identity" and "transgender status" are often used interchangeably and courts have construed the term "gender identity" to encompass "transgender identity." However some have sought to justify discrimination against transgender people by distinguishing it from gender identity. |Bold We therefore urge HHS to amend § 92.101(a)(2) to explicitly include "transgender status" In addition to the other bases listed |These specific protections are necessary to help reduce the pronounced health disparities and higher poverty rates LGBTQ+ older adults experience compared to their heterosexual and cisgender peers |Footnote 18: SAGE & National Resource Center on LGBT Aging: Facts on LGBT Aging
https://www.lgbtagingcenter.org/resources/pdfs/SAGE LGBT Aging Final R2.pdf] Discrimination in health care contributes to these disparities. LGBTQI+ older adults have been denied care provided inadequate care and have been afraid to seek necessary care for fear of mistreatment. |Footnote 19: Mary Beth Foglia & Karen L. Fredriksen Goldsen Health Disparities among LGBT Older Adults and the Role of Nonconscious Bias Hastings Cent Rep. [Mar 2015]
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365932/#s11title] Transgender older adults like transgender people of all ages are frequently denied medically necessary gender-affirming care including gender-affirming surgery despite letters from their physicians demonstrating the medical necessity of these treatments. We have heard from advocacy partners that many transgender older adults also have difficulty finding providers they can trust and who will treat them with dignity. For example earlier this year a transgender Asian American woman in her sixties underwent facial feminization surgery. A part of this surgery involves the Adam's apple (a tracheal shave) which has the temporary side effect of being unable to speak following the surgery. When this transwoman woke up from her surgery multiple nurses misgendered her and harassed her. Because she could not talk she could not stand up for herself. As the advocate who shared this story reported "Older adults are often at the mercy of their healthcare providers and are unable to fight for themselves when harassed."

Justice in Aging

In addition many LGBTQI+ older adults and their loved ones experience discrimination in long-term care facilities |Footnote 23: Justice in Aging et al. LGBT Older Adults in Long-Term Care Facilities: Stories from the Field [updated June 2015] http://www.justiceinaging.org/wp-content/uploads/2015/06/Stories-from-the-Field.pdf] such as verbal and physical harassment denial of basic care [such as a shower] visiting restrictions isolation improper discharge and refusal of admission. |Footnote 24: Noelle Feliciano LGBTQ seniors fear discrimination when searching for housing PBS News Weekend (Oct. 10 2021)
https://www.pbs.org/newshour/show/lgbtq-seniors-fear-discrimination-when-searching-for-housing. ULLA Williams Institute LGBT Aging: A Review of Research Findings Needs and Policy Implications [Aug. 2018]
https://www.lgbtagingcenter.org/resources/pdfs/LGBT-Aging-A-Review.pdf] For example a transgender older woman was discharged from the hospital to a rehabilitation facility after a procedure. When the aide who was assigned to her gave her a sponge bath the next day the aide discovered that she was transgender. The aide then brought in other nurses and made fun of the woman who was already in a vulnerable position being older and recovering from surgery. |Footnote 25: Story reported to SAGE and shared with permission |

Justice in Aging

Discrimination in LTSS settings can also be systemic. We have heard reports of privately operated group homes not accepting people living with HIV for example or making it clear that LGBTQI+ older adults are not welcome. The harms of these discriminations are compounded for older adults residing in smaller cities and rural areas—they are either forced to reinvest themselves to get the care they need or delay or forgo services altogether.

Justice in Aging

LGBTQI+ older adults also fear discrimination in LTSS settings. For example a lesbian older adult who has witnessed discrimination against her own LGBTQI+ clients shared that she worries about whether she will show up and whether it will be welcoming if she needs more assistance. Many choose not to receive home- and community-based services (hospice home health aides or other assistance because they fear discrimination. This type of discrimination stings in a unique way because the services are often administered at home or elsewhere in the community where older adults should feel most comfortable and safe

Justice in Aging

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American Academy of Family Physicians

These problems persist. In 2022, Data in a [build/under-ined: new report] from the Center for American Progress "reveal that LGBTQI+ communities encounter discrimination and other challenges when interacting with health care providers and health insurers underscoring the importance of strengthening nondiscrimination protections through Section 1557 of the Affordable Care Act." Key findings from the report include: 23 percent of LGBTQI+ respondents including 27 percent of LGBTQI+ respondents of color reported that in the past year they postponed or avoided getting needed medical care when sick or injured due to disrespect or discrimination from doctors or other health care providers. Overall 15 percent of LGBQ respondents including 23 percent of LGBQ respondents of color reported experiencing some form of care refusal by a doctor or other health care provider in the year prior; Overall 32 percent of transgender or nonbinary respondents including 48 percent of transgender or nonbinary respondents of color reported that they experienced at least one kind of care refusal by a health care provider in the past year;55 percent of intersex respondents reported that in the past year a health care provider refused to see them because of their sex characteristics or intersex variation. Overall 50 percent of transgender or nonbinary respondents including 47 percent of transgender or nonbinary respondents of color reported experiencing some form of denial by a health insurance company in the past year,-28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender affirming hormone therapy in the year prior and 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported that a health insurance company denied them coverage for gender affirming surgery in the year prior.

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[build/under-ined: LGBTQI+ individuals] experience higher levels of stigma and that shame concealment of one's sexual identity and discrimination leads to an increased rate of eating disorders. For LGBTQI+ youth the research is even more bleak. LGBTQI+ youth report [bold/underlined: higher levels] of sexual minority-specific victimization depressive symptoms and suicidality compared to their heterosexual peers. It is estimated that LGBTQI+ youth that are diagnosed with an eating disorder are [bold/underlined: four times more likely to attempt suicide] than LGBTQI+ youth who never had or suspected they had an eating disorder.

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Eating Disorders Coalition for Research, Policy & Action

system Black Americans have long confronted inequities in health care access treatment and outcomes. These disparities are particularly acute for Black pregnant and LGTBQ+ people and weaken society as a whole. Redlining and other discriminatory practices have fostered ongoing residential segregation that has kept Black Americans in under-resourced neighborhoods left generations of Black communities disproportionately exposed to health hazards and hindered them equal access to health care. [Footnote 11 See generally TOM SHAPIRO ET AL. INST. THURGOOD MARSHALL INST. & INST. ON ASSETS AND SOC. POL'Y AT BRANDEIS U. UNIV. THE BLACK-WHITE RACIAL WEALTH GAP (2019) https://iminstitute.ldf.org/wp-content/uploads/2019/11/FINAL-RWG-Brief-v1.pdf .] Because redlined neighborhoods were often chosen as the sites for new factories or highways people of color are more likely to live in polluted areas and near environmental hazards. [Footnote 12 Laura Wamsley Even many decades later redlined areas see higher levels of air pollution NPR (Mar. 30 2022) https://www.npr.org/2022/03/30/1089588294/redlining-pollution-race-link; Dan Lusick Past Racist "Redlining" Practices Increased Climate Burden on Minority Neighborhoods SCIENTIFIC AM. (Jan. 21 2020) https://www.scientificamerican.com/article/past-racist-redlining-practices-increased-climate-burden-on-minority-neighborhoods/, SHAPIRO ET AL. supra note 11 at 13.] Furthermore until the 1960s hospitals were rigidly segregated and unequal. [Footnote 13 David Barton Smith The Politics of Racial Disparities Desegregating the Hospitals in Jackson Mississippi Am J Public Health (1971). 2005 at 247 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2600142/.] While hospitals are now integrated Black Americans still do not have equal access to health care facilities. Predominantly Black racially isolated neighborhoods are more likely to be in primary care deserts and suffer fewer ambulatory facilities more limited access to physicians and a lower supply of surgeons." [Footnote 14 Mariana C

NAACP Legal Defense and Education Fund, Inc

Youth who identify as transgender and gender diverse face unique health disparities. [Footnote v. Ibid.] These youth often confront stigma and discrimination which contribute to feelings of rejection and isolation that can adversely affect physical and emotional well-being. Youth who identify as transgender or gender diverse experience disproportionately high rates of homelessness physical violence at home and in the community substance abuse and high risk sexual behaviors. [Footnote vi and vii. Tishelman AC Kaltiman R Edwards-Leeper L Mandel FH Shumer DE Spack NP. Serving transgender youth challenges dilemmas and clinical examples. Prof Psychol Res Pr. 2015;46(1):37–45.pmid:26900701; Adelson SL; American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice parameter on gay lesbian or bisexual sexual orientation gender nonconformity and gender discordance in children and adolescents. J Am Acad Child Adolesc Psychiatry. 2012;51(9):957–974.pmid:22917211.] In addition to societal challenges youth who identify as transgender or gender diverse face several barriers within the health care system especially regarding access to care. A 2016 study from the National Center for Transgender Equality found that approximately 25% of individuals who identified as transgender were denied insurance coverage because of being transgender. [Footnote vii: James SE Herman JL Rankin S Keisling M Mottet L Anafi M. The Report of the 2015 U.S. Transgender Survey Washington DC. National Center for Transgender Equality. 2016;] The mental and physical health and well-being of transgender children and adolescents often rely on the ability to access much needed mental and physical health care—care that is in keeping with the widely recognized evidence based standards of care for gender dysphoria.

American Academy of Pediatrics

The Department's proposal to once again recognize Section 1557's application to private insurance continues to claim of properly implementing Congress' intent when drafting Section 1557 to encompass all forms of healthcare across. According to data in a new report from the Center for American Progress [Hyperlink: https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtq-communities/] transgender and nonbinary people at large experience significant discrimination when seeking insurance coverage for medical care. Key findings include that in the past year:• 30 percent of transgender or nonbinary respondents including 47 percent of transgender or nonbinary respondents of color reported experiencing one form of denial by a health insurance company;• 28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported a denial of coverage for gender-affirming hormone therapy, and• 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported a denial of coverage for gender affirming surgery.

88 Members of Congress

The Rule defines "transgender" as referring to "people who identify as a gender other than their sex assigned at birth. This may include people who identify as nonbinary genderqueer or gender nonconforming regardless of whether those individuals explicitly use the term transgender to describe themselves." [Footnote 124: to [the f nal phrase of that definition] "regardless of whether those individuals explicitly use the term transgender to describe themselves" might give the Rule's arbitrary and unfair constructions a chance to appear to privilege anyone who asserts a claim of discrimination on the basis of "gender identity." "Gender-non-conforming" is undefined by the Proposed Rule is an especially problematic expansion of the scope of Section 1557 anti-discrimination protections under the "gender identity" classification. " Gender nonconforming" is used in some places to describe an "identity". Footnote 125: 87 Fed. Reg. 47831. | while elsewhere it suggests non-conformity regarding stereotypical behavior or dress. | Footnote 126: 87 Fed. Reg. 47830 47858 n 333 | Further although a person's self-perception as "gender non conforming" would not ordinarily imply either a transgender identity or an assertion "need" for "gender affirming" medical or surgical interventions the Proposed Rule lists a "gender- nonconforming" identity as one which might require receipt of "gender affirming ... hormone therapy [or] surgery." | Footnote 127: 87 Fed. Reg. 47854.] It's development is without precedent and suggests that the categories of "gender identity" and "transgender" are elastic enough to cover anyone who "simply does not conform to traditional stereotypes of masculinity or femininity associated with being male or female." |Footnote 128: Colin Wright The Transgender Umbrella Casts Its Shadow over Gender Non- Conformity Reality's Last Stand Substack |Aug. 31 2022| https://www.realityslaststand.com/p/the transgender umbrella casts its.|

HS justifies its broad inclusion of a range of self-described identities by claiming "review of the literature" showed "considerable discrimination experienced by transgender and gender non-conforming individuals." |Footnote 129: 87 Fed. Reg. 47854.] However HHS fails to provide any clarifying citation to explain who is included in the category of "gender non conforming" or to provide any evidence supporting the need to extend these individuals (whomever they might be) specific non-discrimination protections under Section 1557. |Footnote 130: 87 Fed. Reg. 47865.] In fact the Proposed Rule uses the "+" designation to indicate that its language describing covered individuals is expansive and nearly infinite. It states that "We use '+' in this acronym [to indicate inclusion of individuals who may not identify with the listed terms but who have a different identity with regards to their sexual orientation gender identity or sex characteristics." Footnote 131: 87 Fed. Reg. 47831 n.77.

Discrimination is one of the biggest barriers that transgender individuals face when accessing health care. Studies indicate that 70% of transgender individuals have experienced mistreatment by medical providers including harassment and violence and 28% of transgender individuals have postponed necessary medical treatment when sick or injured due to previous discrimination by healthcare providers. Footnote 2: Davidge-Pitts C et al. Transgender Health in Endocrinology. Current Status of Endocrinology Fellowship Programs and Practicing Clinicians. J Clin Endocrinol Metab. 2021; 106[4]: 1182–1190. |Footnote 3: Grant Jaime M. Lisa A. Mottet Justin Tanis Jack Harrison Jody L. Herman and Mara Keisling. Injustice at Every Turn. A Report of the National Transgender Discrimination Survey. Washington. National Center for Transgender Equality and National Gay and Lesbian Task Force 2011]. The lack of competence among providers makes it harder for transgender individuals to access quality care which contributes to poorer health outcomes among this population. Nondiscrimination protections for transgender individuals will ensure that they can seek medical care without fear of harassment as well as reports when they have been a victim of discrimination.

These youth report a greater incidence of mental health issues and suicidal behaviors suffer bullying and victimization to a greater extent than heterosexual youth and have difficulty addressing concerns with their medical providers. Footnote 25: Hudaisa Hafeez et al. Health Care Disparities Among Lesbian Gay Bisexual and Transgender Youth: A Literature Review Cureus (Apr. 20 2017) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478216. | One study found that 3% of transgender youth reported a previous suicide attempt and 86% reported suicidal thoughts. [Footnote 26: Ashley Austin et al. Suicidality Among Transgender Youth: Elucidating the Role of Interpersonal Risk Factors. 27 J. of Interpersonal Violence 2696 (2022) https://pubmed.ncbi.nlm.nih.gov/32345113/ The Centers for Disease Control and Prevention found that transgender students are more likely to report feeling unsafe at or going to and from school being bullied threatened or injured with a weapon at school being forced to have sex and experiencing physical and sexual dating violence. [Footnote 27: See Michelle J. Johns et al. U.S. Ctrs. for Disease Control & Prevention Transgender Identity and Experiences of Violence Victimization Substance Use Suicide Risk and Sexual Risk Behaviors Among High School Students 68 Morbidity Mortality Weekly Rep. 67 69 (2019) http://dx.doi.org/10.15585/mmwr.mm6803a3.] Undergoing puberty that does not align with one's gender identity and developing permanent undesired secondary sex characteristics is "often a source of significant distress" for transgender adolescents. |Footnote 28: Rhonda Lopez et al. Statement on Gender-Affirmative Approach to Care From the Pediatric Endocrine Society Special Interest Group on Transgender Health 29 Current Op. Pediatrics 475 480 (2017) https://pubmed.ncbi.nlm.nih.gov/28562420/. Access to gender affirming care improves health outcomes for transgender youth. Transgender teens with access to such support and gender-affirming healthcare experience mental health outcomes equivalent to their cisgender peers. [Footnote 29: Dominici

It NPRM of the pervasiveness and harms of age discrimination to older adults and the particular disparities that the COVID-19 pandemic highlighted and amplified especially for older adults in nursing facilities. In addition to interpersonal discrimination that older adults face in health care such as having their concerns ignored or dismissed as a "normal" part of aging examples of more systemic ageism harm older adults' access to proper diagnoses treatment and services. Two examples are from the U.S. Preventive Services Task Force (USPSTF). First its recommendations for HIV screening. [Footnote 13: USPSTF Final Recommendation Statement Human Immunodeficiency Virus [HIV] Infection: Screening [Jun. 11 2019] https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening. | the USPSTF concludes that all adolescents and adults 15-65 should be screened for HIV but that adults over 65 should only be screened if they have "risk factors." This assumes that individuals age 65 and over do not engage in sex or drug use – a very ageist presumption and it makes an arbitrary distinction between someone age 64 and someone age 65. As a result it is challenging to get Medicare to cover more than one HIV screening per year which is necessary for PrEP to be administered. More recently the USPSTF issued a draft recommendation for anxiety screening for all adults older age 65. |Footnote 14: Draft Recommendation Statement Screening for Anxiety in Adults [Sept. 20 2022] https://uspreventiveservicestaskforce.org/uspstf/draft-recommendation/anxiety-adults-screening#fullrecommendationstart. | In declining to extend the recommendation for people 65 and older the panel said there was not clear evidence regarding the effectiveness of screening tools in older adults because anxiety symptoms can also result from aging. This reasoning points to the ways in which ageism shows up in health care. Instead of focusing on alternatives to [illegible] for older adults the Proposed Rule's [illegible] people over 65 as ineligible for

[illegible] medically necessary gender-affirming care including gender-affirming surgery despite letters from the physicians demonstrating the medical necessity of these treatments. We have heard from advocacy partners that many transgender older adults also have difficulty finding providers they can trust and who will treat them with dignity. For example earlier this year a transgender Asian American woman in her sixties underwent facial feminization surgery. A part of this surgery involves the Adam's apple (a tracheal shave) which has the temporary side effect of being unable to speak following the surgery. When this trans woman woke up from her surgery multiple nurses misgendered her and harassed her. Because she could not talk she could not stand up for herself. As the advocate who shared this story reported "Older adults are often at the mercy of their healthcare providers and are unable to fight for themselves when harassed."

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Older adults also experience discrimination based on their sexual orientation such as doctors making assumptions about their sexual behavior forcing the older adult to disclose their sexual orientation. Others have been harassed and denied care. For example an older adult shared his story about visiting a urologist for a health concern not related to a sexually transmitted infection. He reported that when the doctor asked him if he was married and he said no and that he is gay the doctor replied " It is no wonder you're sick. What you people do is disgusting." The doctor refused to examine the man but he still had to pay for an office visit even though he did not receive treatment. [Footnote 20: Story reported to SAGE and shared with permission.] Many older LGBTQI+ adults especially those age 80 and older express feelings of hesitation about disclosing their sexuality or gender identity to their health care provider or insurer because they fear being denied care or being dropped from their coverage. [Footnote 21: Mary Beth Fogg o & Karen L. Fredriksen Goldsen Health Disparities among LGBT Older Adults and the Role of Nonconscious Bias Hastings Cent Rep. (Mar. 2015) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4364952/#s1title] As one study found this communication may suggest "shared decision-making during the clinical encounter is likely to be compromised thereby contributing to the perpetuation of health inequalities among LGBT older adults." [Footnote 22: Id] Others report delaying care due to this fear.

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Justice in Aging

In addition many LGBTQI+ older adults and their loved ones experience discrimination in long-term care facilities [Footnote 23: Justice in Aging et al. LGBT Older Adults in Long-Term Care Facilities: Stories from the Field (updated June 2015) http://www.justiceinaging.org/wp-content/uploads/2015/06/Stories-from-the-Field.pdf] such as verbal and physical harassment denial of basic care (such as showers) visiting restrictions isolation improper discharge and refusal of admission. [Footnote 24: Noelle Feliciano LGBTQ seniors fear discrimination when searching for housing PBS News Weekend (Oct. 10 2021) https://www.pbs.org/newshour/show/lgbtq-seniors-fear-discrimination-when-searching-for-housing. ULLA Williams Institute LGBT Aging: A Review of Research Findings Needs and Policy Implications (Aug. 2018) https://www.lgbtagingcenter.org/resources/pdfs/LGBT-Aging-A-Review.pdf] For example a transgender older woman was discharged from the hospital to a rehabilitation facility after a procedure. When the aide who was assigned to her gave her a sponge bath the next day the aide discovered that she was transgender. The aide then brought in other nurses and made fun of the woman who was already in a vulnerable position being older and recovering from surgery. [Footnote 25: Story reported to SAGE and shared with permission.] Discrimination in LTSS settings can also be systemic. We have heard reports of privately operated group homes not accepting people living with HIV for example or making it clear that LGBTQI+ older adults are not welcome. The harms of these discriminations are compounded for older adults residing in smaller cities and rural areas—they are either forced to relocate themselves to get the care they need or delay or forgo services altogether.

Justice in Aging

LGBTQI+ older adults also fear discrimination in LTSS settings. For example a lesbian older adult who has witnessed discrimination against her own LGBTQI+ clients shared that she worries about what she will wear and whether it will be welcoming if she needs more assistance. Many choose not to receive home- and community-based services (hospice home health aides or other assistance) because they fear discrimination. This type of discrimination stings in a unique way because the services are often administered at home or elsewhere in the community where older adults should feel most comfortable and safe.

Justice in Aging

Another form of harm is when instances of racial discrimination experience poorer health outcomes in old age. For example studies have shown that Black and Latino people who experience racial discrimination or have higher rates of cognitive decline. [Footnote 33: Univ. of Tx at Austin Cognitive Impairment in Hispanic Adults Linked to Discrimination Experiences (Sept. 13 2022) https://news.utexas.edu/2022/09/13/cognitive-impairment-in-hispanic-adults-linked-to-discrimination-experiences/] This helps explain why Black and Latino older adults have higher rates of Alzheimer's and related dementias compared to non-Hispanic white older adults. Discrimination throughout the lifetime also causes "weathering" [Footnote 34: Arline Geronimus 'Weathering': What are the health effects of stress and discrimination? (Feb. 26 2021) https://www.medicalnewstoday.com/articles/weathering-what-are-the-health-effects-of-stress-and-discrimination] and a lower life expectancy. Recent plunges in overall life expectancy were most severe among people of color. They have died at younger ages during the COVID-19 pandemic than white Americans due to structural racism that pervades our healthcare social support and economic systems. One shocking example is the drop in life expectancy for Native American/Alaska Native people which fell by 6.6 years from 2019 to 2021. [Footnote 35: U.S. Life Expectancy in the U.S. Dropped for the Second Year in a Row in 2021 (Aug. 2022) https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/20220831.htm]

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Other biases result in disparate harm to older adults of color. For example many providers do not accept or limit their intake of patients with Medicaid [Footnote 36: Kayla Hogash & Martha Heberlein Physician Acceptance Of New Medicaid Patients: What Matters And What Doesn't Health Affairs (Apr. 10 2019) https://www.healthaffairs.org/do/10.1377/hblog20190401.678690/full/ MACPAC Physician Acceptance of New Medicaid Patients: Findings from the National Electronic Health Records Survey (June 2021) https://www.macpac.gov/wp-content/uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf]"In 2017 (the most recent year available) physicians were significantly less likely to accept new patients insured by Medicaid (74.3 percent) than those with Medicare (87.8 percent) or private insurance (96.1 percent) "]] which impacts access to care for older adults of color the most as these communities are disproportionately dually eligible for Medicaid and Medicare. [Footnote 37: Kaiser Family Foundation Racial and Ethnic Health Inequities and Medicare (Feb. 16 2021) https://www.kff.org/medicare/issue-brief/racial-and-ethnic-health-inequities-and-medicare/] Even providers who accept Medicare may refuse to see someone who is dually enrolled in Medicaid because Medicaid billing may present some additional administrative burdens and providers do not want to forgo the guarantee that the individual is not required to pay and that the state usually does not pay due to the "lesser of" policy.

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Justice in Aging

Improving access to care access to people with disabilities is critical to reducing health disparities which are often compounded by pervasive ableism and intersecting systems of discrimination. For example Black people are more likely to have a disability relative to White people in every age group and according to the Centers for Disease Control and Prevention three in 10 American Indian/Alaska Native people and one in four Black people live with disabilities. [Footnote 38: "Adults with Disabilities: Ethnicity and Race." Centers for Disease Control and Prevention (6 Sept. 2020) https://www.cdc.gov/ncbddd/disabilityandhealth/materials/factsheet-disabilities-ethnicity-race.html] Additionally older adults with disabilities often experience discrimination based on both ageism and ableism.

The Leadership Conference on Civil and Human Rights

Every day our organizations hear from consumers across the state who face challenges accessing equitable affordable high-quality health coverage and care. We hear from people for whom English is not their primary language seeking culturally and linguistically competent health care services. We hear heartwrenching stories from people who need access to timely and complete abortion services. We hear from people of various genders including transgender people who already have trouble finding the gender-affirming coverage and care they seek. We hear from people with disabilities who face overwhelming obstacles in finding all the services they need to remain in the community. These are real people who already encounter barriers to accessing the health care services and supports they need. HCFA and NLA believe in the critical importance of ensuring that all people can obtain equitable high-quality affordable health care without facing discriminatory barriers. The nondiscrimination requirements of the Affordable Care Act § 1557 are critical to ensuring the health and well being of our communities. We support the administration in strengthening this provision of the ACA and make the below recommendations to further guarantee the robust implementation of this law.

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Health Care For All

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Services (HHS) proposed rule to Strengthen Nondiscrimination in Health Care and to express our support for continued action from HHS to clarify specific guidelines for physicians' and health care providers' ability to prescribe life-saving medications to people specifically people with disabilities and to ensure protections for providers who provide emergency abortions for people with disabilities [Footnote 1]. In this letter we want to clarify "protections" to mean clarifying the ability to provide emergency abortions for people with disabilities]. We ask that the protections in this letter be clearly outlined in the final rule to implement Section 1557 of the Affordable Care Act (ACA) (Section 1557)) [Footnote 2: Centers for Medicare and Medicaid Services, Office for Civil Rights (OCR) Office of the Secretary HHS, proposed rule on Section 1557 of the Affordable Care Act (ACA) (Section 1557) (2022). Document link: Section 1557 Notice of Proposed Rulemaking (hhs.gov)]. The Supreme Court's decision to overturn Roe v. Wade has created confusion for health care providers who often do not have clear guidance on when a pregnant person's life is sufficiently at risk to warrant an exception to an abortion ban. Clinicians have already reported that they are having to put patients' lives in danger while they wait on ethics consults around medically necessary procedures [Footnote 3: Goldhill O. (2022). "A scary time": Fear of prosecution forces doctors to choose between protecting themselves or their patients. [online] STAT. Available at: https://www.statnews.com/2022/07/05/a-scary-time-fear-of-prosecution-forces-doctors-to-choose-between-protecting-themselves-or-their-patients/?utm_source=STAT+Newsletters&utm_campaign=3d445d7be9-Daily_Recap&utm_medium=email&utm_term=0_8cab3d7961-3d445d7be9-148644313 [Accessed 14 July 2022]]. Meanwhile patients with disabilities have reported being denied medications that can be used for medication abortion despite relying on them to treat other conditions [Footnote 4: Sharp S. (2022). Pas

Although a number of federal laws prohibit several forms of discrimination, Section 1557 extends these protections to any health program or activity that receives federal funding any health program or activity that HHS administers the health insurance exchanges and all plans offered by insurers that participate in those marketplaces. This Proposed Rule not only clarifies the broad civil rights protections extended in Section 1557 but, most importantly provides concrete tools to combat racism and other forms of discrimination in health care. First, the Proposed Rule addresses various forms of discrimination that disproportionately affect communities of color including on the basis of disability status, national origin and sex. Second, the Proposed Rule addresses systemic discrimination including policies and practices that harm people of color. Finally, the Proposed Rule lays out vast enforcement authority across all segments of the health care system and related activities — ensuring Section 1557's prohibition against race discrimination is adhered to across the country.

[Bold: C. Discrimination On The Basis Of Pregnancy Related Conditions And the Impact of [Italics: Dobbs]] In the Proposed Rule HHS correctly recognizes that discrimination on the basis of pregnancy or its related conditions is a form of sex discrimination that impacts healthcare access. 87 Fed. Reg. at 47832. Where patients are denied medication, treatment or even information these actions can result in serious health consequences. Id. As HHS recognizes access to healthcare is crucial, particularly for those who experience "intersectional discrimination such as people of color and those with disabilities." Id.

Clients with developmental disabilities (DD) often experience systemic discrimination. When clients with DD go to doctors' offices doctors frequently don't talk to clients and talk to their supporters or others who accompany them to medical appointments. We recently had a client with DD die of pancreatic cancer. He had made multiple trips to the emergency departments and doctors' offices complaining about stomach pain but they didn't do testing etc. and it wasn't diagnosed until shortly before he died. This is not unusual. Previously I related how Deaf clients continually face the same issues regarding communication access. For example we had two cases involving the same communication issue with the same specialist

of disaggregated demographic data supports the department's enforcement efforts. We commend the department for recognizing the critically important role demographic data plays in addressing discrimination and health disparities [Footnote 18: Fed. Reg. at 47836.]. However we are concerned the department does not at minimum require covered entities to collect disaggregated demographic data. Better national standards and uniform data collection practices could have an outsized impact on efforts to narrow health disparities. HHS must require demographic data collection based on multiple demographic variables including sex race ethnicity primary language age gender identity sexual orientation and disability status. At the community and population levels these variables both individually and in combination can reveal health disparities. For example racial and ethnic minority women receive poorer quality care than racial and ethnic minority men who receive poorer care than White men. [Footnote 19: Rosaly Correa de Araujo et al. Gender differences across racial and ethnic groups in the quality of care for acute myocardial infarction and heart failure associated co-morbidities. Women's Health Issues 44 (2006); Ann F. Chou et al. Gender- and racial disparities in the management of diabetes mellitus among Medicare patients. Women's Health Issues 150 (2007).] Spanish-speaking Hispanics experience poorer quality care than English-speaking Hispanics who experience poorer care than non-Hispanic Whites. [Footnote 20: Eric M. Cheng, Alex Chen & William Cunningham. Primary language and receipt of recommended health care among Hispanics in the United States. J. General Internal Medicine 283 (2007); C. Annette DuBard & Ziya Gizlice. Language spoken and differences in health status access to care and receipt of preventive services among U.S. Hispanics. Am. J. Public Health 2021 (2008).] Compared to women without disabilities women with disabilities are more likely not to have regular mammograms or Pap tests [Footnote 21: Marguerite E. Diab & Mary V. Johnston. Relationships between level

during the level of pandemic provides a timely and urgent reminder of why broader and deeper awareness of civil rights is needed among health care entities. Family members friends and paid caregivers who provide the personal care assistance needed by people with a range of disabilities were treated as ordinary "visitors" and turned away by security personnel nurses and other healthcare providers. The result placed people with disabilities at risk of having their communication and health care needs ignored or misunderstood left unable to equally benefit from health care services or being forced to undergo additional invasive procedures such as restraint or the insertion of a feeding tube. The COVID-19 public health emergency only highlighted how hospitals and health care facilities of various sizes have long failed to fully integrate and operationalize civil rights laws leaving people with disabilities their advocates and their family members with few or no timely options to obtain the effective communication and policy modifications necessary for good health outcomes. For example DRM represented a 42-year-old woman diagnosed with Mitochondrial Membrane Protein-Associated Neurodegeneration (MPAN) a rare congenital condition. The nursing home where her guardian placed her refused to allow her family to visit during the beginning of the pandemic even though family visits greatly improved her well-being. Meanwhile nursing home staff were free to come and go. We referred the nursing home administrators to CDC guidances and an OCR guidance about how civil rights laws were still in effect. It made no difference to the administrators. DRM also had clients with developmental disabilities and Autism who required hospitalizations and whose family members were not allowed to visit them. These individuals had communication issues that the treating professionals were not aware of and did not know how to accommodate. The treatment for these individuals suffered. As an organization that works with people with disabilities seeking healthcare we have seen healthcare providers improving access to care access to people with disabilities is key to reducing health disparities which are often compounded by pervasive ableism and intersecting systems of discrimination. For example Black people are more likely to have a disability relative to White people in every age group and according to the Centers for Disease Control and Prevention, three in 10 American Indian/Alaska Native people and one in four Black people live with disabilities. [Footnote 5: "Adults with Disabilities: Ethnicity and Race." Centers for Disease Control and Prevention 16 Sept. 2020. https://www.cdc.gov/ncbddd/disabilityandhealth/materials/factsheet-disabilities-ethnicity-race.html.] Additionally older adults with disabilities often experience discrimination based on both ageism and ableism.

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Senator Kirsten Gillibrand

Alliance of Multicultural Physicians

Attorneys General of California, New York, Massachusetts, and nineteen other States

Disability Rights Maine

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The Leadership Conference on Civil and Human Rights

Disability Rights Maine

The Leadership Conference on Civil and Human Rights

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DRM has represented clients with communication disabilities who have experienced barriers to receiving needed auxiliary aids and services or needed policy modifications and clients who have experienced negative health consequences such as delayed care skipped care inadequate instructions on medications or incomplete examinations for themselves or for a dependent family member because of any of the above failures to notify them of their rights. Communication access increased greatly as a result of the Affordable Care Act (ACA). The ACA required healthcare providers to conform with the communication access regulations of Title II of the ADA. Healthcare providers have to give primary consideration to the methods of communication of patients. However in practice what the issue of what constitutes "primary consideration" for Deaf and Hard of Hearing patients is not always clear. Many providers believe that Video Remote Interpreting (VRI) is the same as in person interpretation. Providers often say they "policy is to provide VRI regardless of whether the individual requests in person interpretation because of vision problems or inadequate VRI which leads to freezing and unstable connections or because they have also visual loss and cannot see a screen. The primary consideration language seems to be giving providers to do more than what has historically been a struggle and often a battle. We've seen it in dialysis centers hospital emergency rooms long-term hospital stays specialist offices. DRM has two cases involving the same GI specialist. Recently a local hospital would not accommodate two individuals who speak traditionally and needed their family to communicate because of COVID restrictions. In one case the hospital accommodated the family but did not accommodate the other individual.

In our work the Tennessee Disability Coalition has seen the consequences when people with disabilities do not receive effective communication or needed auxiliary aids and services in healthcare. A couple of real-life examples follow: A young adult was denied ASL interpretation by a managed care company (MCO) during an initial meeting to discuss services and develop a "person centered" plan. Not only was she not able to fully comprehend the conversation and provide responses to the questions this type of discrimination was painful to her personally adding additional trauma to her life.- Our office has received calls from individuals with disabilities who have been told that it is their responsibility to bring an interpreter with them. When we have contacted the health care provider to help educate them on their responsibilities and provided information and resources to them they mistakenly believe that it is the responsibility of the patient to provide the interpreter. Additionally they express concern about the cost of providing the service.

No comments are associated with this issue.

Coalition appreciates Section VII in the proposed rule and its invitation to comment on the importance of adopting the Access Board's [underlined/bold/blue: 2017 Medical Diagnostic Equipment Accessibility Standards] into enforceable regulation. We now have had almost six years to see what individual health providers and facilities health care systems hospitals health insurers and federal and state health care agencies would voluntarily do with the detailed thorough consensus standards developed by the Access Board. We find that not much has been done. The U.S. Department of [bold/blue/underlined: Veterans' Affairs adopted the standards soon after their completion and applies them to the agency's new equipment acquisitions. However this example was not followed by others. In those five years people with mobility developmental and strength and balance disabilities across a range of ages different races/ethnicity and LGBTQ+ status have continued to be denied access to the most basic medical procedures a physical exam and an accurate measure of weight. As noted by the National Council on Disability in its 2021 letter on [italics/Enforceable Accessible Medical Equipment Standards - A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities:] [Boldfaced italics: The harsh—and discriminatory—reality is that people with mobility disabilities will continue to receive unequal health care until there is regulation.] This means that widespread unavailability of height adjustable examination tables accessible mammography equipment accessible weight scales and lift equipment to facilitate transfers among other accessible medical and diagnostic equipment will remain the status quo. They will continue to be less likely to receive preventive health care services— like cervical cancer screening; colorectal cancer screening; obesity screening, and breast cancer screening. Tragically lack of accurate diagnosis and access to timely treatments will result in preventable deaths. Patients with disabilities who are unfamiliar with their

It is important to adopt the Access Board's 2017 Medical Diagnostic Equipment Accessibility Standards so they become enforceable regulations. Since the development of the standards we have had almost six years to see that individual health providers facilities health care systems hospitals health insurers or federal and state health care agencies have voluntarily adopted the standards. While the U.S. Department of Veterans' Affairs adopted the standards soon after their completion and applies them to the Agency's new equipment acquisitions no others have followed. People with mobility developmental and strength and balance disabilities across a range of ages different races/ethnicity and LGBTQ+ status have been denied access to the most basic medical procedures a physical exam and an accurate measure of weight. As noted by the National Council on Disability in its 2021 letter on [italics] Enforceable Accessible Medical Equipment Standards - A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities:] Without a regulatory widespread unavailability of height adjustable examination tables accessible mammography equipment accessible weight scales and lift equipment to facilitate transfers among other accessible medical and diagnostic equipment will remain the status quo. People with mobility disabilities will remain less likely to receive preventive health care services—like cervical cancer screening; colorectal cancer screening, obesity screening, and breast cancer screening. Inaccessible equipment is not a matter of mere inconvenience. Even if a disabled person has a family member or friend who might be able to accompany them to an appointment and provide transfer assistance the consequences of doing so are borne unequally by low-income individuals and families of color who are least able to afford time off. An aging partner should not be expected to provide transfer assistance but is likely to feel pressured to do so. Patients with disabilities who are unfamiliar with disability signs or already uncomfortable with English are less likely to press for a full exam.

Comments associated with this issue are recorded in the subsections below.

No comments are associated with this issue.

Section 1557 is an important tool to address health inequities including disparities in access to abortion care. The Proposed Rule would clarify and strengthen its anti-discrimination protections. LDF agrees with OCR's interpretation that Section 1557 both provides an "independent basis for regulation of discrimination in covered health programs and activities" and is applicable to an expansive range of "health programs and activities" including programs administered by HHS health insurance plans and Medicare Part B. Footnote 50 Nondiscrimination in Health Programs and Activities 87 Fed. Reg. 47824 47827 (Aug. 4 2022)). LDF also supports OCR's decision to make explicit that Section 1557 prohibits discrimination in telehealth and by clinical algorithms.

We support the Administration's decision to restore and strengthen implementation of Section 1557 of the Affordable Care Act and its protections against discrimination on the basis of race color national origin sex age and disability. We strongly support the proposal to prohibit discrimination in all federally funded health plans.

(b)(5)

Disability Rights Maine

Tennessee Disability Coalition

Tennessee Disability Coalition

(b)(5)

Disability Rights Maine

NAACP Legal Defense and Education Fund, Inc

Tribal Technical Advisory Group to CMS (TTAG)

I write today with serious concerns about the Department of Health and Human Services' proposed rule on Nondiscrimination in Health Programs and Activities regarding "gender affirming care." As I read it, the rule would force hospitals and doctors to administer gender affirmation procedures and prescribe blockers to minors. This is unconscionable. Under no circumstances should a child under the age of 18 undergo gender reassignment surgery or take hormone blockers. This type of surgery and sterilization is irreversible and the fact that the Biden Administration may make it easier for an adolescent who has not fully developed to choose to mutilate his or her body is despicable. To put it bluntly, the Biden Administration is sacrificing children on the altar of wokeness. Many children who receive vaginectomies, mastectomies, puberty blockers and other treatments will mature and realize they made a grave mistake. Men's bone density and growth will be permanently weakened and stunted, women will be made infertile. I could go on but the point is that children are incapable of understanding these lifelong effects. The first promise of the Hippocratic Oath is "do no harm." Unfortunately, as HHS rule advances in its current state, the Biden Administration will be forcing doctors to break their most sacred vow and irreversibly harm our nation's most vulnerable.

(b)(5)

(b)(5)

Rep. Tim Burchett (TN-02)

The Leadership Conference on Civil and Human Rights

American Dental Association

Blue Cross Blue Shield Association

Blue Cross Blue Shield Association

Pennsylvania Health Insurance Exchange Authority d/b/a Pennie

National Association of Health Underwriters

National Association of Health Underwriters

(b)(5)

Center for Elder Law & Justice

Massachusetts Health Connector

(b)(5)

1) HHS must finalize provisions without delay that protect against discrimination in health care programs and activities In the above captioned rule HHS is proposing several provisions that would reinstate safeguards that protect against discrimination in covered health care programs and activities as outlined in Section 1557 of the ACA These proposed provisions include reinstating the scope of Section 1557 clarifies application to health insurance issuers receiving federal financial assistance prohibits discriminatory uses of clinical algorithms used to support decision-making and that nondiscrimination provisions are applicable to services offered through telehealth technologies HHS is right to propose these provisions and ANA urges the agency to finalize this proposed rule ANA is an informed and active stakeholder in the implementation of health care policy. ANA sees the proposed rule to rectify what we saw as the 2020 rulemaking instituting a fundamental change in direction that is antithetical to our principles of health system transformation namely universal access to health care coverage for all citizens and residents. We are pleased that HHS would return key definitions and protection mechanisms that make Section 1557 meaningful especially to people who otherwise face discriminatory barriers to care This is acutely important as nurses and the health care delivery system focus on achieving health equity and identify approaches to overcome health disparities.We believe that existing regulations for Section 1557 and other HHS programs fulfill the intent of Congress to protect people from discrimination in health care that denies their access Section 1557 should be implemented in a manner that promotes access for those who are subject to discrimination [Bold] As such HHS must finalize proposed Section 1557 provisions that protect against discrimination in health care programs and activities We urge HHS to act expeditiously on this rulemaking].

American Nurses Association

Recommendation 4 BCBSA recommends that the scope of the final rule not apply to grandfathered and transitional ("grandmothered") plans Rationale Congress included a grandfathering provision in the Affordable Care Act (ACA) to ensure that consumers with pre-ACA coverage could keep the coverage they had as long as they did not make any material changes in their plans CMS also implemented a transitional relief program permitting certain coverage issued under previous market rules in the individual and small group markets after the ACA's effective date (and therefore not eligible for formal grandfather treatment) to be renewed for policy years to continue in force. CMS has taken a consistent approach to pre-ACA grandfathered and transitional plans across multiple administrations which benefits consumers by allowing them to maintain affordable existing coverage as long as it continues to meet their needs. The additional costs associated with complying with Section 1557 including but not limited to notice and tagline requirements would increase the cost to consumers and would be inconsistent with the longstanding regulatory treatment of these policies

Blue Cross Blue Shield Association

State regulators have further concerns with the absence from proposed section 92 2 of a clear exclusion of the application of nondiscrimination rules for age limitations that are exempt from Age Act rules State legislatures and other regulative bodies sometimes enact legitimate age distinctions for certain benefits or assistance 45 CFR 93 1 holds that such distinctions are not considered discriminatory under the Age Act. The 2016 rule implementing Section 1557 made clear that any age distinctions exempt from the Age Act under 45 CFR 93 1 were also exempt from section 1557 enforcement We urge HHS to consider restoring this clarification to the 1557 rules

National Association of Insurance Commissioners

Given the recent actions that have been taken to eliminate the prohibition of discrimination in health care we commend HHS for taking action to protect individuals from unnecessary discrimination In particular Covered California strongly supports the following proposals • Clarifying and Expanding the Scope of 1557As proposed HHS will increase the number of individuals protected from discrimination by expanding the scope of Section 1557. HHS will require that covered entities prohibit discrimination with their health programs and activities Footnote E The proposed definition of a "covered entity" includes recipients of federal financial assistance HHS and Exchanges[As proposed covered entities would be expanded to many health insurance issuers including qualified health plan (QHP) issuers offering health insurance through an Exchange. To ensure compliance with these requirements HHS will require entities affected to develop and implement policies and procedures clarifying their nondiscrimination policies

(b)(5)

Covered California

The regulation explicitly states it extends to covered entities that are "health insurance issuers and their officials employees agents and representatives" as well as "agents brokers or web-brokers that assist with or facilitate enrollment of qualified individuals qualified employers or qualified employees" through the health insurance exchange marketplaces While the applicability to exchange-based activities is clear when an independent health insurance agent might be considered to be an agent of a health insurance issuer for the purpose of compliance with this rule is not entirely clear to our membership If any final regulation could provide explicit clarification and guidelines NAHU members would appreciate it. We would also like clarification about whether the covered-entity requirements in terms of required notifications written policies and procedures compliance coordinator and grievance process might apply to health insurance agents and brokers especially when they are working under the auspices of another covered entity such as a health insurance exchange or a covered health insurance issuer group health plan or third-party administrator. What if any independent compliance requirements will apply?Finally to assist non-health insurance consumers and covered entities NAHU members urge HHS to consider developing an online applicability tool to help discern whether the extended Section 1557 regulation applies either directly or indirectly to an organization or other health program or activity.

National Association of Health Underwriters

Bold and Italics Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage [§ 92 207)] Bold The AAMC strongly supports proposals to prohibit discrimination in health insurance coverage.' We support the Department's proposal to reinstate the provision from the 2016 Rule to prohibit discrimination on the basis of race color national origin sex age and disability in the provision administration of health insurance coverage and other health-related coverage. We also support the proposal to apply this provision to all federally funded health plans including the Department's administration of its own health-related coverage programs. HHS proposes to apply this provision inclusive of all an issuer's health programs and activities including short-term limited duration insurance and to an issuer's or other entity's operations related to third-party administrative services to ensure all individuals have the protections Congress intended when it enacted the Affordable Care Act. We support this inclusive and broad approach to prohibiting discrimination in health insurance coverage.

Association of American Medical Colleges (AAMC)

9. Scope Applicability In addition to applying to covered health insurance issuers inside and outside of exchanges in the individual and group markets Medicare Advantage organizations Medicare Part D plan sponsors and Medicaid managed care organizations the Proposed Rule also would apply to a covered issuer's excepted benefits and its operations related to acting as a third-party administrator (TPA) for self-funded group health plans.Recommendation 1 BCBSA recommends that TPA operations be excluded from the scope of the final rule whether the TPA is connected to a covered entity or not Rationale BCBSA supports a broad application of Section 1557 but recommends that it not be extended to markets where it would create an unlevel playing field and steer consumers away from covered entities Numerous entities providing insurance or ASO services to employers fall completely outside the scope of Section 1557 creating an unlevel playing field for those TPAs that would be considered in-scope by connection to a covered entity This would place issuers that participate in programs that receive federal funds at a competitive disadvantage to TPAs and issuers who do not participate in programs that receive federal funds from HHS This may lead to some employers that are not subject to the rule (i.e those employers not receiving federal funds from HHS) purchasing insurance or ASO services from insurers and TPAs that do not receive federal funds from HHS to avoid the administrative burden of the new requirements. This might have unintended consequences in markets that trigger being subject to the rule such as participating on exchanges as some entities might not participate in those markets as they view the requirements this triggers as burdensome and adding cost to their TPA business

(b)(5)

Blue Cross Blue Shield Association

(b)(5)

We strongly support the proposal to restore regulatory provisions recognizing that Section 1557 applies to all health programs that receive any form of federal financial assistance including Medicaid and Medicare Health Insurance Exchanges and the plans sold through them and other commercial health plans. These provisions are consistent with the statutory language and the purpose of the ACA to ensure access to and coverage of affordable quality health care. To achieve this goal its provisions had to reach all aspects of the U.S.'s complex network of private and public health care entities. Section 1557's primary nondiscrimination provision embedded in the ACA logically extends to all the same entities as those covered in the Act. We support the clarifications that federal financial assistance includes credits subsidies and contracts of insurance in addition to grants loans and other types of assistance as well as the application of Section 1557's requirements to all operations of an entity principally engaged in the provision or administration of health care. The specific clarifications that recipients of federal financial assistance include any insurer participating in a Health Insurance Exchange and receiving Advance Premium Tax Credits or Cost Sharing Reductions (when available) their third-party administrators and agents and brokers enrolling individuals in their plans is vital to ensuring broad protection against discrimination. Since issuers generally provide plans both on and off the Exchanges these protections will benefit the majority of individuals who receive health coverage through their employers and often have no opportunity to select their health plan. Recipients of Deferred Action for Childhood Arrivals (DACA) who need to buy off-exchange health plans through agents and brokers because they are not yet eligible to use the Exchanges will also benefit.

(b)(5)

National Immigration Law Center

We strongly support the proposal to restore regulatory provisions recognizing that Sec. 1557 applies to federal health programs like Medicaid and Medicare the ACA's state and federal Marketplaces and the plans sold through them as well as other commercial health plans if the insurer receives any form of federal financial assistance. This is consistent with the statutory language and the purpose of the ACA to ensure broad access to and coverage of health care.

Justice in Aging

provisions of the rule we agree or the need for effective regulations to better protect health insurance consumers from unfair discriminatory practices. However state regulators are concerned that application of the rule as proposed would be too broad. While it is appropriate and consistent with the statute to apply Section 1557 protections to health insurers' programs and activities that receive federal financial assistance the proposed rule goes further and would apply to all the operations of health insurers when any part of the enterprise receives federal financial assistance. Because health insurers participate in some markets that receive federal financial assistance and others that do not the proposed rule would require compliance even in activities that do not benefit from federal assistance. Through its definitions in Sec. 92.4 the proposed rule would apply the protections of section 1557 to "All of the operations of any entity principally engaged in the provision" of health insurance coverage if any part of the entity receives federal financial assistance from HHS. Thus an insurer that offers Medicare Advantage coverage funded by HHS would be bound by the nondiscrimination protections in its operations. The same insurer's Medicare supplemental coverage—funded only by enrollee premiums—would be subject to the restrictions on discrimination based on age and the other provisions of the rule. We believe this interpretation goes beyond the intent of Congress. Section 1557 of the ACA prohibits discrimination in "any health program or activity any part of which is receiving Federal financial assistance." Congress did not apply the protections to any entity engaging in health programs or activities but to the programs and activities themselves provided a part of the program or activity receives federal financial assistance. The preamble to the proposed rule discusses the fungibility of funds to justify applying protections to operations that do not directly receive federal assistance. We believe this inappropriate to consider failing to be fully fungible. [Scope of Protections] The NHC strongly supports the inclusion of provisions to restore regulatory provisions recognizing that Section 1557 applies to Medicaid Medicare the ACA's state and federal Marketplaces and the plans sold through them and other commercial health plans if the insurer receives any form of federal financial assistance. This expansive will ensure a broad interpretation of 1557 to include a wide range of insurers and providers. This is consistent with the statutory language and the intent of the ACA to ensure broad access to and coverage of health care.

National Association of Insurance Commissioners

(b)(5)

National Health Council

) HHS must finalize provisions without delay that protect against discrimination in health care programs and activities. In the above captioned rule HHS is proposing several provisions that would reinstate safeguards that protect against discrimination in covered health care programs and activities as outlined in Section 1557 of the ACA. These proposed provisions include reinstating the scope of Section 1557 clarifies application to health insurance issuers receiving federal financial assistance prohibits discrimination in clinical algorithms used to support decision-making and that nondiscrimination provisions are applicable to services offered through telehealth technologies. HHS is right to propose these provisions and AMA urges the agency to finalize this proposed rule. AMA is an informed and active stakeholder in the implementation of health care policy. AMA sees the proposed rule rectifying what we saw as the 2020 rulemaking instituting a fundamental change in direction that is antithetical to our principles of health system transformation namely universal access to health care coverage for all citizens and residents. We are pleased that HHS would return key definitions and protection mechanisms that make Section 1557 meaningful to all especially to people who otherwise face discriminatory barriers to care. This is particularly important as nurses and the health care delivery system focus on achieving health equity and identify approaches to overcome health disparities. We believe that existing regulations for Section 1557 and other HHS programs fulfill the intent of Congress to protect people from discrimination in health care that helps them access Section 1557 should be implemented in a manner that removes access for those who are subject to discrimination. [Build As such HHS must finalize proposed Section 1557 provisions that protect against discrimination in health care programs and activities. We urge HHS to act expeditiously on this rulemaking]

American Nurses Association

We Proposed Rule Section 92.4 Updates the Scope of Nondiscrimination to Health Covered Health Programs and ActivitiesWe applaud HHS for clarifying that the scope of Section 1557 covers an expansive range of programs and activities consistent with Congressional intent. We support the Department's proposal to return to the 2016 interpretation that applies Section 1557 to all health programs and activities receiving funding from the Department or administered by the Department such as state or federally facilitated Exchanges health insurance issuers that receive federal financial assistance and third-party administrators Pharmacy Benefits Managers. Footnote 1: Nondiscrimination in Health Programs and Activities 87 Fed. Reg. 47824 47838 (proposed Aug. 4 2022) (to be codified at 42 CFR Parts 438 440 457 and 460)] We also support the proposed rule's expanded enforcement of nondiscrimination in health insurance coverage to combine discriminatory health plan designs adopted by group health plans as well as marketing practices [Footnote 2: 87 Fed. Reg. at 47876 47912 (Proposed § 92.4)].

Senate Democrats

(b)(5)

The direct attention to nondiscrimination on the basis of sex limited English proficient (LEP) individuals and people with disabilities and the clarification of the specific measures that are anticipated to comply with Section 1557 are welcome. Specifically we support the major clarifications in the rule: • The interpretation of Section 1557 to cover all health programs and activities administered by HHS; • The interpretation that provision of Medicare Part B assistance is federal financial assistance and that entities receiving Medicare Part B funds must comply with the Rule; • The application to health insurance issuers that receive federal financial assistance; • The clarification that the protections against discrimination on the basis of sex including sexual orientation and gender identity and discrimination on the basis of sex stereotypes and the extension of these protections to CMS regulations; • The expectation that compliance will require implementing programs to develop maintain and communicate clear policies and train on the provision of language assistance services for limited English proficient (LEP) individuals and effective communication and reasonable modifications to policies and procedures for people with disabilities; • The requirement that implementing entities provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant states; • The expectation of nondiscrimination based on clinical algorithms; • The expectation that nondiscrimination extends to telehealth services and • The development of clear processes for requesting exceptions from the expectation of compliance.

(b)(5)

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

. Application and Scope of Section 1557 (§ 92.2)We strongly support the proposed Rule's restoration of Section 1557's application to all health programs or activities receiving federal funding through or administered by the Department or a Title I entity which is consistent with the statutory language and the purpose of the ACA to ensure broad access to and coverage of health care.

Center for American Progress

Underline The Rule's expanded definition of federal financial assistance could impact any tax-exempt entity.Section 92.4 of the Rule expands the application of what constitutes federal financial assistance. Why exactly is covered as a recipient of federal financial assistance?" The broad interpretation of this definition could have very far reaching impacts. Recent Title IX district court rulings in Maryland and California classify tax exempt status as federal financial assistance. It is important we that the Department answer these questions as this will determine the scope of entities covered by the Rule. Does the Department agree with the interpretation in these cases that federal financial assistance includes tax exempt status? Does that interpretation apply directly to this Rule? What entities are covered who previously have not been covered through the proposed changes to the definition?

Concerned Women for America

regulation in Section 1557 will interact with state law—that is how Section 1557 a federal agency ruling] may or will preempt conflicting state laws. Conflicts could include state laws protecting minors from sterilizing and irreversible gender transition interventions on state conscience and religious freedom protection laws. It is unclear how strings attached to federal financial assistance could unilaterally preempt incompatible state laws instead of the standard risk of withdrawal of federal funds from entities that are unable to comply either by governing choice or due to a state law.[Footnote 48: Morrison "HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate on Health Care." https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-on-health-care.]Again judging from the 2016 Rule the proposed regulation would apply to any "health programs or activities any part of which receives federal financial assistance administered by HHS" as well as any health programs or activities administered by HHS or those established under Title of the ACA including federally facilitated and state based insurance exchanges. [Footnote 49: 80 Federal Register 54216 (proposed September 8 2015). This includes any "hospital health clinic group health plan health insurance issuer physician's practice community health center nursing facility residential or community-based treatment facility or other similar entity" that receives HHS funds. [Footnote 50: Ibid. 54216.] The proposed regulation would therefore apply to Approximately 153000 health care facilities. "[A] most all practicing physicians in the United States because they accept some form of Federal reimbursement or reimbursement"; - All state Medicaid programs; and - All the businesses and activities of a private insurer if any of its businesses receive any federal financial assistance either directly (such as a through a Medicaid managed care contract) or indirectly (through subsidies provided to its customers as is the case with Medicare Advantage and exchange

(b)(5)

The Heritage Foundation

InterACT strongly support proposed section 92.2's application of the rule to all health programs or activities receiving federal funding through or administered by the Department or a Title I entity consistent with the statutory text structure and purpose.

InterACT Advocates for Intersex Youth

Application (§ 92.2)We strongly support the restoration of Section 1557's application to (italic) all health programs or activities) receiving federal funding through or administered by the Department or a Title I entity. This is consistent with the statutory language and the purpose of the ACA to ensure broad access to and coverage of healthcare.

Equitas Health

Re-expanding the Scope of 1557Our organizations strongly endorse the decision to apply § 1557 to all health programs and activities that receive direct or indirect federal financial assistance from the U.S. Department of Health and Human Services (hereinafter "HHS") the health programs and activities administered by HHS and those administered by State or Federal Health Insurance Exchanges. We believe these non-discrimination protections are vital to ensure access to care and coverage for people in Massachusetts and across the United States.We recommend that HHS additionally apply § 1557 to employers that receive federal funding regarding the role in providing employee health benefits similar to what HHS articulated in § 92.206 of the 2016 rule. Our organizations' vast experience serving clients members and patients with self-insured health plans consistently demonstrates that very few people understand the regulatory frameworks behind the plans in which they are enrolled. Rather than minimizing confusion when applying § 1557 rules to employers receiving federal financial assistance will create greater lack of clarity for people seeking relief from discriminatory plan design network adequacy or other factors in their employer-sponsored health plans.

(b)(5)

Health Care For All

Subpart A General Provisions[Application (§ 92.2)We strongly support the restoration of Section 1557's application to all health programs or activities receiving federal funding through or administered by the Department or a Title I entity. This is consistent with the statutory language and the purpose of the ACA to ensure broad access to and coverage of health care.

Colors+

The TAG also supports the reinstatement of the applicability of Section 1557 to health insurers that receive federal financial assistance recognizing the significant role they have in the provision of health care.

Tribal Technical Advisory Group to CMS (TTAG)

Ibid: Application (§ 92.2)] We strongly support the restoration of 1557's application to all health programs or activities receiving federal funding through or administered by the Department or a Title I entity. This is consistent with the statutory language and the purpose of the ACA to ensure broad access to and coverage of health care.

SIECUS: Sex Ed for Social Change

Because discrimination causes significant harm and many people obtain healthcare services and coverage from other federal agencies the protections of Section 1557 should be expressly extended to health programs and activities administered by or receiving federal funding from agencies other than HHS. We encourage HHS to work with the Department of Justice (DOJ) and other agencies that administer such programs to develop a common rule to implement Section 1557 in such a manner. Such a rule would make it clear that the ACA's nondiscrimination protections do extend to health programs and activities outside of HHS and this would also bolster covered entities in addition to program participants and beneficiaries while also promoting consistent enforcement.

Equitas Health

The proposed rule will ensure that all individuals can access high quality affordable health coverage without being subjected to discrimination. We applaud HHS's commitment to ensuring that all individuals are able to access health care coverage without being subject to discrimination on the basis of race color national origin sex age or disability. We strongly support the application of Section 1557's regulatory requirements to the Federally-facilitated Exchanges (FFEs) the State-based Exchanges (SBEs) and to all health insurance issuers that receive federal financial assistance consistent with the statute's intent. We also appreciate HHS's clarification that covered health programs or activities include all products sold by health insurance issuers even grandmotherable or grandfathered plans short-term limited duration insurance plans and excepted benefits plans.

Body: [Subpart A – General Provisions; Application (§ 92.2)]We strongly support the restoration of 1557's application to all health programs or activities receiving federal funding through or administered by the Department or a Title I entity. This is consistent with the statutory language and the purpose of the ACA to ensure broad access to and coverage of health care.

We strongly support the proposal to restore regulatory provisions recognizing that Sec. 1557 applies to federal health programs like Medicaid and Medicare the ACA's state and federal Marketplaces and the plans sold through them as well as other commercial health plans if the insurer receives any form of federal financial assistance. This is consistent with the statutory language and the purpose of the ACA to ensure broad access to and coverage of health care.

Body: Application of Section 1557 Requirements]Penn Medicine agrees with HHS that section 1557 requirements should apply to all entities that receive federal financial assistance every health program or activity administered by HHS and every program or activity established under Title I of the ACA. The consistent application of section 1557 requirements throughout these various programs will create continuity in the interpretation and implementation of nondiscrimination standards established therein.

The Proposed Rule Clarifies and Establishes the Scope of Nondiscrimination in Covered Health Programs and Activities.We applaud HHS for clarifying that the scope of Section 1557 covers an expansive range of programs and activities consistent with Congressional intent. We support the Department's proposal to return to the 2016 interpretation that applies Section 1557 to all health programs and activities receiving funding from the Department or administered by the Department such as state or federally facilitated Exchanges health insurance issuers that receive federal financial assistance and third-party administrators (e.g. Pharmacy Benefits Managers). [Footnote 1: Nondiscrimination in Health Programs and Activities 87 Fed. Reg. 47824 47838 (proposed Aug. 4 2022) (to be codified at 42 CFR Parts 438 440 457 and 460)]. We also support the proposed rule's expanded enforcement of nondiscrimination in health insurance coverage to include discriminatory health plan designs adopted by group health plans as well as marketing practices [Footnote 2: 87 Fed. Reg. at 47876 47912 (Proposed § 92.4)].

The direct attention to nondiscrimination on the basis of sex limited English proficient (LEP) individuals and people with disabilities and the clarification of the specific measures that are anticipated to comply with Section 1557 are welcome. Specifically we support the major clarifications in the rule: • The interpretation of Section 1557 to cover all health programs and activities administered by HHS. • The interpretation that provision of Medicare Part B assistance is federal financial assistance and that entities receiving Medicare Part D funds must comply with the Rule. • The application to health insurance issuers that receive federal financial assistance. • The clarification that the protections against discrimination on the basis of sex as including sexual orientation and gender identity and discrimination on the basis of sex stereotypes and the extension of these protections to CMS regulations. • The expectation that compliance will require implementing programs to develop maintain and communicate clear policies and train on the provision of language assistance services for limited English proficient (LEP) individuals and effective communication and reasonable modifications to policies and procedures for people with disabilities. • The requirement that implementing entities provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states. • The expectation of nondiscrimination based on clinical algorithms. • The expectation that nondiscrimination extends to telehealth services and. • The development of clear processes for requesting exceptions from the expectation of compliance.

. Application and Scope of Section 1557 (§ 92.4)We strongly support the Proposed Rule's restoration of Section 1557's application to all health programs or activities receiving federal funding through or administered by the Department or a Title I entity which is consistent with the statutory language and the purpose of the ACA to ensure broad access to and coverage of health care.

In regard to the Department's request for comment on whether or not to apply this rule to all HHS programs – and not just health programs we support doing so and recommend that such application be done through separate rulemaking.

regulation in Section 1557 will interact with state law—that is how Section 1557 a federal agency ruling] may or will preempt conflicting state laws. Conflicts could include state laws protecting minors from sterilizing and irreversible gender transition interventions or state conscience and religious freedom protection laws. It is unclear how strings attached to federal financial assistance could unilaterally preempt incompatible state laws instead of the standard disallowance of federal funds from entities that are unable to comply—either by covers gnt choice or due to a state law. [Footnote 48: Morrison: HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate on Health Care" https://thedise.org/commentary/thedise-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-in-health-care-1/Again judging from the 2016 Rule the proposed regulation would apply to any "health programs or activities any part of which receives federal financial assistance administered by HHS" as well as any health programs or activities administered by HHS or those established under Title I of the ACA including federally facilitated and state-based insurance exchanges. [Footnote 49: 80 Federal Register 54218 (proposed September 8 2015)." This includes any "hospital health clinic group health plan health insurance issuer physician's practice community health center nursing facility residential or community based treatment facility or other similar entity" that receives HHS funds. [Footnote 50: Ibid. 54216.] The proposed regulation would therefore apply to: - Approximately 133000 health care facilities, - "[A] most all practicing physicians in the United States.. because they accept some form of Federal remuneration or reimbursement" All state Medicaid programs; and - All the businesses and activities of a private insurer if any of its businesses receive any federal financial assistance either directly (such as through a Medicaid managed care contract) or indirectly (through subsidies provided to its customers as is the case with Medicare Advantage and exchange.

InterACT strongly supports proposed section 92.2's application of the rule to all health programs or activities receiving federal funding through or administered by the Department or a Title I entity consistent with the statutory text structure and purpose.

Application [§ 92.2]We strongly support the restoration of Section 1557's application to "[all] covered health programs or activities] receiving federal funding through or administered by the Department or a Title I entity. This is consistent with the statutory language and the purpose of the ACA to ensure broad access to and coverage of healthcare.

(b)(5)

(b)(5)

U.S. House Committees on Energy and Commerce Ways and Means and Education and Labor

Eating Disorders Coalition for Research Policy & Action

Justice in Aging

Pennsylvania Health Insurance Exchange Authority d/b/a Pennie

Senate Democrats

(b)(5)

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Center for American Progress

88 Members of Congress

(b)(5)

The Heritage Foundation

InterACT - Advocates for Intersex Youth

Equitas Health

Re expanding the scope of 1557Our organizations strongly endorse the decision to apply § 1557 to all health programs and activities that receive direct or indirect federal financial assistance from the U.S. Department of Health and Human Services (hereinafter "HHS") the health programs and activities administered by HHS and those administered by State or Federal Health Insurance Exchanges. We believe these non-discrimination protections are vital to ensure access to care and coverage for people in Massachusetts and across the United States. We recommend that HHS additionally apply § 1557 to employers that receive federal funding regarding the role in providing employee health benefits similar to what HHS articulated in § 92.208 of the 2016 rule. Our organizations' vast experience serving clients members and patients with self-insured health plans consistently demonstrates that very few people understand the regulatory frameworks behind the plans in which they are enrolled. Rather than minimizing confusion and applying § 1557 rules to employers receiving federal financial assistance will have greater lack of clarity for people seeking relief from discriminatory plan design network adequacy or other factors in their employer-sponsored health plans

(b)(5)

Health Care For All

Add: Reinstate Application of Section 1557 Protections to all HHS Programs and Activities[The TTAG generally supports the proposal to interpret Section 1557 to cover all of the health programs and activities administered by the Department ensuring protection from discrimination to people in those programs. However as discussed above it is important that the Department as well as Department personnel including personnel in the Office of Civil Rights and the Office of the General recognize that Section 1557 does not prohibit IT/U programs from limiting services to IHS beneficiaries nor does it prohibit the Department from taking actions in furtherance of the trust responsibility on behalf of Indian health care providers and AI/AN beneficiaries. Such actions include the issuance of Indian specific regulations and sub-regulatory guidance the approval of Indian specific State Plan Amendments and the approval of State Demonstration waivers that address issues unique to Indian health care providers. The United States and its federal agencies have the constitutional authority to take unique action on behalf of Indian Country. The Department has taken many such actions in the past and should continue to do so in the future. See Section 1557 issues re Department to the Department carrying out its statutory obligations and federal trust responsibility to Indian Country

Tribal Technical Advisory Group to CMS (TTAG)

Overall the recent actions that have been taken to eliminate the prohibition of discrimination in health care we commend HHS for taking action to protect individuals from unnecessary discrimination particularly Covered California strongly supports the following proposals • Clarifying and Expanding the Scope of 1557As proposed HHS will increase the number of individuals protected from discrimination by expanding the scope of Section 1557. HHS will require the covered entities prohibit discrimination with their health programs and activities [Footnote 8: The proposed definition of a "covered entity" includes recipients of federal financial assistance HHS and Exchanges]. As proposed covered entities would be expanded to many health insurance issuers including qualified health plan (QHP) issuers offering health insurance through an Exchange. To ensure compliance with these requirements HHS will require entities affected to develop and implement policies and procedures clarifying their nondiscrimination policies

Covered California

(b)(5)

Howard Brown Health

Finally: Reinstatement of the scope of 1557 to cover all Health and Human Services (HHS) programs and activities including making it applicable to private health insurance issuers receiving federal funding.]We strongly support the restoration of 1557's application to all health programs or activities receiving federal funding as LGBTQI+ patients still face many instances of discrimination in healthcare that can be life threatening. For example one Howard Brown provider recounted the story of a client a trans woman who was physically attacked during burglary in her apartment. When the EMTs arrived and realized she was trans they refused to touch her and properly treat her injuries. When she arrived at the hospital no provider would see her. It was not until a shift change this patient was finally able to locate a provider who would see her. She would later come to Howard Brown for aftercare for her injuries. Insurance companies also routinely discriminate against TNB individuals in particular and our patient navigators often must help our TNB patients navigate complex and burdensome prior authorization processes only to be eventually denied coverage for gender affirming care. These experiences are reflected in scientific research that shows that 1 in 4 trans patients were denied hormone therapy by their insurance providers in the past year [Footnote 8: Ibid].

Equitas Health

The proposed HHS asks for comment as to whether these non-discrimination protections should be extended to other non-health programs and activities of the agency. We strongly encourage the adoption of such protections for these other programs. A separate rulemaking and urge HHS to make those protections as fully as robust as those proposed here for health programs and activities. As an agency we offer a host of programs and initiatives across the community and we firmly believe that the extension of these non-discrimination protections to these non-health programs and activities of HHS is crucial to the work of our agency and similarly positioned health centers across the country. As such we are strongly in favor of the extension of these non-discrimination protections [italics across all areas of HHS.

(b)(5)

SIECUS: Sex Ed for Social Change

Add: Application [§ 92.2)] We strongly support the restoration of 1557's application to all health programs or activities receiving federal funding through or administered by the Department or a Title I entity. This is consistent with the statutory language and the purpose of the ACA to ensure broad access to and coverage of health care

Additionally HHS is proposing to apply this rule to all health programs and activities under HHS except for an employer with regard to its employment practices including the provision of employee health benefits. Other federal agencies would handle enforcement of non-discrimination provisions for these entities. HHS indicates in the preamble that based on enforcement experience with the previous non-discrimination rules this would reduce confusion and burden on individuals filing discrimination complaints. The AAFP supports extending this rule to all activities under HHS as this will ensure groups of individuals who currently and historically face higher rates of discrimination are appropriately protected and able to access care. The AAFP agrees with IHS's statement that it is also important to ensure that the over 55 percent of the U.S. population currently covered by employer sponsored health plans also have appropriate protection from discriminatory action or benefit design [Footnote 4: Catherine Keisler-Starkey & Lisa N. Bunch U.S. Dep't of Commerce U.S. Census Bureau Health Insurance Coverage in the United States: 2019 p. 4 (2020) (https://www.census.gov/content/dam/Census/library/publications/2020/demo/p60-271.pdf.)] While this rule will not extend to those plans most employer-sponsored health plans are required to comply with ERISA and HIPAA non-discrimination regulations from the Department of Labor (DOL) and Department of Treasury. The AAFP urges HHS to work with DOL Treasury and other appropriate agencies to ensure non-discrimination protections are applied and upheld under other federal regulation

(b)(5)

American Academy of Family Physicians

Add: [Subpart A General Provisions Application [§ 92.2)]We strongly support the restoration of 1557's application to all health programs or activities receiving federal funding through or administered by the Department or a Title I entity. This is consistent with the statutory language and the purpose of the ACA to ensure broad access to and coverage of health care.

Eating Disorders Coalition for Research Policy & Action

|Bold. 7. Application of Section 1557 to all HHS-Administered Health Programs and Activities.The States also support the Proposed Rule's inclusion of all HHS-administered health programs and activities in the scope of coverage. 87 Fed. Reg. at 47838. |Footnote 10: The States concur with HHS that clarifying that Section 1557 applies to Federally administered health programs and activities appropriately conforms to the purpose and intent of Section 1557. See 87 Fed. Reg. at 47838.| The 2020 Rule restricted the scope of covered federal programs to those "administered by [HHS] under Title I" of the Affordable Care Act. 45 C.F.R. § 92.4(a)(2). But this restriction contravened the language and intent of Section 1557 which states that it applies to programs and activities that are "administered by an Executive Agency or any entity established under [Title I of the ACA]." 42 U.S.C. § 18116(a) (emphasis added). The States concur with HHS that to the extent Section 1557's text leaves any ambiguity a better and more reasonable reading of this language "in line with Congress' intent to cover a broad swath of activities means that it should apply to all HHS-administered programs. See 87 Fed. Reg. at 47829. |Footnote 11: Although the Proposed Rule only covers HHS-administered health programs and activities the States encourage other Federal agencies to adopt conforming regulations mirroring the Proposed Rule to clarify Section 1557's application to Federal health programs and activities administered by other Federal agencies.| As with HHS's proposed changes regarding the definition of entities receiving Federal financial assistance the States support this broader ring of coverage for HHS-administered programs and activities because it will reduce confusion and prevent discrimination resulting in lists of adverse health outcomes that might otherwise be borne by the States' public health systems.

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Attorneys General of California, New York, Massachusetts, and nineteen other States

Separate rulemaking that extends nondiscrimination protections to the "non-health" HHS programs and activities that plan coordinate new initiatives set interagency priorities and grant funding work will lead to much needed consideration throughout the Department on how to improve protected groups under Section 1557 and achieve greater equity in all of HHS's work.

National Immigration Law Center

We inform HHS's consideration as to whether these nondiscrimination protections should be extended to other non-health programs and activities of the agency. We strongly encourage the adoption of such protections for these other programs. A separate rulemaking and urge HHS to make these protections equally as robust as those proposed here for health programs and activities. Because discrimination causes significant harm and many people obtain health care services and coverage from other federal agencies the protections of 1557 should be expressly extended to health programs and activities administered by or receiving federal funding from agencies other than HHS. We encourage HHS to work with the Department of Justice and other agencies that administer such programs to develop a common rule to implement section 1557. Such a rule would make it clear that the ACA's nondiscrimination protections do not extend to health programs and activities outside of HHS assisting both covered entities as well as program participants and beneficiaries and promoting consistent enforcement.

Eating Disorders Coalition for Research, Policy & Action

We strongly support the proposal to restore regulatory provisions recognizing that Section 1557 applies to all health programs that receive any form of federal financial assistance including Medicaid and Medicare Health Insurance Exchanges and the plans sold through them and other commercial health plans. These provisions are consistent with the statutory language and the purpose of the ACA to ensure access to and coverage of affordable quality health care. To achieve this goal its provisions had to reach all aspects of the U.S.'s complex network of private and public health care entities. Section 1557 the primary anti-discrimination provision embedded in the ACA logically extends to all the programs and activities as those covered in the Act. We support the clarifications that federal financial assistance includes credits subsidies and contracts of insurance in addition to grants loans and other types of assistance as well as the application of Section 1557's requirements to all operations of an entity principally engaged in the provision or administration of health care. The specific clarifications that recipients of federal financial assistance include any insurer participating in a Health Insurance Exchange and receiving Advance Premium Tax Credits or Cost Sharing Reductions (when available) their third-party administrators and agents and brokers enrolling individuals in their plans is vital to ensuring broad protection against discrimination. Since insurers generally provide plans both on and off the Exchanges these protections will benefit the majority of individuals who receive health coverage through their employers and often have no opportunity to select their health plan. Recipients of Deferred Action for Childhood Arrivals [(DACA) who need to buy off exchange health plans through agents and brokers because they are not yet eligible to use the Exchanges will also benefit.

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National Immigration Law Center

We strongly support the proposal to restore regulatory provisions recognizing that Sec. 1557 applies to federal health programs like Medicaid and Medicare the ACA's state and federal Marketplaces and the plans sold through them as well as other commercial health plans if the insurer receives any form of federal financial assistance. This is consistent with the statutory language and the purpose of the ACA to ensure broad access to and coverage of health care.

Justice in Aging

The Department should issue guidance to clarify that insurers cannot avoid the application of Section 1557 to all of their operations by creating subsidiaries or other separate entities.

National Immigration Law Center

Bold: |Subpart A – General Provisions' Application |§ 92.2|We strongly support the restoration of 1557's application to all health programs or activities receiving federal funding through or administered by the Department or a Title I entity. This is consistent with the statutory language and the purpose of the ACA to ensure broad access to and coverage of health care.

Eating Disorders Coalition for Research, Policy & Action

We also concur in the HHS's proposal that whether these nondiscrimination protections should be extended to non-health programs and activities of the agency. We strongly encourage the adoption of such protections for these other programs in separate rulemaking and urge HHS to make these protections equally as robust as those proposed here for health programs and activities. HHS operates many programs including some authorized by the Older Americans Act that are not "health" programs but are nonetheless vital to older adults' well being and often contribute directly to social determinants of health. Similarly we urge HHS to work with the Department of Justice and other agencies that administer health programs to develop a common rule to implement Sec. 1557. We believe establishing unified standards and bond scrimination protections across HHS programs and among health programs of other agencies would provide clarity both for covered entities and program participants as well as promote consistent enforcement.

Justice in Aging

We also concur in the HHS's proposal that whether these nondiscrimination protections should be extended to non-health programs and activities of the agency. We strongly encourage the adoption of such protections for these other programs in separate rulemaking and urge HHS to make these protections equally as robust as those proposed here for health programs and activities. HHS operates many programs including some authorized by the Older Americans Act which are not "health" programs but are nonetheless vital to older adults' well being and often contribute directly to social determinants of health. For example access to food is a critical social determinant of health. FeedMore WNY provides access to affordable and nutritious food by delivering two meals a day five days a week to the older community and persons with disabilities. [Footnote 1: About FeedMore WNY https://www.feedmorewny.org/about/ (2019).] Similarly we urge HHS to work with the Department of Justice and other agencies that administer health programs to develop a common rule to implement Sec. 1557. We believe establishing unified standards and bond scrimination protections across HHS programs and among health programs of other agencies would provide clarity both for covered entities and program participants as well as promote consistent enforcement.

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Center for Elder Law & Justice

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a. All Health Programs In the Proposed Rule HHS seeks comment as to whether the nondiscrimination protections enumerated in Section 1557 should be extended to other non-health programs and activities of the agency. We strongly encourage the adoption of such protections for these other programs in separate rulemaking and urge HHS to make these protections equally as robust as those proposed here for health programs and activities. Because many people obtain health care services and coverage through other federal agencies we believe that the protections of Section 1557 should be expressly extended to health programs and activities administered by or receiving federal funding from agencies other than HHS. We support the Department working in coordination with the Department of Justice and other agencies responsible for administering these programs to develop a common rule to implement Section 1557. Such a rule could clarify that the ACA's nondiscrimination protections extend to health programs and activities outside of HHS, assist covered entities program participants and beneficiaries; and promote consistent enforcement.

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Center for American Progress

[Italics Extension to Other Agency Programs] HHS asks for comment on whether these nondiscrimination protections should be extended to non-health programs and activities of the agency. We strongly encourage the adoption of such protections for these other programs in separate rulemaking and urge HHS to make those protections equally as robust as those proposed here for health programs and activities. HHS operates many non-health care programs that are vital to well-being and often contribute directly to social determinants of health. The department's multiple agencies and offices support social and economic well-being in children families and older adults emergency and disaster preparation public health health and policy research regulation of food and medical devices disease control and many aspects of administrative and legislative coordination. For example HHS Agencies and Offices that engage in public health investigation into the social drivers of health and health disparities are making connections that must include all the groups protected under Section 1557 including ensuring language assistance services when stakeholder feedback and public comment is sought.

National Immigration Law Center

In the NPRM HHS asks for comment as to whether these nondiscrimination protections should be extended to other non-health programs and activities of the agency. We strongly encourage the adoption of such protections for these other programs in separate rulemaking and urge HHS to make those protections equally as robust as those proposed here for health programs and activities. Because discrimination causes significant harm and many people obtain health care services and coverage from other federal agencies the protections of 1557 should be expressly extended to health programs and activities administered by or receiving federal funding from agencies other than HHS. We encourage HHS to work with the Department of Justice and other agencies that administer such programs to develop a common rule to implement section 1557. Such a rule would make it clear that the ACA's nondiscrimination protections do extend to health programs and activities outside of HHS assisting both covered entities as well as program participants and beneficiaries and promoting consistent enforcement.

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Colorg+

In the NPRM HHS asks for comment as to whether these nondiscrimination protections should be extended to other non-health programs and activities of the agency. We strongly encourage the adoption of such protections for these other programs in separate rulemaking and urge HHS to make those protections equally as robust as those proposed here for health programs and activities. As further explained below we also urge HHS to (1) work with other agencies with Section 1557-covered programs to adopt a Section 1557 Common Rule (2) expressly enumerate nondiscrimination protections in CMS and other health program-specific regulations; and (3) use its existing statutory authorities to extend clarify and enforce nondiscrimination protections in its human service programs

Eating Disorders Coalition for Research, Policy & Action

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Bold. G HHS should use its statutory authorities to extend clarify and enforce nondiscrimination protections in its human service programs including on the basis of sex characteristics.]We strongly urge HHS to use its various statutory authority to similarly codify enumerated SOGI/SC nondiscrimination protections in its human service programs. Broad requirements for program quality accessibility and equity and delegations of authority to adopt appropriate rules to ensure program effectiveness as well as statutory sex discrimination provisions in some programs—provide ample basis for such rulemaking. Examples of such programs include Title IV child welfare programs Family Violence Prevention and Services Act Head Start and the Low Income Home Energy Assistance Program (LIHEAP) administered by ACF, as well as programs administered by ACL under the Older Americans Act the Developmental Disabilities Assistance And Bill of Rights Act and other statutes

ed for Social Change

Advocates for Intersex Youth

Bold. 3 Exclusion of Employment Practices]The Proposed Rule clarifies that section 1557 does not apply to employment practices including the provision of employee health benefits. 87 Fed. Reg. at 47838. The States agree that allegations of discrimination in employment should be handled by other Federal agencies. This clarification of the 1557 regulation's coverage is logical as persons seeking to file employment-related complaints of discrimination will need to abide by timing requirements of other Equal Employment Opportunity-related laws and ambiguity in where such complaints may be filed increases the risk that these complainants will miss applicable deadlines. The States support the Office for Civil Rights' intent to refer employment-related complaints to other appropriate Federal agencies for adjudication under their jurisdiction. See id. Footnote 12: The States believe that the Section 1557's nondiscrimination requirements do apply to employment-related practices [and the Proposed Rule does not say otherwise]. Indeed as HHS recognized eliminating employee health benefits from the provisions would leave over 55 percent of the U.S. population at an unacceptably high number without the protections of Section 1557. 87 Fed. Reg. at 47838]

Advocates for Intersex Youth

No comments are associated with this issue

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Recommendations and responses to HHS questionsBelow we provide answers to regarding the Department's specific request for comment on [the] Whether the application of this Title to health programs and activities that receive Federal funding to health programs and activities of executive agencies and to all programs and activities of executive agencies should be considered in a different manner. Protections of 1557 should be expressly extended to health programs and activities administered by or receiving federal funding from agencies other than HHS but done so in a separate rule so as to not potentially confuse or dilute the importance of this rule.

Attorneys General of California, New York, Massachusetts, and nineteen other States

Because discrimination causes significant harm and many people obtain health care services and coverage from other federal agencies the protections of 1557 should be expressly extended to health programs and activities administered by or receiving federal funding from agencies other than HHS. We encourage HHS to work with the Department of Justice and other agencies that administer such programs to develop a common rule to implement section 1557. Such a rule would make it clear that the ACA's nondiscrimination protections do extend to health programs and activities outside of HHS assisting both covered entities as well as program participants and beneficiaries and promoting consistent enforcement

Howard Brown Health

No comments are associated with this issue

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IECLIS Sex Ed for Social Change

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Additional Recommendations We urge HHS to work with the Department of Justice (DOJ) and other agencies to adopt a Section 1557 common rule that expressly enumerates protection against sex discrimination. The protections established in Section 1557 extend to all health programs and activities funded or administered by federal agencies. Similar to the Title IX common rule adopted jointly by several agencies in 2000 a common rule would make clear that the ACA's nondiscrimination protections extend across all federal agencies allowing for consistent enforcement for program beneficiaries and covered entities.

Similarly we support HHS's intention to work with the Department of Justice and other agencies that administer health programs to develop a common rule to implement section 1557. We believe establishing unified standards and nondiscrimination protections across all HHS programs and ensuring health programs of other agencies would provide clarity both for covered entities and program participants as well as promote consistent enforcement.
No comments are associated with this issue.

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88 Members of Congress

National Immigration Law Center

The NHC supports the proposed definition of benefit design to include but not be limited to "coverage exclusions and limitations of benefits; prescription drug formularies; cost sharing (including copays coinsurance and deductibles); utilization management techniques (such as step therapy and prior authorization); medical management standards (including medical necessity standards); provider network design; and reimbursement rates to providers and standards for provider admission to participate in a network." Similarly we support your definition of marketing practices to "broadly include for example activities designed to encourage individuals to participate or enroll in particular health plans or certain types of plans or to discourage them from doing so and activities that steer (or attempt to steer) individuals towards or away from a particular plan or certain types of plans."

National Health Council

[Italics] The Proposed Rule equates Pregnancy and Abortion. "Title IX's proposed rule defines pregnancy itself as "pregnancy childbirth termination of pregnancy or lactation." This is a shift from existing conditions protected from discrimination as the current rule does: "pregnancy childbirth false pregnancy termination of pregnancy or recovery therefrom." It's a distinction that makes all the difference. Under the department's new definition abortion is given equal status with pregnancy and childbearing. This requires an acceptance of abortion as morally equivalent to pregnancy and childbirth. From a moral (and for that matter medical) standpoint this could not be further from the truth. A pregnancy is a natural process in which new life begins at the moment of conception when an ova and sperm join: the single celled zygote quickly develops into an embryo. This embryo is a new separate and distinct human being implants on the uterine wall where it continues to grow and become after about nine months. This human being is just that – a human being – from its earliest stage of development. Lactation is the natural response of a mother's body to the needs of her baby as she provides milk and essential nutrients for her newborn child. Abortion on the other hand is the intentional direct destruction of preborn human life. It is the preborn baby and halts the natural process of pregnancy. In short Title IX's proposed definition erroneously conflates pregnancy and lactation a natural and life-giving process with abortion a medically induced procedure intended to kill preborn life. The department has not explained why the current definition is scientific enough has the department sufficiently demonstrated its reasons for changing it. The department must explain its reasoning and justification.

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The Heritage Foundation

National Health Council

Finally we ask that CMS make the definition of sex consistent by using same definition for Medicaid and the Program for All Inclusive Care for the Elderly (PACE). This proposed rule makes considerable progress in clarifying what discrimination on the basis of sex entails. It will help assure that patients are fully protected if the definitions are consistent and applied in all healthcare systems.
[Bold/Underline] B. Companion[/We appreciate the inclusion of the definition of the term "companion" and HHS's explanation that a companion may include a "family member friend or associate of an individual" who is "an appropriate person with whom a covered entity should communicate." [Footnote 5: 87 Fed. Reg. 47911.] We note however that the determination of who is appropriate must lie with the individual with a disability for their designated decision maker pursuant to state law) and not with the provider.

National Disability Rights Network

Title VII The department relies on guidance from the Pregnancy Discrimination Act an amendment of Title VII for their definition of "sex." The Act bans employers from "discriminating against employees on the basis of pregnancy childbirth or related medical conditions." 42 U.S.C. 2000e(k)[.] As the department clarifies in this proposed rule "the fact that Congress did not amend Title IX's definition of 'sex' to explicitly include pregnancy as it did for Title VII in 1978 does not signal Congress's intent to exclude pregnancy coverage under Title IX." Title VII's definition of sex then is the basis of Title IX's own interpretation. Unlike Title IX Title VII does not have an explicit abortion neutrality clause. It states that employers are not required to cover the cost of an abortion on their health insurance as a benefit or otherwise. They are however expected to cover medical issues that may arise from an abortion complication like excessive hemorrhaging as it may result in subsequent surgeries or medical care beyond the scope of the abortion. Additionally employers are required to provide medical insurance coverage when the life of the mother is at risk. Title VII does not provide a clear definition as to what falls under the "or related medical conditions" clause though subsequent district court rulings and guidance announcements have clarified that it includes lactation or breastfeeding and complications arising from abortion. By following the department's own reasoning as it relates to Title VII and Title IX definitions and protections Title IX's proposed definition of "or related conditions" is derived from Title VII's "related medical conditions." The department defines Title IX's "pregnancy or related conditions" which is later defined as "(1) Pregnancy childbirth termination of pregnancy or lactation; (2) Medical conditions related to pregnancy childbirth termination of pregnancy or lactation; or (3) Recovery from pregnancy childbirth termination of pregnancy lactation or their related medical conditions." In this #2 and #3 follows the logic of Title VII as it relates to abortion namely categorizing abortion as a subsequent

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The Heritage Foundation

1. A number of specific expectations of covered entities are enumerated in the revised Rule extend to the training role and function of "employee[s]." The MRCT Center suggests that the definition of employee be extended to include contractors service providers sponsored staff and other designees of the covered entity. In the absence of this clarification one that can be accomplished by definition or reference the covered entity can escape many of its obligations under the Rule.

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

[Bold/Underline] A. Auxiliary Aids and Services[/We support HHS's proposal to incorporate the definition of "auxiliary aids and services" from the Americans with Disabilities Act (ADA) regulations. [Footnote 3: 28 C.F.R. § 35.104. 28 C.F.R. § 36.303(b).] We recommend that the text clarify that "similar services and actions" are available for all individuals with disabilities not just for deaf and hard of hearing individuals and blind and low vision individuals referenced in subsections (1) and (2).[Bold/Underline] RECOMMENDATION[:] Amend the definition of auxiliary aids and services as follows to clarify that "similar services and actions" are available for all individuals with disabilities.[Bold/Italics] (4) Staff acting as interpreters. A covered entity must not use staff who use sign language or another communication modality. [Footnote 4: Throughout these comments we use the term "communication modality" to refer to a variety of ways interpreters may communicate with clients including for example cued speech transliteration or oral transliteration. We recognize that ASL interpreters for example are translating from one language to another while other types of interpreters may be transliterating spoken English into a method of communication that facilitates understanding for an individual with a disability. In these cases we are using the term communication modality in instances where the interpreter is not translating between two different languages.] to act as interpreters and relay information to individuals with disabilities unless: a[i] they meet the definition of a qualified interpreter for an individual with a disability found with in this section, and; b[ii] meet the unique needs of the individual requesting the accommodation, and[(5) Other similar services and actions.[Bold/Italics: that support people with disabilities in effective communication.]
No comments are associated with this issue.
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National Disability Rights Network

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The States support these changes because among other reasons ensuring that a broader swath of entities refrain from discrimination in the healthcare system will reduce adverse health outcomes the costs of which would otherwise be borne by the States' public health systems. In addition limiting the scope of Section 1557 as the 2020 Rule sought to do increases the burden on the States to monitor and enforce nondiscrimination laws. For similar reasons the States also support HHS's proposal to add specific notice and skirmish notice requirements in health insurance coverage and other health-related coverage as discussed further below.

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Attorneys General of California, New York, Massachusetts, and nineteen other States

As HHS notes in the Proposed Rule Section 1557 "identifies three examples of federal financial assistance all of which pertain to health insurance." 87 Fed. Reg. at 47829 and to its logical to clarify to application to entities providing health insurance. *Italics* See Schmidt v. Kaiser Found. Health Plan of Wash. 965 F.3d 945 946 954-55 (9th Cir. 2020). The Proposed Rule accomplishes this clarification in part through defining "federal financial assistance" to include grants loans and other types of assistance from the HHS as well as "credits subsidies and contracts of insurance" in accordance with the text of Section 1557. See 87 Fed. Reg. at 47842. [Footnote 9]. Although the Proposed Rule only covers entities receiving Federal financial assistance from HHS-administered programs the States further encourage other Federal agencies to adopt conforming regulations that would mirror the Proposed Rule to clarify application of Section 1557 to those agencies' Federally assisted health programs and activities. The Proposed Rule thus clarifies that entities receiving Federal financial assistance from HHS include those participating in Medicaid the Children's Health Insurance Program Medicare Parts A-D as well as HHS grant programs. See id. The Proposed Rule would further clarify that financial assistance includes "advance payments of the premium tax credit and cost-sharing reductions . . . to ensure the affordability of health insurance coverage purchased through the Health Insurance Exchanges" Id. at 47843 thus applying when an insurer participating in a Health Insurance Exchange receives such payments on behalf of any of the issuer's enrollees. See id.

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Attorneys General of California, New York, Massachusetts, and nineteen other States

No comments are associated with this issue

[Bold: II. THE PROPOSED RULE ADDRESSES DISCRIMINATION AND RESTATES SECTION 1557'S PROPER SCOPE AND PROTECTIONS][Bold: A. Scope of Section 1557 [Bold: 1. Application of Section 1557 to Health Insurers and Other Entities] The States support HHS's decision to revise the definition of "health program or activity" which the 2020 Rule had limited to exclude some health insurers and other entities that were not "principally engaged" in providing medical treatments directly to patients. This has led to the exclusion of certain entities to which Section 1557 was plainly meant to apply including many health insurers. The Proposed Rule by contrast adheres to the unambiguous statutory language making the law's nondiscrimination mandate apply to "any health program or activity [italics] any part of which is receiving Federal financial assistance." 42 U.S.C. § 18116(a) (emphasis added).

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Attorneys General of California, New York, Massachusetts, and nineteen other States

The States support these changes because among other reasons ensuring that a broader swath of entities refrain from discrimination in the healthcare system will reduce adverse health outcomes the costs of which would otherwise be borne by the States' public health systems. In addition limiting the scope of Section 1557 as the 2020 Rule sought to do increases the burden on the States to monitor and enforce nondiscrimination laws. For similar reasons the States also support HHS's proposal to add specific notice and skirmish requirements in health insurance coverage and other health-related coverage as discussed further below.

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Attorneys General of California, New York, Massachusetts, and nineteen other States

venture or undertaking to...(v) Engage in health research, and][2] . . . All of the operations of any entity principally engaged in the provision or administration of any health projects enterprises ventures or undertakings described in paragraphs [1] of this definition including but not limited to a State or local health agency hospital health clinic health insurance issuer physician's practice pharmacy community-based health care provider nursing facility residential or community-based treatment facility or other similar entity or combination thereof. In our opinion it would be preferable to change the bullet to "Engage in health [sic] or clinical] research" for clarity and in the list of entities to include "[bold: clinical trial sites including wherever potential clinical trial participants are screened or recruited]" for absence of doubt. The fact that there is a long list of non-exhaustive list of entities that does not currently include mention of clinical trial sites may imply that these sites are not "principal and/or that primary research was not intended to be included in the context of advocating for a change in definition we note that "access to clinical research" does not imply the expectation of enrollment into a research protocol or trial but rather the expectation that the individual is not precluded from consideration for reasons of [Forcrote 2 ...ins I Peinquin D Barnes M Rieke BF. Applying Civil Rights Law to Clinical Research: Title VI's Equal Access Mandate. Journal of Law Medicine & Ethics. 2022;50(1):101-8]. Practically this clarification would imply that inclusion or exclusion criteria are justified based on scientific medical or ethical considerations, language assistance provided where necessary removal of architectural communication or transportation barriers, and other modifications or accommodations provided as necessary. The MRCT Center fully appreciates that the proposed Rule makes clear that reasonable modifications are an expectation and we applaud the focus on practical action. We think it would be helpful to include examples of reasonable modifications in clinical research in

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Kaiser Permanente; Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard; MRCT Center]

[Bold: Defining Gender-Affirming Care.] Pennie generally supports the proposed rule's prohibition of categorical coverage exclusions or limitations for all health services related to gender transition or other gender-affirming care. Notwithstanding Pennie's general agreement with the proposed rule Pennie urges HHS to provide a comprehensive definition of "gender affirming care" within the regulations itself as opposed to only in the preamble. This regulatory definition is necessary for Pennie to properly assess whether the benefit is offered within an insurance plan meets the baseline standard. This definition will allow Pennie and the issuers operating on the Pennsylvania exchange to appropriately display the new "gender affirming care" benefit category. Without this definition insurers will be left to define this category individually making this new benefit category inconsistent across plans and potentially misleading for consumers shopping for coverage on the exchange. Pennie does not wish to omit the definition of gender-affirming care with in the final rule. However a federal definition is necessary for Pennie to include this as a benefit category in a way that supports clear consumer access to these services. Ideally this definition would include the array of services that support an individual throughout their transition including services ... ge hormone therapy gender reassignment surgeries and behavioral health care.

(b)(5)

Pennsylvania Health Insurance Exchange Authority d/b/a Pennie

The Proposed Rule also reinstates a definition of "health program or activity" that adheres to the plain language of the statute and conforms with the reading of similar statutes such as Title IX. The Proposed Rule would apply to "any project enterprise venture or undertaking to provide or administer health-related services health insurance coverage or other health-related coverage; providing "assistance to persons in obtaining health-related services health insurance coverage or other health-related coverage;" providing "clinical pharmaceutical or medical care" or providing "health education for health care professionals or others." See id. at 47844.

(b)(5)

Attorneys General of California, New York, Massachusetts, and nineteen other States

The Proposed Rule further clarifies that all of the operations of such entities principally engaged in these activities are covered by Section 1557. See id. The States concur that all of these activities should appropriately fall within the scope of Section 1557.

(b)(5)

Attorneys General of California, New York, Massachusetts, and nineteen other States

The Proposed Rule further clarifies that all of the operations of such entities principally engaged in these activities are covered by Section 1557. See id. The States concur that all of these activities should appropriately fall within the scope of Section 1557.

(b)(5)

Attorneys General of California, New York, Massachusetts, and nineteen other States

changes that the proposed rule makes is expanding the definition of "health program or activity" to include more operations by health insurers and providers. Under existing regulations only the activities funded by federal financial assistance are subject to the protections of section 1557. [Footnote 7: Mary Beth Musumeci et al. "The Trump Administration's Final Rule on Section 1557 Non-Discrimination Regulations Under the ACA and Current Status" Kaiser Family Foundation September 18 2020 https://www.kff.org/health-reform/issue-brief/the-trump-administrations-final-rule-on-section-1557-non-discrimination-regulations-under-the-aca-and-current-status/]. The proposed rule by the Biden administration would expand this to include all activities by any health insurer that receives federal financial assistance. This approach is important to ensuring that all patients are protected by section 1557 as only around 9.7 million of the 32 million people who enrolled in marketplace coverage in 2021 received premium subsidies. [Footnote 8: "Estimated Total Premium Tax Credits Received by Marketplace Enrollees" Kaiser Family Foundation April 4 2022 https://www.kff.org/health-reform/state-indicator/average-monthly-advance-premium-tax-credit-apts/?currentTimeframe=0&sortModel=%7B%22colId%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D; "Marketplace Enrollment 2014-2022" Kaiser Family Foundation April 14 2022 https://www.kff.org/health-reform/state-indicator/average-monthly-advance-premium-tax-credit-apts/?currentTimeframe=0&sortModel=%7B%22colId%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D; https://www.kff.org/health-reform/state-indicator/marketplace-enrollment/?currentTimeframe=1&sortModel=%7B%22colId%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D] While this number is likely higher in 2022 as Marketplace coverage increased to 14.5 million people in light of 1557 protections no comments are associated with this issue.

(b)(5)

We agree with the inclusion of a definition of ICT in § 92.4 given how important interoperable electronic health records will become if/when people with disabilities seek things like care coordination and integrated care among multiple providers.

The Century Foundation

We agree that a definition of ICT in § 92.4 be included. Interoperable electronic health records need to be accessible as people with disabilities seek things like care coordination and integrated care among multiple providers.

Disability Rights Maine

We support the 2022 proposed rule's restored provisions from the 2016 Final Regulations regarding definitions for language assistance services required terms to provide meaningful access to limited English proficient (LEP) individuals standards for video remote interpretation and provision of notices to inform individuals of their rights. We do however see opportunities to clarify and strengthen these provisions.

Tennessee Disability Coalition

[Italics] Limited English proficient individual.] The Department proposed to change terminology from "individuals with limited English proficiency" to "limited English proficient individual" to reflect "widely used terminology." We request that OCR not adopt this change. In general person-centered language conveys more respect indicating that someone's lack of proficiency in English is not central to their identity. Community partners have confirmed that they prefer to use person-centered language in this way though there is overall with the definition-centered wording of "limited English" in the first place. OCR does not provide justification for why it believes that "limited English proficient" is more widely used which is not reflective in our experience or that of our partners. A search of Google Scholar for example turns up 1830 results for "individuals with limited English proficiency" compared to 705 results for "limited English proficient individuals." It's May 2020 guidance on COVID-19 OCR itself uses the term "Persons with Limited English Proficiency." [Footnote 6 "Ensuring the Rights of Persons with Limited English Proficiency in Health Care During COVID-19" HHS Office for Civil Rights May 15 2020 https://www.hhs.gov/sites/default/files/lep-bulletin-5-15-2020-english.pdf] It also uses the terms "settlement agreements such as in a December 2019 agreement with Pennsylvania over inadequate language services. Footnote 7 "Voluntary Resolution Agreement Between the U.S. Department Of Health And Human Services Office For Civil Rights And The Pennsylvania Department Of Human Services" HHS Office for Civil Rights December 30 2019 https://www.hhs.gov/sites/default/files/phs-padhs-vra.pdf] This terminology is also used by the Department of Justice on its LEP.gov platform. [Footnote 8 "About Us" Department of Justice Interagency Working Group on Limited English Proficiency https://www.lep.gov/about]

(b)(5)

National Immigration Law Center

[Italics] Limited English proficient individual.] We urge HHS to consider revising its terminology with respect to people whose primary language is not English. The term "limited English proficient" is deficit oriented. Alternatives to LEP include non-dominant language users" and "linguistically marginalized communities." We recognize the term LEP is a defined term and used in other regulations and laws and changing it is beyond the scope of this rulemaking. However at a minimum we urge HHS to use person-first language to describe people with limited English proficiency (e.g. individuals with LEP) in the final rule.

Justice in Aging

Narrowing language access requirements for patients The final major change this proposed rule would make is to improve language access requirements for disabled patients and patients with limited English proficiency (LEP). The rule reinstates several definitions that were rescinded by the Trump administration for both disability access and language access discrimination. These definitions help explicitly clarify to whom access requirements apply to and how providers and insurers can meet them. For example the proposed definition of "limited English proficient individual" highlights that a patient may be proficient in speaking English but not reading it or vice versa.

The Century Foundation

(b)(5)

Change in the definition of limited English proficient (LEP) individual The definition of LEP individuals states: § 92.4 Definitions A limited English proficient individual means an individual whose primary language for communication is not English and who has a limited ability to read write speak or understand English. A limited English proficient individual may be competent in English for certain types of communication (e.g. speaking or understanding) but still be limited English proficient for other purposes (e.g. reading or writing). While the MRCT Center agrees in large part with this definition we feel strongly that the word "and" in the definition should be revised to read "[bold: or]." Specifically we propose: A limited English proficient individual means an individual whose primary language for communication is not English [bold: or] who has a limited ability to read write speak [bold: or] understand English. A limited English proficient individual may be competent in English for certain types of communication (e.g. speaking or understanding) but still be limited English proficient for other purposes (e.g. reading or writing). There are many people in the United States whose primary language is English but who have a limited ability to read write speak or understand English for reasons that may or may not be related to disability who deserve protection from discrimination. Only by replacing the word "and" with "or" will such protections be provided.

(b)(5)

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

The proposed rule improves language access by emphasizing that the definition of "limited English proficient individual" includes those who may be competent in English for certain types of communication (e.g. speaking or understanding) but still be LEP for other purposes (e.g. reading or writing). [Footnote 4: Ibid. at 58. Proposed Sec. 92.4.] This will ensure providers and other covered entities understand that people who have some English competency may still need translated written materials for example.

The Leadership Conference on Civil and Human Rights

(b)(5)

The Proposed Rule improves language access by emphasizing that the definition of "limited English proficient individual" includes those who may be competent in English for certain types of communication (e.g. speaking or understanding) but still be LEP for other purposes (e.g. reading or writing). This will ensure providers and other covered entities understand that people who have some English competency may still need translated written materials for example. The Proposed Rule also ensures "meaningful access" to healthcare services by providing clarity on the steps providers and other covered entities must take to effectuate this goal. For example the Proposed Rule requires covered entities to provide a qualified interpreter when providing interpretative services and requires human translators to review materials generated by machine translation in most cases. Clarifying the definition of LEP and ensuring quality translation services will have far-reaching consequences for patients who both seek and receive care thus reducing barriers to quality health care for people of color. Again this comes down to greater nuance in understanding of diverse individuals and communities including a more nuanced understanding of what LEP constitutes in a care setting.

CCJ strongly supports the inclusion of a definition of machine translation and recognition that machine translation of critical information must be reviewed by a qualified human translator.

[Italics] Machine Translation. We appreciate the inclusion of a definition of machine translation and support the language as proposed though note the importance of adaptability and potential for future regulation or guidance over time as technology changes. For example machine translation companies may have optimized versions of their technology that include some level of human review but remain insufficient for the purposes of confirming with the intent of this regulation. We discuss below the importance of the proposed regulations restrictions or the use of this technology.

No comments are associated with this issue.

No comments are associated with this issue.

[Italics] Qualified interpreter for an individual with a disability] We echo the comments of the National Health Law Program that the definition for a qualified interpreter for a person with a disability be strengthened and more aligned with that of an interpreter for a person with LEP.

We further agree with the proposal to require covered entities to provide language assistance for those with limited English proficiency free of charge and to offer a qualified interpreter to these individuals when oral interpretation is necessary. As proposed these individuals should not be required to provide their own interpreter or rely on anyone other than a qualified interpreter.

...

...support HHS's proposal to incorporate the definition of "qualified interpreter for a person with a disability" from the ADA. [Footnote 6 28 C.F.R. 35.104, 36.104.] However we suggest closer alignment between the definitions related to qualified interpreter for a limited English proficient individual [LEP] and qualified interpreter for an individual with a disability. Alignment of the standards should increase confusion for covered entities increase the likelihood that all interpreters are provided with sufficient standards and meet the requirements and increase the likelihood that people who need interpretation or access to auxiliary aids and services will have the access to care they need. [Bold/Underline. RECOMMENDATION.] Amend the definition of qualified interpreter for an individual with a disability as follows:Qualified interpreter for an individual with a disability means an interpreter who via a video remote interpreting service (VRI) or an on-site appearance:[Bold/Italics:]1) Has demonstrated proficiency in communicating, and aural understanding both English and a non-English language (including American Sign Language other sign languages); or- In another communication modality [such as cued-language transliterators or oral transliteration). [Footnote 7 We note that not all interpreters for people with disabilities are translating between English and another language. In some cases they are acting as transliterators interpreting from one communication modality into English. Another example would be Certified Deaf Interpreters who are individuals who are deaf or hard of hearing and may be interpreting between an individual who is deaf and uses a unique version on ASL or foreign or home signs unfamiliar to the medical interpreter. See e.g. Registry of Interpreters for the Deaf Certified Deaf Interpreter (CDI) https://rid.org/rid-certification-overview/available-certification/rid-certification/]- [2] Is able to interpret effectively accurately and impartially both receptively and expressively using any necessary specialized vocabulary or terms.

We recommend that the definition of a qualified interpreter for an individual with a disability be amended to align with the definition more closely for a qualified interpreter for an LEP individual. For instance a qualified interpreter for a person with a hearing disability should demonstrate proficiency in speaking and understanding both English and another relevant sign language. For transliterators this should include proficiency in the relevant alternative communication modality. Finally interpreters for an individual with a disability should communicate "without changes omissions or additions and while preserving the tone sentiment and emotional level of the original...statement" and adhere to generally accepted ethics principles including client confidentiality. These standards should apply whether an interpreter is interpreting for a person with a disability or for an LEP individual.

Bold: We further recommend that the definition of "Qualified interpreter for an individual with a disability" be aligned with the definition of "Qualified Interpreter for a limited English proficient individual."]

We also encourage OCR to issue additional guidance on how covered entities can determine whether someone has demonstrated proficiency in a language is able to interpret effectively and adheres to ethics principles. For example there are several avenues for interpreter certification and the most appropriate one in determining whether an interpreter should be considered qualified will depend on the circumstances. [Footnote 10 "Interpreting Certifications" "The Community Interpreter" https://www.thecommunityinterpreter.com/interpreting-certifications] Specifically OCR should lay out examples of when would be appropriate to require a qualified interpreters to obtain certification in order for the covered entity to be in compliance with Section 1557 such as for doctor patient interactions that require specificity and medical knowledge to avoid harmful outcomes. We do wish to acknowledge that the people best suited to serve as interpreters often come directly from LEP communities. In our conversations with community members we have heard that ever second generation language speakers may be difficult to understand particularly for new immigrants. People in LEP communities face barriers to obtaining credentials such as the time and financial cost. However we have heard a desire from community members that having a high-quality and appropriately trained interpreter is very important. Therefore we encourage OCR to work with partners to develop more resources to help people in immigrant and LEP communities become certified interpreters.

Qualified Interpreters and Machine Translation.CCJ supports the proposed rule's definitions for qualified interpreter for an LEP individual qualified translator and qualified interpreter for an individual with a disability.

[Italics] Definitions of Qualified Interpreter.[As written the proposed definition of Italics] "Qualified interpreter for a limited English proficient individual" requires demonstrated proficiency in speaking and understanding spoken English and one other spoken language. [Bold: We recommend the term be expanded to recognize qualified interpreters who have demonstrated proficiency in speaking and understanding both English languages and otherwise meet the requirements under the definition.] Such qualified interpreters in conjunction with other qualified interpreters may need to be utilized in "relay interpretation" situations to ensure effective communication with individuals who use emerging languages or are part of smaller linguistic communities [e.g. an interpreter who is qualified to interpret between an indigenous language and Spanish or a Deaf interpreter who is qualified to interpret between American Sign Language and other sign languages] We also propose that this and other definitions include the concept of linguistic variants as a distinct form of a language used by people from a specific community or region. It is important to recognize that many languages spoken in the U.S. are actually language families with many distinct linguistic variants or "dialects" that may be used in the same country of origin but are frequently not mutually intelligible.

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Alliance of Multicultural Physicians

Genesee County Legal Aid Society dba Center for Civil Justice

National Immigration Law Center

National Immigration Law Center

UPAC

(b)(5)

National Disability Rights Network

Genesee County Legal Aid Society dba Center for Civil Justice

Justice in Aging

(b)(5)

National Immigration Law Center

Genesee County Legal Aid Society dba Center for Civil Justice

Justice in Aging

health related scenarios such as in a doctor's office or when communicating responsibilities for payment under health insurance the quality of an interpreter is as important as the availability of one. Community partners have shared stories with us about interpreters both employed by covered entities and through contracting services whose lack of medical interpretation skills led to errors and poor outcomes. For example we have heard that frequently interpreters for one dialect of a language such as Nepali may be used for a patient who speaks a different version of that language such as someone from Bhutan. In one situation an interpreter used a word for "surgery" that also could mean "funeral" to people from Bhutan who instead use "operation". We also heard from someone who worked as a patient navigator in a hospital who had been asked to be an interpreter for a medical situation something they felt uncomfortable with due to a lack of training in medical terminology despite being fluent in their language. Research has shown that bilingual staff who are not formal interpreters often do not feel comfortable with this role. [Footnote 9 Moreno Maria R et al. "Assessing dual role staff-interpreter linguistic competency in an integrated healthcare system." Journal of General Internal Medicine 2007 https://pubmed.ncbi.nlm.nih.gov/17957420/]Therefore we encourage OCR to go beyond the proposed definition of Qualified Interpreter which focuses on broad competencies such as language proficiency and ability to interpret effectively. These terms require additional nuance. For example we encourage OCR to consider adding "and dialect" after "spoken language" under (1) to acknowledge that speakers of a language may not always be qualified to interpret for a person who speaks a variation of that language. We also encourage adding "understanding and" before "using necessary specialized vocabulary or terms." Under [2] in the case that to provide effective interpretation for complex situations such as communicating a treatment regimen requires understanding of the terminology

No comments are associated with this issue.

Qualified Interpreters and Machine Translation(C) supports the proposed rule's definitions for qualified interpreter for an LEP individual qualified translator and qualified interpreter for an individual with a disability.

No comments are associated with this issue.

No comments are associated with this issue.

The Proposed Rule Clarifies Protections for Pregnancy or Related Conditions(We support that the Department's proposed rule explicitly includes "pregnancy or related conditions" in its definition of discrimination on the basis of sex [Footnote 29 87 Fed. Reg. at 47858 47916]Proposed § 92.101[. Congress intended Section 1557 to prohibit discrimination against patients because of their medical history or needs which includes if they had an abortion or miscarriage or other pregnancy-related care. We also support HHS's proposal to repeal 45 C.F.R. § 92.6 which incorporates the language of Title IX's abortion provision [Footnote 30: Id. at 47859 (Proposed § 92.206)]

Remedial ActionThe ADA is concerned about the Department's proposal to reinstate the 2016 rule's requirements regarding remedial action. The 2016 rule state that if a health program or activity has discriminated the Office for Civil Rights (OCR) may require the recipient to take remedial action to overcome the effects of the discrimination. This remedial action may be with respect to[1] individuals who are no longer participants in the health program or activity or [2] individuals who would have been participants in the health program or activity had the discrimination not occurred. ADA urges OCR to limit the application of remedial action to individuals who either (1) applied to participate but were unable to participate due to alleged discrimination or (2) who had been participants but are no longer participants due to alleged discrimination. Failure to adopt such limits could unfairly expose dentists to spurious and potentially devastating claims by individuals who would not have been participants notwithstanding any alleged discrimination.

No comments are associated with this issue.

Designation and responsibilities of a Section 1557 Coordinator [§ 92.7)]We support the proposal to require covered entities to have a designated Sec. 1557 coordinator.

[Italics: Designation and Responsibilities of a Section 1557 Coordinator [§ 92.7)]]We support the proposed requirement that covered entities have a designated Section 1557 coordinator and encourage OCR to adopt a final rule that does not exempt covered entities of any size from this requirement. Under the proposed rule covered entities have a number of responsibilities that do not vary based on their size. Therefore there should always be a person responsible for carrying out those responsibilities. If the responsibilities are uniform across entities then identifying a responsible staff member should not be a significant burden. Additionally a 15-person employee standard may encourage smaller covered entities with 13 or 14 staff to seek out ways to avoid compliance by hiring contractors or making more staff part time. At least one third of physicians work in practices with less than five physicians which could exempt a significant number of health providers from designating a coordinator under this rule [Footnote 11 Kane Carol "Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less Than 50 Percent of Physicians in 2020." American Medical Association 2021 ama-assn.org/system/files/2021-05/2020-prp-physician-practice-arrangements.pdf]. In rural areas and other small communities a small independent practice may be the backbone of the available care network. In these circumstances particularly where alternatives are less readily available it is important that there be a designated point of accountability within the practice for patients who feel they have experienced discrimination.

We also strongly encourage the Department to provide civil rights cultural and implicit bias training to support Coordinators as they will facilitate the training of other employees in the covered entity. Training is especially important in providing equitable services to communities that include people of color people with disabilities and limited English proficiency (LEP) individuals who have specific communication needs essential to quality care.

Designation and Responsibilities of a Sec. 1557 Coordinator(WPHCA supports the new provision proposed in §92.7 that allows covered entities to assign one or more designees to carry out some responsibilities of the Section 1557 Coordinator. Having a 1557 Coordinator is crucial to have a designated person to track requirements and create required systems/trainings related to nondiscrimination. The COVID-19 pandemic has placed an incredible strain on an already exhausted health care workforce with workers spread thin, compliance with these provisions would fall through the cracks if health care facilities were not intentional on having a team member to address it. Community Health Centers are struggling to maintain an adequate workforce. 68% of Community Health Centers reported losing 5-25% of their workforce in mid-2021 with employees citing competition from other employers and pandemic stress as the most common reasons for departing. WPHCA appreciates OCR's flexibility to some providers and facilities like Community Health Centers to spread 1557 responsibilities across multiple staff to ensure maximum compliance by having §92.7 in place. It holds all health care facilities accountable especially in states that are not prioritizing health equity.

[Bold: Designation and Responsibilities of a Section 1557 Coordinator:] [Bold: TPCA supports the new provision proposed in §92.7 that allows covered entities to assign one or more designees to carry out some responsibilities of the Section 1557 Coordinator.] Having a 1557 Coordinator is crucial to have a designated person to track requirements and create required systems/trainings related to nondiscrimination. The COVID-19 pandemic has placed an incredible strain on an already exhausted health care workforce with workers spread thin, compliance with these provisions would fall through the cracks if health care facilities were not intentional on having a team member to address it. Health centers are struggling to maintain an adequate workforce. 68% of health centers reported losing 5-25% of their workforce in mid-2021 with employees citing competition from other employers and pandemic stress as the most common reasons for departing. TPCA appreciates OCR's flexibility to some providers and facilities like health centers to spread 1557 responsibilities across multiple staff to ensure maximum compliance. By having §92.7 in place it holds all health care facilities accountable especially in states that are not prioritizing health equity.

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National Immigration Law Center

Genesee County Legal Aid Society dba Center for Civil Justice

Senate Democrats

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American Dental Association

Justice in Aging

National Immigration Law Center

(b)(5)

Center for American Progress

Wisconsin Primary Health Care Association

Tennessee Primary Care Association

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[Bold. Designation and Responsibilities of a Section 1557 Coordinator MNACHC supports the new provision proposed in §92.7 that allows covered entities to assign one or more designees to carry out some responsibilities of the Section 1557 Coordinator. | Having a 1557 Coordinator is crucial to have a designated person to track requirements and create required systems/trainings related to nondiscrimination and discrimination. The COVID-19 pandemic has placed an incredible strain on an already exhausted health care workforce with workers spread thin. Compliance with these provisions would fall through the cracks if health care facilities were not intentional on having a team together to address it. Health centers are struggling to maintain an adequate workforce. 68% of health centers reported losing 5-25% of their workforce in mid-2021 with employees citing competition from other employers and pandemic stress as the most common reasons for departing. YOUR ORGANIZATION appreciates OCR's flexibility to some providers and facilities like health centers to spread 1557 responsibilities across multiple staff to ensure maximum compliance. By having §92.7 in place, it holds all health care facilities accountable especially in states that are not prioritizing health equity.

(b)(5)

Minnesota Association of Community Health Centers

the "responsible employee" provision from the 2016 rule the Proposed Rule would require covered entities with 15 or more employees to designate at least one employee to serve as a Section 1557 Coordinator to coordinate the efforts to comply with and carry out the covered entity's responsibilities under Section 1557. HHS proposes to include a list of responsibilities to assist covered entities in developing a position description for the Section 1557 Coordinator and to identify the provisions over which Coordinators must have direct responsibility.Recommendation: BCBSA recommends HHS give covered entities 120 days to designate a Section 1557 Coordinator. BCBSA recommends that HHS allow covered entities to provide the Section 1557 Coordinator job title and description instead of the name of an individual. Rationale: While "responsible employees" as described in the 2016 rule may still be in place the responsibilities may not be as uniform passing as Section 1557 Coordinators described in the Proposed Rule. Some plans may need to develop/revise job descriptions and to recruit and hire a Section 1557 Coordinator after the new requirements policies and procedures are established which will take considerable time. The Preamble indicates people need to be listed not a staff position. We appreciate that the proposed rule allows designation of the role and responsibilities even as a covered entity provides the name of a primary point of contact (POC). This helps ensure a person is responsible when the role is in transition. If the primary POC takes a vacation or is otherwise unreachable. However, for privacy security and staffing reasons BCBSA recommends HHS should not require covered entities to identify actual employee names publicly. For example unfortunately in our society today some people are opposed to the protections provided by Section 1557 and providing the name of the Section 1557 Coordinator publicly could make them subject to harassment or even worse place them in danger. Because of this BCBSA recommends that a job

Blue Cross Blue Shield Association

Additional Provisions:We support the Department's requirements that a covered entity develop civil rights policies and procedures and take proactive measures to prevent discrimination through training as well as the hiring of a Section 1557 coordinator. (Footnote 34: 87 Fed. Reg. at 47843 47914 (Proposed § 92.8) 47915 (Proposed § 92.9)) These provisions will allow OCR to better identify patterns or practices of discrimination through the availability of information on past complaints and aid in delivering effective and efficient care to people. [footnote 35: Id.]

Senate Democrats

[Bold: 1557 Coordinator Policies and Procedures Training] DRM strongly supports the proposed rule's requirement for covered entities appoint a designated Section 1557 coordinator establish clear civil rights policies and procedures and train public-facing and other relevant employees on those procedures. Experience teaches us that these work to elevate the knowledge and awareness of people within covered entities. Individual patient complaints should not be the primary means of enforcement. Covered entities have a responsibility to know, provide notice of and acknowledge the rights of individuals. Requiring a designated Section 1557 coordinator is similar to a provision in the Americans with Disabilities Act (ADA) requiring a designated ADA/504 coordinator. The ADA also requires that entities covered by the ADA have a grievances process so individuals can report violations to the covered entity. DRM has successfully had process on several different occasions. DRM suggests that covered entities have their own grievance process similar to the ADA grievance process.

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Disability Rights Maine

The proposed rule requires a Sec. 1557 coordinator who has the ultimate responsibility and authority to ensure that people with disabilities receive their rights along with the requirement for establishing civil rights policies procedures and staff training will go far toward achieving a true merger of medical and public health regulations with civil rights regulations. While smaller entities cannot be expected to have the same financial human and infrastructure resources as large healthcare systems and that consideration is already built into consideration 1 in this section it is to their own benefit to have an internal source of information on these matters and to establish clear policies and procedures rather than rely on the discretion of individual public-facing employees some of whom may be newly employed given high employment turnover rates. We strongly recommend that smaller health care entities with less than 15 employees be subject to proposed §§ 92.7 92.8 and 92.9 since they are still obligated to comply with Section 1557's nondiscrimination mandate and need to have written policies for patients requesting reasonable modifications and receiving civil rights grievances. All sizes of entities should have full access to the technical assistance materials that HHS OCR will develop and the tools to promote civil rights adherence within their own practices. Being a smaller entity is not a license to ignore and violate civil and human rights.

Disability Rights Maine

employs fifteen or more persons must designate and authorize at least one employee as a "Section 1557 Coordinator" to coordinate the covered entity's compliance with its responsibilities under Section 1557 and the proposed rule in its health programs and activities including the investigation of any grievance communicated to it alleging noncompliance with Section 1557 or the proposed rule or alleging any action that would be prohibited by Section 1557 or this proposed rule. According to the proposed rule responsibilities of this Section 1557 Coordinator "include: [1] receiving reviewing and processing grievances (2) coordinating the covered entity's recordkeeping requirements; [3] coordinating effective implementation of the covered entity's language access procedures; [4] coordinating effective implementation of the covered entity's effective communication procedures, [5] coordinating effective implementation of the covered entity's reasonable modification procedures, and [6] coordinating training of relevant employees including maintaining documentation HHS OCR seeks comment on this requirement including whether OCR should require covered entities with fewer than 15 employees to designate a Section 1557 Coordinator and if so whether there should be a requisite number of employees or whether all covered entities should be required to designate a Section 1557 Coordinator. [Bold: NCPA opposes the designation of a Section 1557 Coordinator in its entirety. In 2021 independent pharmacy owners on average employed 12.3 full and part time workers. [Footnote 2: 2022 NCPA Digest page 9 Table 4.] However NCPA opposes OCR requiring any entities regardless of number of employees to designate a Coordinator. Such a coordinator would greatly increase administrative burden to community pharmacies with greater than 15 employees and we are also concerned from its comment request that HHS OCR would expand the Coordinator role to our members with fewer than 15 employees as well.' We agree with HHS OCR's original reasoning in 2020 as stated in the

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NCPA

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3. Change the expected duration for record retention of grievances that have been filed with a entity from calendar years from the date of filing to calendar years from the date of [bold resolution] "Section § 92.7 Designation and responsibilities of a Section 1557 Coordinator section [c.2] Grievance procedures states that [2] A covered entity to which this paragraph applies must retain records related to grievances filed with it that allege discrimination on the basis of race color national origin age disability for no less than three (3) calendar years from the date of the filing of the grievance.The MRCT Center strongly advocates that the expectation of record retention be changed to no less than three [3] calendar years from the date of resolution of the grievance. It is entirely too easy for a covered entity to extend investigation and delay resolution such that the suggested record retention period expires leaving little documentation to review or upon which to rely.Specifically we propose that the paragraph reads [2] A covered entity to which this paragraph applies must retain records related to grievances filed with it that allege discrimination on the basis of race color national origin age disability for no less than three (3) calendar years from the date of the [bold resolution] of the grievance

We note that the description of prohibited sex discrimination in this section differs from the language of section 92.101. While the differences are not problematic for the sake of clarity it would be preferable to use consistent language throughout the rule, the more expansive definition in 92.101 should be used. [92.7(] We support the proposal to require entities with more than 15 employees to designate a Section 1557 coordinator to carry out the responsibilities necessary for complying with the law and protecting patients civil rights. OCR has requested whether this requirement should apply to entities with fewer than 15 employees. [Bold: We urge OCR to require all covered entities regardless of their size to designate a coordinator.] Having such a role designated coordinator will help ensure greater compliance with the law's requirements for all patients. Covered entities must follow the law regardless of the entity's size. part of the rationale for requiring a coordinator is that without a specific allocation of responsibility for compliance violations are more likely. Studies show (Hyperlink
https://www.sciencedirect.com/science/article/abs/pii/S0196064405000100) that in a variety of contexts assigning responsibilities to particular individuals makes a significant difference in improving performance including in organizations or organizational units with fewer than 15 employees. The proposed rule's regulatory preamble cites 45 CFR §86.8(a)'s requirement that each recipient of federal funding must "designate at least one employee to coordinate its efforts" to comply with Title IX of the Education Amendments of 1972. Notably that regulation applies to "each recipient" which 45 CFR §2.2(l)(4)(i) defines to include any "entity or any person to whom federal financial assistance is extended." This obligation is not limited to entities with at least 15 employees. Congress's intent (Hyperlink
https://www.help.senate.gov/imo/media/doc/15575%20Letters%20FINAL.pdf) in passing Section 1557 was to incorporate the highest levels of protection according by prior civil rights statutes including Title IX. To effectuate that intent it is essential that the final rule eliminate the restrictive coordinator obligations to entities with 15 or more employees.

(b)(5)

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Eating Disorders Coalition for Research, Policy & Action

UnitedUS

Justice in Aging

HHS requested comment on whether this provision should apply to entities with fewer than 15 employees and we recommend that it should. Regardless of the size person at a covered entity should be responsible for developing the required policies and procedures ensuring relevant employees are trained receiving and addressing grievances and informing individuals of their rights when they interact with the entity

Duties. Designation and Responsibilities of a Section 1557 Coordinator [§ 92.7(]We support the proposed requirement that covered entities have a designated Section 1557 coordinator and encourage OCR to adopt a final rule that does not exempt covered entities of any size from this requirement. Under the proposed rule covered entities have a number of responsibilities that do not vary based on their size. Therefore there should always be a person responsible for carrying out those responsibilities. If the responsibilities are uniform across entities their identifying a responsible staff member should not be a significant burden. Additionally a 15-person employee standard may encourage smaller covered entities with 14 or 14 staff to seek out ways to avoid compliance by hiring contractors or making more staff part time. At least one third of physicians work in practices with less than five physicians which could be right a significant number of health providers from designating a coordinator under this rule (Outrote 11 Kane Carol "Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less Than 50 Percent of Physicians in 2020." American Medical Association 2021 ama-assn.org/system/files/2021-05/2020-prp-physician-practice-arrangements.pdf). In rural areas and other small communities a small independent practice may be the backbone of the available care network. In those circumstances particularly where alternatives are less readily available it is important that there be a designated point of accountability within the practice for patients who feel they have experienced discrimination

(b)(5)

National Immigration Law Center

We support the proposal to require covered entities to have a designated Sec 1557 coordinator. HHS requested comment on whether this provision should apply to entities with fewer than 15 employees and we recommend that it should. Even in smaller covered entities it is essential that someone is responsible for coordinating implementation of Sec. 1557 including developing the required policies and procedures ensuring relevant employees are trained receiving and addressing grievances and informing individuals of their rights when they interact with the covered entity. We believe this is especially important for entities providing long-term services and supports (LTSS) to older adults and people with disabilities. Smaller LTSS providers are common and often preferred by older adults and people with disabilities because the services they provide are often daily and intimate. While preventing discrimination is critical in all health care settings having a coordinator to ensure that Sec. 1557 is implemented is essential to a safe life for someone who resides at a covered entity or receives home- and community-based services. The coordinator role will likely vary from entity to entity and we believe the proposed description of the coordinator's duties allows for such variation and minimizes burden on smaller entities. For example a smaller entity would not have to have the coordinator role be a full time job.

(b)(5)

Center for Elder Law & Justice

The "responsible employee" provision from the 2016 rule the Proposed Rule would require covered entities with 15 or more employees to designate at least one employee to serve as a Section 1557 Coordinator to coordinate the efforts to comply with and carry out the covered entity's responsibilities under Section 1557. HHS proposes to include a list of responsibilities to assist covered entities in developing a position description for the Section 1557 Coordinator and to identify the provisions over which Coordinators must have direct responsibility.Recommendation: • BCBSA recommends HHS give covered entities 120 days to designate a Section 1557 Coordinator. • BCBSA recommends that HHS allow covered entities to provide the Section 1557 coordinator job title and description instead of the name of an individual Rationale: While "responsible employees" as described in the 2016 rule may still be in place the responsibilities may not be as enforceable as Section 1557 Coordinators described in the Proposed Rule. Some plans may need to develop/revise job descriptions and train current and new Section 1557 coordinators after the new requirements policies and procedures are established which will take considerable time.The Preamble indicates people need to be identified as a staff assistant. We appreciate that the proposed rule allows designation of the role and responsibilities even as a covered entity provides the name of a primary point of contact (POC). This helps ensure a person is responsible when the role is in transition. If the primary POC takes a vacation or is otherwise unavailable. However for privacy security and staffing reasons BCBSA recommends HHS should not require covered entities to identify actual employee names publicly. For example unfortunately in our society today some people are opposed to the protections provided by Section 1557 and providing the name of the Section 1557 Coordinator publicly could make them subject to harassment or even worse place them in danger. Because of this BCBSA recommends that a job

(b)(5)

Blue Cross Blue Shield Association

(b)(5)

proposed rule and supports its goal of eliminating discrimination in health care. We have concerns about the unintended consequences that the rule may have if implementation carries a disproportionately high cost for physician practices, especially those that are small or medium sized. For example, while interpretation services are vital to ensuring quality care for immigrant families, the cost of interpretation is often borne by the physician practice. Many pediatricians and pediatric subspecialists, especially those practicing in small or medium sized groups, may experience barriers such as financial or other resource constraints that limit implementation of the proposed standards. In many parts of the U.S. such as New York and Los Angeles, the number of preferred languages and dialects is so great that providing accessibility to language assistance services during all hours of operation (i.e., twenty-four hours a day, seven days a week, in the case of hospitals) – imposes an enormous workload and financial burden on health care organizations. Moreover, for immigrant enclaves and enclaves in immigrant families, the inability of a practice to provide interpreter services could have the unintended consequences of providers being unwilling to accept these patients, presenting an already critical access problem for many vulnerable children. In addition to the costs associated with translation services used when seeing patients, the ability to provide communication to patients in multiple languages and modalities such as in written materials and online have large financial implications. Payment for interpreter services should become a mandatory rather than optional service if this standard is to be realistically implemented by providers. Private and public insurance payers should pay for qualified medical interpreter and translation services. Given the increased cost effectiveness and quality of care provided with medical interpretation, payers should recognize and reimburse for the increased time needed during a medical encounter when using an interpreter. Pediatricians have also voiced concerns

APMA also recommends that HHS not require covered entities that employ fewer than 15 people to have a Section 1557 Coordinator and grievance procedures as proposed, given the already noted overwhelming burdens and costs above that frequently fall disproportionately on small and solo practices.

Requiring a Section 1557 Coordinator for entities employing greater than fifteen people creates consistency with Sec. 504 however it does not take into account how crucial the provision of accessible health care is for everyone and how many barriers can exist for people with disabilities who are often seeking and receiving care at a higher rate than the general population. We recommend that every entity be required to have a Sec. 1557 Coordinator.

|Bold, Designation and Responsibilities of a Section 1557 Coordinator and Staff Training|Pennie supports the proposed rule's provision requiring covered entities with fifteen or more employees to designate at least one employee to serve as a section 1557 coordinator. It is important that covered entities have the requisite knowledge of these requirements to ensure that they are being implemented correctly. Pennie urges HHS to make clear in the final rule that the duties of the section 1557 coordinator can be shared by more than one employee of the exchange. Pennie further requests clarification regarding any reporting requirements between the exchange's section 1557 coordinator and HHS.

Section 1557 Coordinator:CCJ supports the proposed rule that would require covered entities with 15 or more employees to designate at least one employee to serve as a Section 1557 Coordinator. CCJ suggests that entities that have fewer than 15 employees should still have a designated person to act as its coordinator to ensure compliance with the law and these regulations.

|Bold, Compliance Coordinator Requirement: The proposed rule requires covered entities with 15 or more employees to appoint a Section 1557 compliance coordinator. In addition, comments are solicited as to whether that threshold should be lower. Given the human capital and financial costs associated with designating an employee to be responsible for compliance, NAHU members do not believe this requirement should be extended to smaller entities. In fact, our recommendation is to raise the threshold to exempt all businesses and industries classified as small businesses by the Federal Small Business Administration.

|Bold and Underline: Designation and Responsibilities of a Section 1557 Coordinator (§ 92.7)|OCR proposes to require covered entities with 15 or more employees to designate at least one employee to serve as a Section 1557 Coordinator, and to allow covered entities to designate one or more designees to carry out some of the responsibilities of the Section 1557 Coordinator. Should OCR finalize the rule to include the requirement for a Section 1557 Coordinator, then NACDS would welcome the proposed change to allow for designees. This should help covered entities deploy their resources and employees more effectively. However, NACDS does not support OCR's delegating the specific responsibilities of the Section 1557 Coordinator. As they had in the past, each covered entity should have the ability to determine the responsibilities to best comply with the provisions of the rule for their own operations.

III. Designation and Responsibilities of a Section 1557 Coordinator (§ 92.7)|We support the Proposed Rule's requirement of a designated Section 1557 Coordinator in covered entities in addition to the enumeration of the Coordinator's responsibilities.

We encourage the Department to require covered entities with fewer than 15 employees to designate a Coordinator particularly because this could proactively increase the protection of individuals receiving care from smaller providers. People with disabilities for instance often seek home and community-based services from smaller providers that would benefit from a designated employee to coordinate reasonable modifications and communication preferences. [Footnote 22: Amber Christensen, Natalie Kean, Medicaid Home and Community-based Services for Older Adults with Disabilities: A Primer, Justice in Aging, (April 2021) https://justiceinaging.org/wp-content/uploads/2021/04/HCBS-Primer.pdf] Smaller physician practices are also more likely to be found in rural communities with less provider choice with a reasonable distance compared to urban communities and this is a large consideration for people with disabilities seeking health care services. Although covered entities with fewer than 15 employees may not have the same financial or human resources as larger entities, designating an employee to ensure the protection of rights of particularly vulnerable communities is key to achieving nondiscrimination policies and procedures.

We believe that the duties of the coordinator as proposed in this rule allows for necessary workload so that smaller entities will not be burdened. For example, a smaller entity would not have to have the coordinator role be a full-time job. While preventing discrimination is critical in all health care settings, having a coordinator to ensure that Sec. 1557 is implemented is essential to daily life for someone who resides at a covered entity such as a nursing home or receives home- and community-based services (HCBS). It is common for entities providing HCBS such as assisted living and group homes to be small. And older adults and people with disabilities often prefer small providers because the nature of HCBS such as personal care requires longer and intimate interaction often on a daily basis.

|Bold, Designation and Responsibilities of a Section 1557 Coordinator and Staff Training|Pennie supports the proposed rule's provision requiring covered entities with fifteen or more employees to designate at least one employee to serve as a section 1557 coordinator. It is important that covered entities have the requisite knowledge of these requirements to ensure that they are being implemented correctly. Pennie urges HHS to make clear in the final rule that the duties of the section 1557 coordinator can be shared by more than one employee of the exchange. Pennie further requests clarification regarding any reporting requirements between the exchange's section 1557 coordinator and HHS.

No comments are associated with this issue

(b)(5)

American Academy of Pediatrics

American Podiatric Medical Association

ND Protection & Advocacy Project

Pennsylvania Health Insurance Exchange Authority d/b/a Pennie

Genesee County Legal Aid Society dba Center for Civil Justice

(b)(5)

National Association of Health Underwriters

National Association of Chain Drug Stores

Center for American Progress

(b)(5)

Center for American Progress

Justice in Aging

Justice in Aging

Pennsylvania Health Insurance Exchange Authority d/b/a Pennie

(b)(5)

The direct attention to nondiscrimination on the basis of sex limited English proficient (LEP) individuals and people with disabilities and the clarification of the specific measures that are anticipated to comply with Section 1557 are welcome. Specifically we support the major clarifications in the rule: • The interpretation of Section 1557 to cover all health programs and activities administered by HHS; • The interpretation that provision of Medicare Part B assistance is federal financial assistance and that entities receiving Medicare Part B funds must comply with the Rule; • The application to health insurance issuers that receive federal financial assistance; • The clarification that the protections against discrimination on the basis of sex as including sexual orientation and gender identity and discrimination on the basis of sex stereotypes and the extension of these protections to CMS regulations; • The expectation that compliance will require implementing programs to develop maintain and communicate clear policies and train on the provision of language assistance services for limited English proficient (LEP) individuals and effective communication and reasonable modifications to policies and procedures for people with disabilities; • The requirement that implementing entities provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant states; • The expectation of nondiscrimination based on clinical algorithms; • The expectation that nondiscrimination extends to telehealth services and • The development of clear processes for requesting exceptions from the expectation of compliance.

Add: Written Policies and Procedures:If finalized this proposed regulation will require covered entities to implement written Section 1557 policies and procedures. These policies and procedures must be reasonably designed consistent with the size complexity and type of health programs and activities undertaken by the covered entity and include an effective date. The written policy must at minimum state that the covered entity in its health programs and activities does not unlawfully discriminate on the basis of race color national origin (including limited English proficiency and primary language) sex (including pregnancy sexual orientation gender identity and sex characteristics) age or disability and provides language-assistance services and appropriate auxiliary aids and services free of charge when necessary for compliance with Section 1557. In addition if applicable the policy document must include the contact information for the covered entity's Section 1557 compliance coordinator as well as address the entity's grievance and recordkeeping procedures including how the entity will ensure that the grievance process is accessible to individuals with limited English proficiency.The preamble to the proposed rule indicates that HHS plans to publish sample policies online if the regulation is finalized. NAHU members strongly support this plan.

(b)(5)

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) I

National Association of Health Underwriters

We note that the description of prohibited sex discrimination in this section differs from the language of section 92.101. While the differences are not problems we for the sake of clarity it would be preferable to use consistent language throughout the rule, the more expansive definition in 92.101 should be used.

NECUS Service for Social Change

Section 1557 Policies and Procedures are a necessary step toward preventing racism and other discriminatory conduct in health care.As the Proposed Rule notes for patients of color trust in their health care providers would increase if these patients could voice their concerns directly to their health care providers which would in turn improve these patients' overall health care experiences. However existing Section 1557 policies and procedure requirements are unwanted confusing and ineffective. The Proposed Rule would streamline these requirements by requiring covered entities to adopt and implement nondiscrimination policies against all forms of discrimination including language and disability access procedures (collectively Section 1557 Policies and Procedures). The revised Section 1557 Policies and Procedures aim to prevent discrimination from occurring in the first place by ensuring covered entities have greater knowledge of their obligations under Section 1557.

(b)(5)

Alliance of Multicultural Physicians

Additional Provisions:We support the Department's requirements that a covered entity develop civil rights policies and procedures and take proactive measures to prevent discrimination through training as well as the hiring of a Section 1557 coordinator. (Footnote 84: 87 Fed. Reg. at 47849 47914 (Proposed § 92.8) 47915 (Proposed § 92.9)). These provisions will allow OCR to better identify patterns of practices of discrimination through the availability of information on past complaints and aid in delivering effective and efficient care to people. [Footnote 84: Id.].

Senate Democrats

Compliance burdens resulting from the proposed 1557 compliance requirements will overwhelm providers' offices particularly small practices and solo practitioners that HHS seeks additional comment on. Specifically we are concerned about the resources needed to write and implement Section 1557–specific policies and procedures identify a Section 1557 Compliance Coordinator and train practice employees on new nondiscrimination standards. Pediatric physicians like other physician specialties are increasingly underreimbursed for the patient care they provide particularly when compared to other types of health care providers and Medicare Advantage plans. Medicare payments to physicians have failed to keep up with inflation which has recently hit record highs and with the passage of the Medicare Access and CHIP Reauthorization Act of 2015 no longer incorporate inflation as a factor for determining annual payment updates. As a result of this and other structural challenges with the Medicare Physician Fee Schedule Medicare payment rates are scheduled for a third straight year of payment reductions in 2023. Moreover providers already face significant administrative burdens due to federal and state regulations and payer contract requirements for example related to audits and medical record reviews prior authorizations and quality reporting requirements. These requirements consume clinical and administrative staff time and attention and limit practices' ability to focus on delivering high-quality care. Pairing this already overwhelming administrative burden with these strong funding constraints and healthcare workforce challenges will impair physicians' ability to simply hire additional staff to manage more. Providers are already struggling and cannot afford another unfunded mandate in the current environment.Given the above APMA asks that HHS not finalize policies that would add to providers' administrative burden. If HHS chooses to finalize the rule with no changes APMA asks that it strive to minimize the burdens created by developing and making available free-of-charge

American Podiatric Medical Association

will be created as a result of the proposed requirements for physicians' offices related to Section 1557 compliance. Specifically we are concerned about the resources needed to write and implement Section 1557–specific policies and procedures identify a Section 1557 Compliance Coordinator and train practice employees on new nondiscrimination standards. Rheumatology practices are grossly underreimbursed for the patient care they provide particularly when compared to other types of health care providers and Medicare Advantage plans since the inception of the resource-based relative value scale the Medicare Physician Fee Schedule (PFS) conversion factor has remained consistently flat. Even with passage of the Medicare Access and CHIP Reauthorization Act of 2015 physician payments no longer incorporate inflation which has reached record levels in recent months.In addition to unsustainable payments rheumatology practices face increasing administrative burdens primarily associated with utilization management such as prior authorizations step therapy and other actions which divert clinical and administrative staff away from direct patient care and related activities. This is on top of the punitive quality reporting and program integrity audits. Simply stated our practices cannot afford another unfunded mandate in the current environment.As such we ask the Department not to create additional administrative burdens on already overburdened physicians' offices. If the Department finalizes these requirements despite this concern then at a minimum (italic bold) we seek your assistance in helping rheumatology practices with compliance. Specifically we request that HHS develop and make available free of charge to the following: • Template Section 1557 policies and procedures that rheumatology offices can incorporate into their existing compliance materials as-is; • Section 1557 educational materials and training resources including materials that would help practices test their employees understanding of the new requirements and how to comply; and • Patient

(b)(5)

Coalition of State Rheumatology Organizations (CSRO)

(b)(5)

However we are deeply concerned with the [more] proposed requirement that providers including physicians must write and implement Section 1557–specific policies and procedures identify a Section 1557 Compliance Coordinator and train their employees on these new standards.Physicians' offices are overwhelmed by administrative tasks that stem from a multitude of federal regulators and requirements including quality reporting utilization management and medical review/audits. Indeed many allergy/immunology (A/I) practices are small and have limited administrative and clinical staff that can be diverted from patient care activities to manage yet another compliance program. Considering the year-over-year reductions in payments to Medicare physicians coupled with significant and extreme workforce challenges we are frustrated that the Department is proposing this unfunded mandate on physician offices. And while we support the intent of this new policy our practices simply lack the financial and staffing resources to properly comply.Should the Department proceed with finalizing this proposal HHS must develop templates Section 1557 policies and procedures and compliance guidance that physician offices can easily incorporate into their existing compliance manuals. HHS should also develop educational materials that assist practices with training activities and with testing staff understanding of the policies. HHS should develop patient notices and other patient education materials for practices. These resources should be downloadable from the HHS website and made available free-of-charge.
Importantly any enforcement action resulting from a Section 1557 complaint should start with enhanced education and the provision of technical assistance so providers can come into compliance without sanctions or penalties.

(b)(5) — American Academy of Allergy Asthma and Immunology (AAAAI)

[Added: 1557 Coordinator Policies and Procedures Training] DRM strongly supports the proposed rule's requirement for covered entities to appoint a designated Section 1557 coordinator establish clear civil rights policies and procedures and train public-facing and other relevant employees on those procedures. Experience teaches us that these work to elevate the knowledge and awareness of people within covered entities. Individual patient complaints should not be the primary means of enforcement. Covered entities have a responsibility to know provide notice of and acknowledge the rights of individuals. Requiring a designated Section 1557 coordinator is similar to a provision in the Americans with Disabilities Act (ADA) requiring a designated ADA/504 coordinator. The ADA also requires that entities covered by the ADA have a grievances process so individuals can report violations to the covered entity. DRM has successfully used that process on several different occasions. DRM suggests that covered entities make their own grievance process similar to the ADA grievance process.

Disability Rights Maine

2) HHS must provide support and resources to covered entities to ensure consistency in fulfilling language assistance training procedural and notice requirements. HHS is proposing to require covered entities provide notices of nondiscrimination and availability of language assistance services and other services to patients especially those with limited English proficiency (LEP). The agency also is proposing that covered entities have in place policies and procedures that support compliance with Section 1557 and train staff accordingly. ANA supports these proposed requirements and the goal of creating consistent procedural requirements for covered entities.However ANA is concerned that not all covered entities have the resources and staff support to ensure compliance with these requirements. We urge HHS to provide guidance templates and other resources to ensure some level of uniformity in the policy procedure and notice requirements in plain language. This allows fulfillment of the requirements across covered entities removing potential confusion for patients as they navigate between entities. Further many covered entities are experiencing workforce challenges that may limit their ability to devote the necessary staff time to come into compliance with the proposed requirements. To mitigate these we urge HHS to provide support to covered entities to appropriately complete and institute the policies and procedures and the necessary staff training. By providing this HHS can ensure consistency and fulfillment of the compliance training and patient education requirements in the above-captioned proposed rule. [Bold: As such ANA urges HHS to provide support and resources with notice training and other procedural requirements to guarantee consistency in compliance with Section 1557 across covered entities.]

(b)(5) — American Nurses Association

The Proposed Rule requires that covered entities implement policies and procedures to ensure compliance with Section 1557 and to provide training to staff interacting with patients. As part of those requirements and specifically for telehealth the provisions should require covered entities to establish internal processes for communicating with patients before during and after telehealth visits. This will allow for effective communication and continuity of care for patients who have challenges accessing follow-up or in-person care. For example HHS could require development of pre-appointment screening and communication policies to ensure necessary equipment or technology for the appointment or to determine whether the patient has the requisite technological skills for participation. Provisions might also include planning and development of training resources for patients who lack access to or familiarity with telehealth prior to the appointment. A communication by the provider for follow-up care whether for subsequent telehealth visits referrals or for in-person care should occur in a timely manner to ensure continuity of care.

Attorneys General of California, New York, Massachusetts, and nineteen other States

[Added: § 92.8 – Policies and Procedures] We strongly support the provisions requiring covered entities to adopt Section 1557 policies and procedures and to ensure their employees are trained on them. We agree with HHS that both employees in "public contact" positions and those who make decisions about these policies and procedures should receive training so they understand the requirements of Section 1557. We hope that such policies and procedures will ensure that covered entities are better able to meet the requirements of Section 1557.

National Disability Rights Network

The proposed rule requires a Sec. 1557 coordinator who has the ultimate responsibility and authority to ensure that people with disabilities receive the rights along with the requirement for establishing civil rights policies procedures and staff training will go far toward achieving a true merger of medical and public health regulations with civil rights regulations. While smaller entities cannot be expected to have the same financial human and infrastructure resources as large healthcare systems and that consideration is already built into consideration in this section it is to their own benefit to have an internal source of information on these matters and to establish clear policies and procedures rather than rely on the discretion of individual public facing employees some of whom may be newly employed given high employment turnover rates. We strongly recommend that smaller health care entities with less than 15 employees be subject to proposed §§ 92.7 92.8 and 92.9 since they are still obligated to comply with Section 1557's nondiscrimination mandate and need to have written policies for patients requesting reasonable modifications and resolving civil rights grievances. All sizes of entities should have full access to the technical assistance materials that HHS OCR will develop and the tools to promote civil rights adherence within their own practices. Being a smaller entity is not a license to ignore and violate civil and human rights.

(b)(5) — Disability Rights Maine

We note that the description of prohibited sex discrimination in proposed section 92.8 differs slightly from the language of proposed section 92.101 and we urge HHS to adopt the more expansive language of section 92.101 here.

(b)(5) — Advocates for Intersex Youth

Policies and Procedures and Training[CCI supports the requirement that each covered entity in its health programs and activities adopt and implement a nondiscrimination policy grievance procedures language across procedures auxiliary aids and services procedures and procedures for reasonable modifications for individuals with disabilities.

(b)(5) — Genesee County Legal Aid Society dba Center for Civil Justice

Policies and Procedures [§ 92.8]We support the requirement that covered entities develop and implement written policies and procedures to ensure compliance with this rule and that the procedural requirements apply across all covered non-discrimination bases.We note that the description of prohibited sex discrimination in this section differs from the language of section 92.101. Where the differences are not extensive it would be preferable to use consistent language throughout the rule, specifically the more expansive definition in 92.101 should be used. This is especially important to ensure that the finalized rule uses a definition that accurately captures the lived experience of the intersex community.

(b)(5) — Equitas Health

(b)(5)

The Health Connector supports the proposed requirement for covered entities to establish certain nondiscrimination policies and procedures and to train certain employees. Health Connector staff and residents of the Commonwealth will benefit from OCR's proposal to require covered entities to write and implement certain nondiscrimination policies and procedures. Ensuring clear guidance and training on nondiscrimination policies and procedures will strengthen staff understanding of such policies and procedures and further support access to health coverage and care for members and applicants.

(b)(5) — Massachusetts Health Connector

raises First Amendment concerns. [Proposed § 92.8 requires training on the proposed nondiscrimination regulations while proposed § 94.10 requires notices of nondiscrimination. Both requirements could raise concerns under the First Amendment. The Sixth Circuit recently found that a teacher who was disciplined for not using a student's preferred title and pronouns was able to claim protection under the First Amendment. [Footnote 253: Meriwether v. Hartup 992 F.3d 492 (6th Cir. 2021) (reversing dismissal of First Amendment free speech and free exercise claims by professor disciplined by university for not following university's gender identity nondiscrimination policy when he refused to address transgender identifying student by student's preferred title and pronouns and instead used only student's last name] settled & voluntarily dismissed sub nom. Meriwether v. Trustees of Shawnee State Univ. No. 1:18-cv-00758 (S.D. Ohio Apr. 14 2022) (press release available at https://adfmedia.org/case/meriwether-v-trustees-shawnee-state-university [university agreed to pay teacher $400000 plus attorneys' fees and agreed teacher has a right to choose when to use or avoid using titles or pronouns when referring to or addressing students, including when student requests preferred pronouns).] HHS should clarify that under its proposed regulations medical professionals retain free speech protections and it will not be considered discriminatory based on the sex to acknowledge a patient's biological sex or choose not to use a person's preferred pronouns based on gender identity. Further, HHS should clarify whether it would be discriminatory to use the word "woman" or say that "there are only males and females." It is unclear whether such statements would be deemed discriminatory and whether signs or statements about, for example, pregnancy, women would be permitted under the Proposed Rule. HHS should also clarify that its regulations do not prohibit talk therapy [sometimes mischaracterized as "conversion therapy"] as it relates to discussing issues of gender or sexuality with a patient.

Ethics & Public Policy Center

We support the requirement that covered entities develop and implement written policies and procedures to ensure compliance with this rule and that the procedural requirements apply across all covered nondiscrimination bases.

Eating Disorders Coalition for Research, Policy & Action

[Bold: Written Policies and Procedures.]It is finalized this proposed regulation will require covered entities to implement written Section 1557 policies and procedures. These policies and procedures must be reasonably designed to consider the size, complexity, and type of health programs and activities undertaken by the covered entity and include an effective date. The written policy must at minimum state that the covered entity in its health programs and activities does not unlawfully discriminate on the basis of race, color, national origin, [including limited English proficiency and primary language], sex [including pregnancy, sexual orientation, or gender identity, and sex characteristics], age, or disability, and provides language assistance services and appropriate auxiliary aids and services free of charge when necessary for compliance with Section 1557. In addition, if applicable, the policy document must include the contact information for the covered entity's Section 1557 compliance coordinator as well as address the entity's grievance and recordkeeping procedures, including how the entity will ensure that the grievance process is accessible to individuals with limited English proficiency. The preamble to the proposed rule indicates that HHS plans to publish sample policies online if this regulation is finalized. NAHU members strongly support this plan.

(b)(5) — National Association of Health Underwriters

[Bold: Policies and Procedures.] [§ 92.8] We support the requirement that covered entities develop and implement written policies and procedures to ensure compliance with this rule and that the procedural requirements apply across all covered nondiscrimination bases.

SIECUS: Sex Ed for Social Change

Policies and procedures [§ 92.8]We strongly support this provision which requires covered entities regardless of size to adopt Sec. 1557 policies and procedures.

Just Care In Aging

Covered entities to develop and implement written Sec. on 1557 anti-discrimination policies and procedures to give staff clear guidance on the provision of language assistance services for limited English proficient (LEP) individuals effective communication and reasonable modifications to policies and procedures for people with disabilities. HHS would require each covered entity in its health programs and activities to adopt and implement a written nondiscrimination policy, written language access procedures, written effective communications procedures, and written procedures for reasonable modifications to policies practices or procedures that allow individuals with disabilities equal opportunity to participate in their health programs and activities. Recommendation: BCBSA recommends HHS provide 12 months after the effective date of the rule for Plans to review and implement new policies and procedures. Rationale: While policies and procedures may still exist they may be outdated or no longer in effect and previously implemented policies and procedures would require modification to comply with the new requirements. Plans would need to identify previously implemented policies and procedures [which may be retired] review and compare these policies and procedures to requirements in the Proposed Rule and determine modifications necessary to comply with the new requirements. In Plans' experience 60 days is not a reasonable timeframe for implementation of these types of administrative changes.

(b)(5) — Blue Cross Blue Shield Association

develop and implement written language access procedures to provide meaningful access to LEP individuals. At a minimum language access procedures must include: contact information for the Section 1557 Coordinator; [if applicable] how an employee identified whether an individual is LEP how an employee able to the services of a qualified interpreters and translators names of any qualified bilingual or multilingual staff members and a list and the location of any electronic and written translated materials the covered entity has the languages they are translated into and the publication date Recommendation: BCBSA recommends HHS allow an issuer to identify the process and business rules they use to identify LEP individuals how they provide language services and how they create and store translation resources or translated materials. Rationale: It is proposed requirement seems designed for smaller businesses where translation or interpretation is ad hoc, rather than automated. A large insurer that translates all member facing materials into Spanish or even a smaller insurer that defaults to Spanish because of the population they serve would have an overwhelming amount of work cataloging every version of every communication. We recommend allowing the issuer the option of providing the business rules it uses to identify LEP individuals and ensure they receive appropriate interpretation or translation service vendors. For translated materials that would mean looking at how and where those materials are stored in the normal course of business rather than creating a duplicative process. Most issuers use a vendor for the purpose of translation and interpretation. It is not reasonable to assume the issuer will be able to track the staff the vendor relies on or assume that the vendor uses a staff model given the range of languages the vendor may need to support and how much the demand for any given language might vary. One large insurer provided interpretation services for 76 unique languages for 48 months starting in 2019. Twenty-eight percent of the languages requested were unique

Blue Cross Blue Shield Association

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|Bold: A. Section 1557 policies and procedures are a necessary step toward preventing discriminatory conduct. "Health care] The proposed rule notes that for patients with systemically marginalized identities trust in their health care providers would increase if these patients were aware of their rights and how they can address their concerns directly to their healthcare providers which would in turn improve these patients' overall health care experiences. However existing Section 1557 policies and procedures requirements are disjointed confusing and ineffective. We support changes to the proposed rule that would streamline these requirements by requiring covered entities to adopt and implement written nondiscrimination policies against all forms of discrimination including language and disability access procedures (collectively Section 1557 policies and procedures). "Footnote 12 Fed. Reg. at 47847. Proposed Sec. 92.8. The proposed rule also requires covered entities with 15 or more employees to adopt grievance procedures. | The revised Section 1557 policies and procedures aim to prevent discrimination from occurring in the first place by ensuring covered entities have greater knowledge of their obligations under Section 1557.

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The Leadership Conference on Civil and Human Rights

We likewise strongly support the proposed requirement that covered entities develop and implement written policies and procedures to ensure compliance with each of Section 1557's prohibited grounds of discrimination. To date many covered entities have failed to do so or have done so inconsistently.

InterACT: Advocates for Intersex Youth

Policies and Procedures (§ 92.8)We support the requirement that covered entities develop and implement written policies and procedures to ensure compliance with this rule and that the procedural requirements apply across all covered nondiscrimination bases.We note that the description of prohibited sex discrimination in this section differs from the language of section 92.101. While the differences are not extensive for the sake of clarity it would be preferable to use consistent language throughout the rule; the more expansive definition in 92.101 should be used.

Colorgy

The designation of requirements that 1557 coordinators be in place in all covered entities will also be of assistance to patients who are facing discriminatory practices. We urge CMS to include provisions that assure that patients know of the existence of 1557 coordinators and how to access them if they face discrimination. Too often in the middle of a problematic experience it is difficult for a patient to know the right course of action unless they are socialized to protections before the experience. Once again we encourage CMS to collaborate with patients to identify the most successful ways to educate people about this important resource.Finally the proposed rule includes a request about whether 1557 coordinators should be required in smaller businesses and we recommend that they are indeed included. No matter the size of the plan or provider people need redress when facing discriminatory

National Health Council

|Underlined: Required Section 1557 policies and procedures including mandatory training:] The proposed rule requires covered entities to establish and maintain a comprehensive set of written policies and procedures to facilitate and promote compliance with Section 1557. This includes an obligation to train all relevant employees of the covered entity on these policies and procedures. While CalHHS agrees with the intent and goals behind mandating this compliance framework and support training these requirements constitute a substantial implementation lift both on the front end and on a recurring basis. Accordingly CalHHS requests that states and covered entities be provided additional time to implement

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California Department of Health Care Services

No comments are associated with this issue.

|Bold: A. Section 1557 policies and procedures are a necessary step toward preventing discriminatory conduct. "Health care] The proposed rule notes that for patients with systemically marginalized identities trust in their health care providers would increase if these patients were aware of their rights and how they can address their concerns directly to their healthcare providers which would in turn improve these patients' overall health care experiences. However existing Section 1557 policies and procedures requirements are disjointed confusing and ineffective. We support changes to the proposed rule that would streamline these requirements by requiring covered entities to adopt and implement written nondiscrimination policies against all forms of discrimination including language and disability access procedures (collectively Section 1557 policies and procedures). "Footnote 12 Fed. Reg. at 47847. Proposed Sec. 92.8. The proposed rule also requires covered entities with 15 or more employees to adopt grievance procedures. | The revised Section 1557 policies and procedures aim to prevent discrimination from occurring in the first place by ensuring covered entities have greater knowledge of their obligations under Section 1557.

The Leadership Conference on Civil and Human Rights

|Bold: Grievance Procedures|The proposed rule also requires covered entities with 15 or more employees to develop and implement grievance procedures for employees and others that believe the covered entity has violated these proposed changes to the Section 1557 nondiscrimination rule. Given the cost and difficulties small businesses will have in developing and implementing such grievance procedures our recommendation is to raise this compliance threshold to exempt all businesses and industries classified as small businesses by the federal Small Business Administration. For smaller entities the federal Office of Civil Rights should be the enforcement entity not the small employer.

National Association of Health Underwriters

|Bold: Records Retention: We propose to require that covered entities retain records of filed discrimination grievances for at least three years. We support this requirement although we do not agree with a limit of three years on the retention of these records and suggest that OCR make retaining records permanent. With the adoption of electronic systems for retaining these records there is little burden on a covered entity in retaining them for a longer period. If an entity has received so many grievances that retention of more than three years' worth would be a burden it would raise concerning questions about why the entity has been unable to improve its level of service. Meanwhile when considering enforcement action or potential discovery in litigation those with an interest in an entity's history of complaints should have no less interest in having readily available records available beyond a three year period. A complaint filed five ten or more years ago may be of less relevance depending on the circumstances.

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National Immigration Law Center

|Bold and Underline: Policies and Procedures|HCSC proposes that covered entities with 15 or more employees establish written civil rights grievance procedures along with a record retention requirement for grievances filed against the covered entity. NACDS requests that OCR limit the grievance retention requirement to actionable Section 1557 claims. Unfortunately covered entities can receive complaints in which the complainant alleges a Section 1557 claim when in fact no Section 1557 claim exists. For example one covered entity reports that it receives employment relations concerns that complainants allege to be Section 1557 claims.

National Association of Chain Drug Stores

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requirement that covered entities implement written language access procedures ensuring compliance with Section 1557's nondiscrimination policies which must include the contact information for the 1557 coordinator the names of bilingual staff and a list of translated materials (which should be updated regularly) as well as processes for identifying LEP patients obtaining language access services. . We have heard from community members that medical staff will often express ignorance about how to obtain language access services when requested and the existence of such procedures will serve as an important resource in those circumstances.However we are concerned that the proposed rule does not require the procedures to include content expected in a language access plan. The proposed requirements focus on what is supposed to occur when someone with LEP comes into contact with the covered entity. However they do not appear to require any specific planning for identifying the likelihood of such an event and the types of communities who are likely to be served. These data points are typically the realm of a language access plan. For example one survey of community groups during the COVID-19 pandemic found that "more than 1/5 of respondents identified insufficient multilingual and culturally informed information/outreach (37%) as a top communications challenge throughout the pandemic." [Footnote 12 "Supporting Communities and Local Public Health Departments During COVID-19 and Beyond" Public Health Alliance of Southern California July 2022 https://2m.15a7emb87419.5dkww8g.wpengine.netdna-ssl.com/wp-content/uploads/2022/07/Public-Health-Alliance_Supporting-Communities-and-LHDs-Report-July-2022.pdf 13 Karliner Leah S. and Sarita Mutha. "Achieving Quality in Health Care Through Language Access Services: Lessons From a California Public Hospital." American Journal of Medical Quality Jan 2013 https://journals.sagepub.com/doi/abs/10.1177/1062860612451237] Developing a comprehensive language access plan can help a hospital for

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National Immigration Law Center

Access Plan" outlines several elements not mentioned in the proposed regulation such as a needs assessment how the entity will provide notice of the availability of language access services how staff will be trained and how staff will monitor and evaluate their policies [Footnote 14 "Guide to Developing a Language Access Plan" Centers for Medicare and Medicaid Services https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan-508.pdf] Similarly HHS's 2003 guidance for Title VI compliance recommended a plan should identify which individuals with LEP need language access and include processes for staff training and monitoring. [Footnote 15 "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons" U.S. Department of Health and Human Services August 4 2003 https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-vi/index.html]We do not want entities that have language access plans particularly plans developed in response to the 2016 rule to believe that the proposed rule's language access procedures supplants their existing and more robust process. OCR should also consider that some larger entities should also be required to adopt much more robust documentation than even a language access plan such as for hospitals the Agency for Healthcare Research and Quality's "Improving Patient Safety Systems for Patients With Limited English Proficiency" which calls for detailed plans for investigating disparities in medical errors and improving staff communication and understanding about how to use interpreters. [Footnote 16 "Improving Patient Safety Systems for Patients With Limited English Proficiency" Agency for Healthcare Research and Quality 2012 www.ahrq.gov/health-literacy/professional-training/longguide/index.html]We therefore recommend that OCR either amend §92.8(d) to include how the entity will plan for which populations are likely to be

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National Immigration Law Center

we recommend HHS require covered entities to develop a communications access plan that addresses the needs in their service area for language access and accessibility for individuals with disabilities [] tailed Communications Access Plan It is important for covered entities to plan in advance of what types of language services and communication supports it may need to provide by gathering data about the LEP population in its service area for example. This information is necessary to develop the effective "language access procedures" and "communications procedures" described in § 92.8 such as how to schedule an interpreter how to identify whether an individual has LEP etc. that the proposed rule requires. Managed care plans should be required to include in their plan how the providers in the network will access interpreter services and other communication supports.To support development of the plans and compliance with these provisions HHS can assist covered entities by providing a template plan that includes key questions the entity should answer about the language and communications related demographics of the service area target population and/or existing client base. HHS can also refer entities to resources for finding this information. For smaller entities and non-profit community based providers HHS should consider facilitating access to interpreter and translation services. For example HHS could contract with a language line and allow smaller entities to opt in to using that service which may help defray costs for an entity otherwise negotiating their own contract. HHS through its regional offices could also help connect providers with local community-based organizations who have qualified interpreters and can translate documents and provide other language services This approach would be especially beneficial for smaller language communities concentrated in particular geographic areas. Similarly the regional offices could connect covered entities with organizations and vendors who may be able to provide materials in plain language Braille or other alternative formats

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Justice in Aging

covered entities to develop and implement written Section 1557 anti-discrimination policies and procedures to give staff clear guidance on the provision of language assistance services for limited English proficient (LEP) individuals and effective communication and reasonable modifications to policies and procedures for people with disabilities. HHS would require each covered entity in its health programs and activities to adopt and implement: a written nondiscrimination policy; written language access procedures; written effective communications procedures; and written procedures for reasonable modifications to policies practices or procedures that allow individuals with disabilities equal opportunity to participate in their health programs and activities.Recommendation: BCBSA recommends HHS provide 12 months after the effective date of the rule for Plans to review and implement new policies and procedures.Rationale: While policies and procedures may still exist they may be redundant or no longer in effect and previously implemented policies and procedures would require modifications to comply with the new requirements. Plans would need to identify previously implemented policies and procedures which may be retired review and compare those policies and procedures to requirements in the Proposed Rule and determine modifications necessary to comply with the new requirements. In Plans' experience 60 days is not a reasonable timeframe for implementation of these types of administrative changes.

Blue Cross Blue Shield Association

Another missing element from the list of language access procedures is how staff will be determined to be qualified to provide interpretation services (if the entity has on-staff interpreters) or how staff will be determined to be capable of providing services in languages other than English and discussions with community members and those in the health provider field there is no uniform process for conducting such assessments. Some entities require their staff interpreters to be certified medical interpreters while others have no assessment process at all. The latter appears to be particularly common when it comes to health care providers who claim to be bilingual. Equating a statement that may be taken at face value even if the provider did not receive medical training in the related languages Because of the complexity of medical care even growing up bilingual does not necessarily mean a doctor should treat a patient with LEP when a certified medical interpreter may have more specialized knowledge of technical terminology in the language Because health outcomes are improved when patients receive care in their preferred language it is important that OCR address opportunities for additional multilingual training and certification through this regulation. [Footnote 17 Diamond Lisa et al. "A Systematic Review of the Impact of Patient-Physician Non-English Language Concordance on Quality of Care and Outcomes." Journal of general internal medicine vol. 34,8 (2019) https://pubmed.ncbi.nlm.nih.gov/31147980/" Seijo Rosa et al. "Language as a Communication Barrier in Medical Care for Hispanic Patients." Hispanic Journal of Behavioral Sciences November 1991 https://doi.org/10.1177/07399863910134001]

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National Immigration Law Center

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We also recommend HHS provide guidance on other language access measures such as effective phone trees that allow callers to access an interpreter immediately with minimal English-only instructions. As much as possible phone trees should provide "language instructions for connecting to an interpreter (i.e. a translation of "press # for [language]" in the top languages in their service area. We also recommend that HHS work to develop standard best practices for phone trees and help provide public education. Such as to how pressing "3" is widely known and used to reach an operator or agent pressing another specific digit could become standard for connecting to an interpreter. Finally we recommend HHS work with the Department of Education and other agencies to invest in medical interpreter training for small or rare language communities that may not have qualified interpreters nor access to training in their language. For example there are over 20 indigenous language communities in the Los Angeles area. [Footnote 8: CHLLA UCLA A&A UCLA Promise Inst. for Human Rights ULLA Bunche Ctr. We are Here: Indigenous Diaspora in Los Angeles (Jan. 2024) https://storymaps.arcgis.com/stories/618566fa29f2a4d2faa2f3dd3bedb669] Investing directly in these communities would yield not only language services for people who might otherwise not have access but also higher quality health care because of the additional benefits of cultural competency native language speakers bring.

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develop and implement written language access procedures to provide meaningful access to LEP individuals. At a minimum language access procedures must include contact information for the Section 1557 Coordinator; [if applicable] how an employee identifies whether an individual is LEP; how an employee obtains the services of qualified interpreters and translators; names of any qualified bilingual or multilingual staff members and a list and the location of any electronic and written translated materials the covered entity has the languages they are translated into and the publication date. Recommendation: BCBSA recommends HHS allow an issuer to identify the process and business rules it uses to identify LEP individuals how they provide language access and how they create and store translation resources or translated materials. Rationale: This proposed requirement seems designed for smaller businesses where translator or interpretation is ad hoc rather than automated. A larger insurer that translates all member facing materials into Spanish or even a smaller insurer that defaults to Spanish because of the population they serve would have an overwhelming amount of work take on by every version of every communication. We recommend allowing the issuer the option of providing the business rules it uses to identify LEP individuals and ensure they receive appropriate interpretation or translation services vendors. For translated materials that would mean disclosing at how and where those materials are stored in the normal course of business rather than creating a duplicative process.Most issuers use a vendor for the purpose of translation and interpretation. It is not reasonable to assume the issuer will be able to track the staff the vendor relies on or assume that the vendor uses a staff model given the range of languages the vendor may need to support and how much the demand for a given language might vary. One large insurer provided interpretation services for 76 unique languages for 43 months starting in 2019. Twenty eight percent of the languages requested were unique

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Lisa Coleman Aging

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Blue Cross Blue Shield Association

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UnitedHealthcare

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Genesee County Legal Aid Society dba Center for Civil Justice

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Blue Cross Blue Shield Association

covered entities to develop and implement written Section 1557 anti-discrimination policies and procedures to give staff clear guidance on the provision of language assistance services for limited English proficient (LEP) individuals and effective communication and reasonable modifications to policies and procedures for people with disabilities. HHS would require each covered entity in its health programs and activities to adopt and implement: a written nondiscrimination policy; written language access procedures; written effective communications procedures; and written procedures for reasonable modifications to policies practices or procedures that allow individuals with disabilities equal opportunity to participate in their health programs and activities. Recommendation: BLBSA recommends HHS provide 12 months after the effective date of the rule for Plans to review and implement new policies and procedures. Rationale: While policies and procedures may exist they may be outdated or no longer in effect and previously implemented policies and procedures would require modification to comply with the new requirements. Plans would need to identify previously implemented policies and procedures [which may be retired] review and compare those policies and procedures to requirements in the Proposed Rule and determine modifications necessary to comply with the new requirements. In Plans' experience 60 days is not a reasonable timeframe for implementation of these types of administrative changes.	(b)(5)	Blue Cross Blue Shield Association
The proposed rule requires covered entities to proactively ensure patients with disabilities are provided with reasonable accommodations. For example the department clarifies that a covered entity must provide modifications in the absence of a request when it had knowledge of an individual's disability or when the individual's inability is obvious. [Footnote 7: Fed. Reg. at 47,850.' Policies and Procedures: The Association believes that the requirement in § 92.8 to develop and implement written Policies and Procedures would be overly burdensome for dental offices. The Department should continue the previous rulemaking's flexibilities to allow covered entities to develop these policies and procedures voluntarily based on the dental office's needs (as well as their patients' needs).		The Leadership Conference on Civil and Human Rights
No comments are associated with this issue		American Dental Association
1. Bring in the voices and experiences of people with disabilities to include in new and ongoing staff training. People with lived experience of disability experience unique health disparities and biases when receiving health care. In order to achieve effective communication and reduce these biases staff need to hear directly from people with disabilities to fully grasp the subject matter and gain understanding and familiarity. Utilize first-hand experiences of people with lived experience of disability to advance knowledge of staff		The Arc of Pennsylvania
The direct attention to nondiscrimination on the basis of sex limited English proficient (LEP) individuals and people with disabilities and the clarification of the specific measures that are anticipated to comply with Section 1557 are welcome. Specifically we support the major clarifications in the rule: • The interpretation of Section 1557 to cover all health programs and activities administered by HHS. • The interpretation that provision of Medicare Part B assistance is federal financial assistance and that entities receiving Medicare Part B funds must comply with the Rule. • The application to health insurance issuers that receive federal financial assistance. • The clarification that the protections against discrimination on the basis of sex as including sexual orientation and gender identity and discrimination on the basis of sex stereotypes and the extension of these protections to CMS regulations. • The expectation that compliance will require implementing programs to develop maintain and communicate clear policies and train on the provision of language assistance services for limited English proficient (LEP) individuals and effective communication and reasonable modifications to policies and procedures for people with disabilities. • The requirement that implementing entities provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states. • The expectation of nondiscrimination based on clinical algorithms. • The expectation that nondiscrimination extends to telehealth services and. • The development of clear processes for requesting exceptions from the expectation of compliance. As with guidelines like the CLAS Standards enforceable mechanisms that promote health equity and actively reduce discrimination require change from top to bottom. Implementation of said nondiscrimination policies must be paired with education of staff including providers and administrators with cultural considerations and wherever possible engagement with local multicultural communities adjacent to the covered entities		The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)
Training (§ 92.8)We support OCR's proposal to require covered entities to train their staff on the policies and procedures that would be required by the regulation. No number of internal policies can help people avoid discrimination if staff do not know or do not follow the rules. Implementing trainings should not just entail the policies and procedures are but also why they fit the mission of the entity to encourage better compliance. A front desk staffer encountering a person with LEP should understand that providing them with an interpreter helps improve patient health outcomes rather than seeing it as an abstract. We appreciate the note in the narrative that "the more thoroughly a covered entity trains its staff on its Section 1557 Policies and Procedures the more likely it is that the covered entity will successfully provide services to individuals in a nondiscriminatory manner" and encourage OCR to continue to remind covered entities of this fact through guidance and other resources.		Alliance of Multicultural Physicians
		National Immigration Law Center
[Board: 1557 Coordinator Policies and Procedures Training] DRM strongly supports the proposed rule's requirement for covered entities to appoint a designated Section 1557 coordinator establish clear civil rights policies and procedures and train public-facing and other relevant employees on these procedures. Experience teaches us that these work to elevate the knowledge and awareness of people within covered entities. Individual patient complaints should not be the primary means of enforcement. Coverage entities have a responsibility to know provide notice of and acknowledge the rights of individuals. Requiring a designated Section 1557 coordinator is similar to a provision in the Americans with Disabilities Act (ADA) requiring a designated ADA/504 coordinator. The ADA also requires that entities covered by the ADA have a grievances process so individuals can report violations to the covered entity. DRM has successfully that process on several different occasions. DRM suggests that coverage entities have their own grievance process similar to the ADA grievance process		National Immigration Law Center
[Board: Addressing Bias and Discrimination Through Better Training] To support providers in adhering to nondiscrimination requirements CMS should support better education/training and resources for providers most of whom receive little exposure to IDD. [Hyperlink: Medical students, https://www.ie-care.org/ASC3] receive an average of 11 minutes of exposure to IDD and there is no developmental medicine specialty for adult care of patients. According [Hyperlink to a recent study; https://labablog.ucdmchealth.org/ired.w/teaching-medical students-how-to-care-for-people-disabilities] more than 75 percent of first-year medical students were more comfortable interacting with patients with disabilities after finishing training or disabilities.	(b)(5)	Disability Rights Maine
		Institute for Exceptional Care

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2) HHS must provide support and resources to covered entities to ensure consistency in full ng language assistance training provided and nutile requirements. HHS is proposing to require covered entities provide notices of none scrimination and availability of language assistance services and other services to patients especially those with limited English proficiency (LEP). The agency also is proposing that covered entities have in place policies and procedures that support compliance with Section 1557 and train staff accordingly. AMA supports these proposed requirements and the goal of creating consistent procedural requirements for covered entities. However AMA is concerned that not all covered entities have the resources and staff support to ensure compliance with these requirements. We urge HHS to provide guidance templates and other resources to ensure some level of uniformity in the policy procedure and notice requirements—in plain language. This allows fulfillment of the requirements across covered entities removing potential confusion for patients as they navigate between entities. Furthermore many covered entities are experiencing workforce challenges that may limit their ability to devote the necessary staff time to come into compliance with the proposed requirements. To mitigate this we urge HHS to provide support to covered entities to appropriately customize and institute the policies and procedures and the necessary staff training. By providing this HHS can ensure consistency and fulfillment of the compliance training and patient education requirements in the above-captioned proposed rule. [Bold As such AMA urges HHS to provide support and resources with notice training and other procedural requirements to guarantee consistency in compliance with Section 1557 across covered entities]

The Proposed Rule requires that covered entities implement policies and procedures to ensure compliance with Section 1557 and to provide training to staff interacting with patients. As part of those requirements and specifically for telehealth the provisions should require covered entities to establish internal processes for communicating with patients before during and after telehealth visits. This will allow for effective communication and continuity of care for patients who have challenges accessing follow up or in person care. For example HHS could require development of pre appointment screening and communication modalities to ensure necessary equipment or technology for the appointment or to determine whether the patient has the requisite technological skills for participation. Provisions might also include planning and development of training resources for patients who lack such skills or familiarity with telehealth prior to the appointment. As in communication by the provider for follow up care whether for subsequent telehealth visits referrals or for in-person care should occur in a timely manner to ensure continuity of care

Bold and Underline: Training (§ 92.8)[JNACDS urges OCR to reconsider the training requirement under proposed Section 92.8. Covered entities often have contractual requirements for cultural competency training such as through contracts with health insurers and have not found that the training makes a discernible impact on Section 1557 complaints or compliance. However should OCR decide to move forward with the training requirement then OCR should allow the Section 1557 training to be incorporated with other employee training and not be a standalone training requirement. Moreover covered entities should be allowed to determine the elements of the training program to best fit their operations, the specific training requirements should not be prescribed unless the covered entity needs to enter into a corrective action plan

The proposed rule requires a Sec. 1557 coordinator who has the ultimate responsibility and authority to ensure that people with disabilities receive their rights along with the requirement for establishing civil rights policies procedures and staff training will go far toward achieving a true merger of medical and public health regulations with civil rights regulations. While smaller entities cannot be expected to have the same financial human and infrastructure resources as large healthcare systems and that consideration is already built into consideration in this section it is to their own benefit to have an internal source of information on these matters and to establish clear policies and procedures rather than rely on the discretion of individual public-facing employees some of whom may be newly employed given high unemployment numbers. We strongly recommend that smaller health care entities with less than 15 employees be subject to proposed §§ 92.7 92.8 and 92.9 since they are still obligated to comply with Section 1557's none scrimination mandate and need to have written policies for patients requesting reasonable modifications and receiving civil rights grievances. All sizes of entities should have full access to the technical assistance materials that HHS OCR will develop and the tools to promote civil rights adherence within their own practices. Being a smaller entity is not a license to ignore and violate civil and human rights

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American Nurses Association

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Attorneys General of California, New York Massachusetts, and nineteen other States

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National Association of Chain Drug Stores

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Disability Rights Maine

TrainingThe ADA is concerned about the new training requirement in § 92.9. We appreciate the Department's efforts to reduce the burden of this requirement by applying it to only relevant staff and to only the covered entity's Policies and Procedures. However the lack of specificity on the training requirements including their content and length) could be confusing to dental offices who are trying to implement the requirements. Additionally requiring documentation of the training would impose more paperwork requirements on the dental offices.

American Dental Association

Pennie likewise supports the provisions requiring covered entities to train their employees on the section 1557 requirements. Although the proposed rule states that HHS is not prescribing a specific training program Pennie requests that HHS provide sample section 1557 training materials to ensure consistency in employee training across covered entities. Entities—such as Pennie—after use federally designed training in designing and creating their own internal training programs and materials. Creating new training programs and materials takes time and resources to develop which can be limited for many exchanges. A model training program provided by HHS on the requirements set forth in the Final rule will enable Pennie and entities like it to train staff to the highest standards in a timely and resource efficient manner.

Pennsylvania Health Insurance Exchange Authority d/b/a Pennie

The Health Connector supports the proposed requirement for covered entities to establish certain nondiscrimination policies and procedures and to train certain employees. Health Connector staff and residents of the Commonwealth would benefit from OCR's proposal to require covered entities to write and implement certain nondiscrimination policies and procedures. Ensuring clear guidance and training on nondiscrimination policies and procedures will strengthen staff understanding of such policies and procedures and further support access to health coverage and care for members and applicants.

Massachusetts Health Connector

We strongly support the provisions requiring covered entities to adopt Sec. 1557 policies and procedures and to ensure their employees are trained on them. We agree with HHS that both employees in "public contact" positions and those who make decisions about these policies and procedures should receive training so they understand the requirements of Sec. 1557.

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We strongly support the new proposed requirement that covered entities train their employees on their Sec. 1557 policies and procedures. We agree with HHS that both employees in "public contact" positions and those who make decisions about these policies and procedures should receive training so they understand the requirements of Sec. 1557. We recommend that HHS should clarify in the final rule that relevant individuals includes temporary staff who are interacting with the public or clients. This is especially important in IT/BS settings where that staff person may be the only person interacting with an individual [Footnote 4 See discussion of nursing facility guidance for surveyors in transmittal memo in the access.]

Center for Elder Law & Justice

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Justice in Aging

(b)(5)

A. Training Requirements (§ 92.9): HHS proposes to require covered entities to train relevant employees in their health programs and activities on their Section 1557 Policies and Procedures as soon as practicable but no later than one year after the effective date of the Final Rule and to train new relevant employees within a reasonable period of time after they join a covered entity's workforce. Also HHS would require training for relevant employees whose roles are affected by material changes to the covered entity's Section 1557 Policies and Procedures. This includes documentation requirements for such training.Recommendation: BCBSA recommends providing covered entities with 18 months to implement the new training requirements.Rationale: An 18 month implementation period would provide covered entities with the time necessary to establish policies and procedures and then develop training materials to communicate those policies and procedures. In addition, an 18-month period affords covered entities the flexibility to incorporate the new training requirements into their existing annual compliance training cycles.

Blue Cross Blue Shield Association

Section 92.9 – Training]We support the provision that requires training on civil rights policies and procedures for all relevant employees. We note that the preamble to the 2022 proposed rule includes a definition of "relevant employees" asserting that HHS anticipates that relevant health program and activity staff will include those involved in client and patient interactions as well as those involved with drafting, approving and training policies and procedures for compliance with this part. [Footnote 8: 87 Fed. Reg. 47850.]We agree it is critical that not only individuals in "public contact" positions understand civil rights policies and procedures, but also that those who make decisions about these policies and procedures understand the requirements of Section 1557. We believe the above definition reflects that and suggest that HHS should include this definition either here or in the definitions in § 92.4.

National Disability Rights Network

Underlined: Require Section 1557 policies and procedures including mandatory training | The proposed rule requires covered entities to establish and maintain a comprehensive set of written policies and procedures to facilitate and promote compliance with Section 1557. This includes an obligation for the covered entity's all relevant employees of the covered entity on these policies and procedures. While CalHHS agrees with the intent and goals behind mandating this compliance framework and supports training these requirements constitute a substantial implementation lift both for the front-end and on a recurring basis. Accordingly, CalHHS requests that states and covered entities be provided additional time to implement.

California Department of Health Care Services

The report describing the proposed rule also acknowledges limited access due to websites and portals often failing to include non-English language instructions. A lack of translation of basic vital documents is an additional barrier. Discharge summaries are a prime example. [Footnote 8: L. Malevanchik, M. Wheeler, K. Gagliano, L. Karliner, and S. J. Shah, "Disparities After Discharge: The Association of Limited English Proficiency and Postdischarge Patient-Reported Issues," Jt. Comm. J. Qual. Patient Saf., vol. 47, no. 12, pp. 775–782, Dec. 2021, doi: 10.1016/j.jcjq.2021.08.013.] Where vital information on diagnosis, health plans, medicine follow-up care are essential for patient participation and adherence directly impacting health outcomes and disparities. This happens thousands of times a day across America. Often only short or headlines are translated [e.g. Call limited ability if this symptom occurs] without essential content [i.e. the specific sign or symptom].

(b)(5)

No comments are associated with this issue.

We recommend that the required training go beyond the organization's policies and procedures and include best practices and ethical obligations in working with interpreters. This training would respond to community concerns that providers do not understand their ethical obligation to translate the entire conversation with a patient rather than just portions of it. A robust training requirement would also include training in cultural competence, including for example how speakers of the same language from different regions may use different terminology. Training should also address responses stigma felt by people with LEP who may be reluctant to request an interpreter out of concern of being a burden or problem for the provider.

National Immigration Law Center

Compliance burdens resulting from the proposed 1557 compliance requirements will overwhelm providers' offices, particularly small practices and solo practitioners that HHS seeks additional comment on. Specifically, we are concerned about the resources needed to write and implement Section 1557–specific policies and procedures, identify a Section 1557 Compliance Coordinator and train practice employees on new nondiscrimination standards. Pediatric physicians, like other physician specialties, are increasingly underresourced for the patient care they provide, particularly when compared to other types of health care providers and Medicare Advantage plans. Medicare payments to physicians have failed to keep up with inflation, which has recently hit record highs, and with the passage of the Medicare Access and CHIP Reauthorization Act of 2015 no longer incorporate inflation as a factor for determining annual payment updates. As a result of this and other structural challenges with the Medicare Physician Fee Schedule, Medicare payment rates are scheduled for a third straight year of payment reductions in 2023. Moreover, providers already face significant administrative burdens due to federal and state regulations and payer contract requirements, for example related to audits and medical record reviews, prior authorizations, and quality reporting requirements. These requirements consume clinical and administrative staff time and attention and limit practices' ability to focus on delivering high-quality care. Pairing this already overwhelming administrative burden with these strong funding constraints and healthcare workforce challenges (which impair physicians' ability to simply hire additional staff to manage more) providers are already struggling and cannot afford another unfunded mandate in the current environment. Given the above, APMA asks that HHS not finalize policies that would add to providers' administrative burden. If HHS chooses to finalize the rule with no changes, APMA asks that it strive to minimize the burdens created by developing and making available free-of-charge

(b)(5)

American Podiatric Medical Association

will be created as a result of the proposed requirements for physicians' offices related to Section 1557 compliance. Specifically we are concerned about the resources needed to write and implement Section 1557–specific policies and procedures, identify a Section 1557 Compliance Coordinator and train practice employees on new nondiscrimination standards. Rheumatology practices are grossly underresourced for the patient care they provide, particularly when compared to other types of health care providers and Medicare Advantage plans. Since the inception of the resource based relative value scale, the Medicare Physician Fee Schedule (PFS) conversion factor has remained consistently flat. And with passage of the Medicare Access and CHIP Reauthorization Act of 2015, physician payments no longer incorporate inflation, which has reached record levels in recent months. In addition to unstable Medicare payments, rheumatology practices face increasing administrative burdens primarily associated with utilization management such as prior authorizations, step therapy and other actions which divert clinical and administrative staff away from direct patient care and related activities. This is on top of the punitive quality reporting and program integrity audits. Simply stated, our practices cannot afford another unfunded mandate in the current environment. As such we ask the Department not to create additional administrative burdens on already overburdened physicians' offices. If the Department finalizes these requirements despite this concern then, at a minimum, [italic bold] we seek your assistance in helping rheumatology practices with compliance. Specifically we request that HHS develop and make available free of charge to the following: • Template Section 1557 policies and procedures that rheumatology offices can incorporate into their existing compliance manuals as-is; • Section 1557 educational materials and training resources including materials that would help practices test their employee understanding of the new requirements and how to comply; and • Patient

Coalition of State Rheumatology Organizations (CSRO)

However we are deeply concerned with the [redacted] proposed requirement that providers including physicians must write and implement Section 1557–specific policies and procedures identify a Section 1557 Compliance Coordinator and train their employees on these new standards.Physicians' offices are overwhelmed by administrative tasks that stem from a multitude of federal regulators and requirements including quality reporting utilization management and medical review/audits. Indeed many allergy/immunology (A/I) practices are small and have limited administrative and clinical staff that can be diverted from patient care activities to manage yet another compliance program. Considering the year-over-year reductions in payments to Medicare physicians coupled with significant and extreme workforce challenges we are frustrated that the Department is proposing this unfunded mandate on physician offices. And while we support the intent of this new policy our practices simply lack the financial and staffing resources to properly comply.Should the Department proceed with finalizing this proposal HHS must develop templates Section 1557 policies and procedures and compliance guidance that physician offices can easily incorporate into their existing compliance materials. HHS should also develop educational materials that assist practices with training activities and with testing staff understanding of the policies. HHS should develop patient notices and other patient education materials for practices. These resources should be downloadable from the HHS website and made available free-of-charge.

[redacted]

Regarding any enforcement action resulting from a Section 1557 complaint we would start with enhanced education and the provision of technical assistance so providers can come into compliance without sanctions or penalties.

https://arinegamblingbot.com/

We strongly support the notice requirements in section 92.10 and the Department's attempt to strike a balance so that covered entities are not overly burdensome but that program participants and beneficiaries are aware of their rights

Notice Requirements and Enforcement It is important that the implementation and enforcement of the § 1557 be comprehensive enough to meet the intended goals of minimal or no requirements of the ACA. Our organizations strongly support the requirements related to notice of nondiscrimination enforcement and procedures. We offer recommendations to enhance the scope of the nondiscrimination protections.Notice of Nondiscrimination We strongly support the requirements related to the notice of nondiscrimination. When the notice of nondiscrimination was removed by prior rulemaking many individuals never received information about their rights, did not know how to access interpreters auxiliary aids and services; and did not know how to file a complaint or a grievance.We ask that HHS include in the notice requirement that any entity claiming a religious exemption under proposed section 92.302 include the existence and scope of such exemption in its required notices. It would be misleading and inaccurate to require entities to their participants and beneficiaries and the public generally that the entity does not discriminate if the entity does in fact discriminate in certain circumstances and has been granted permission to do so.

We note that the description of prohibited sex discrimination in this section differs from the language of section 92.101. While the differences are not [redacted] for the sake of clarity it would be preferable to use consistent language throughout the rule; the more expansive definition in 92.101 should be used

Notice of Nondiscrimination (§ 92.10)| We strongly support the notice requirements in section 92.10 and the Department's attempt to strike a balance so that covered entities are not overly burdensome but that program participants and beneficiaries are aware of their rights.We note that the description of prohibited sex discrimination in this section differs from the language of section 92.101. While the differences are not extensive for the sake of clarity it would be preferable to use consistent language throughout the rule; the more expansive definition in 92.101 should be used

The proposed rule facilitates access to health care services for people with disabilities.We are pleased that the proposed rule creates standards that seek to create equity in quality of care for all patients including those with disabilities who often experience stigma bias and discrimination in the health care system that adversely affects their ability to access needed care and can lead to missed delayed or inaccurate diagnosis and treatment sometimes with deadly consequences. [Footnote 1] [redacted] National Council on Disability Enforceable Accessible Medical Equipment Standards: A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities (May 20 2021).] The proposed rule ensures that those with disabilities—including mobility impairments—are not excluded from competent care based on a facility's physical design ensures that people are informed of the accommodations available to them and requires that covered entities provide auxiliary aids for those with sensory mental or auditory disabilities

We ask that HHS include in the notice requirement that any entity claiming a religious exemption under proposed section 92.302 include the existence and scope of such exemption in its required notices. It would be misleading and inaccurate to require entities to their participants and beneficiaries and the public generally that the entity does not discriminate if the entity does in fact discriminate in certain circumstances and has been granted permission to do so

[redacted]

require each covered entity to provide a notice of nondiscrimination relating to its health programs and activities annually and upon request to participants beneficiaries enrollees and applicants of its health programs and activities as well as members of the public. Notice can be provided through written translations in language recorded audio or video clips.Recommendations: • BCBSA supports the requirement to provide the notice of nondiscrimination annually and upon request. We recommend that HHS clarify that plans may comply with the requirement by including the notice with other routine annual mailings. • While the proposed rule identifies certain notices with which the nondiscrimination notice may be combined BCBSA recommends that this list of notices should be expanded further to include individual and group health plan documents that are annually distributed to enrollees and other annual notices that issuers are required to send (e.g. Part D credentiable Coverage Child Women's Health and Cancer Rights Act (WHCRA)). • BCBSA recommends that the final rule clarify that the notice of nondiscrimination may be provided in English if it is accompanied by the notice of availability of language assistance services. • BCBSA recommends that Medicare Advantage and Part D plans be deemed compliant if they meet standards set forth in 42 CFR §§ 422.2267(e) and 423.2267(e) as promulgated in the Contract Year 2023 Policy and Technical Changes Final Rule (CMS–4192–F; CMS–1744–F and CMS–5401–F) published in the Federal Register on May 9 2022 This would reduce the use of the CMS model NOI. We strongly encourage maximum possible consistency so that the same language/tagline could be used for both MA/Part D and the commercial business. • BCBSA recommends HHS provide the flexibility for electronic access or delivery such as website links QR codes emails or texts for enrollees to post in to a digital channels.Rationale Currently in the commercial market requiring the notice of nondiscrimination to be sent annually would increase costs significantly. • CCA strongly supports the requirements related to providing notice of nondiscrimination. Notifying individuals of their rights is fundamental to successful implementation of any civil rights law including Sec. 1557. After the 2020 rule removing eliminated this provision individuals receiving health care and long-term services and supports (LTSS) were no longer made aware of their rights under 1557. This has been especially detrimental to older adults with LEP who do not know that they have a right to an interpreter or how to access other language access services and to people with disabilities who may not have the information they need to access necessary auxiliary aids and services. In addition without this notice people who experience discrimination may not know that they can file a complaint or a grievance or how to do so

[redacted]

[redacted]

[redacted]

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2) HHS must provide support and resources to covered entities to ensure consistency in full ng language assistance train ng provide and notice requirements. HHS is propos ng to require covered entities provide notices of nond scr mination and availabi ty of language assistance services and other services to patients especially those with mited English proficiency (LEP). The agency also s proposing that covered e nti es have in place polic es and procedures that support compliance with Section 1557 and train staff accordingly. AMA supports these proposed requirements and the goal of creating consistent procedural requirements for covered entities. However AMA is concerned that not all covered entities have the resources and staff support to ensure compliance with these requirements. We urge HHS to provide guidance templates and other resources to ensure some level of uniformity in the policy procedure and notice requirements— n plain language. This allows fulfillment of the requirements across covered entities removing potential confusion for patients as they navigate between entities. Fu rther many covered entities are experiencing workforce challenges that may limit their ability to devote the necessary staff time to come into compliance with the proposed requirements. To mitigate this we urge HHS to provide support to covered entities to appropriately communicate and implement the policies and procedures and the necessary staff training. By providing this HHS can ensure consistency and full ment of the compliance training and patient education requirements in the above-captioned proposed rule. [Bold. As such AMA urges HHS to provide support and resources with notice training and other procedural requirements to guarantee consistency in compliance with Section 1557 across covered entities]

We support the restoration of a notice of nondiscrimination under the proposed rule. In the experience of our community partners many immigrants are unaware of their language access rights. Even when they are verbally informed many immigrants are reluctant to seek language access services without written confirmation from the covered entity itself. A notice stating the availability of written and oral language access services is also an important tool for community advocates working with people with LEP to use in encouraging them to affirmatively request services.

[Bold. Patient Notification and 1557 Coordination:] After the changes in the 2020 rule patients were not required to receive information about their rights under 1557. The restoration of requirements that inform about 1557 protections be made widely available and posted publicly will help patients understand their rights and act when those rights are violated. This critical information is of vital importance to patients. We strongly support this provision and the requirements for when this notice must be made available.

-Reinstating notice requirements on covered entities to inform the public beneficiaries and potential participants of nondiscrimination policies and avenues for redress, in particular CMS appreciates the flexibility to combine the content of this Section 1557 notice with other federally mandated notices relating to nondiscrimination and civil rights as proposed in Section 92.10(e).

Additionally we applaud the expanded notice of nondiscrimination and language access requirements included in the proposed rule that would require covered entities to provide a notice of nondiscrimination to participants beneficiaries enrollees and applicants of its health programs and activities as well as members of the general public. This transparency and consumer education element of the proposed rule will help to ensure that providers are held accountable to the provisions of Section 1557 while ensuring that all individuals know they are protected from discrimination under federal law.

In the preamble HHS notes that although it does not propose restoring the 2016 Final Rule language the protections still apply because of the underlying Title IX regulations. We agree that the Title IX definition applies but given the pervasive nature of discrimination related to termination of pregnancy particularly post-Dobbs we urge HHS to specifically include termination of pregnancy in this definition. Additionally HHS does not define sex discrimination consistent with the proposed rule; it notes that sex discrimination includes "pregnancy or related conditions" at § 92.101(a)(2) but only "pregnancy" under § 92.101 and § 92.10. We urge HHS to be consistent throughout the final rule.

Notice of Nondiscrimination [§ 92.10]We strongly support the notice requirements in section 92.10 and the Department's attempt to strike a balance so that covered entities are not overly burdened but that program participants and beneficiaries are aware of their rights. We note that the description of prohibited sex discrimination in this section differs from the language of section 92.101. While the differences are not extensive it would be preferable to use consistent language throughout the rule; the more expansive definition in 92.101 should be used for a variety of reasons including those relative to the interests community [as noted above]. We ask that HHS include in the notice requirement that any entity receiving a religious exemption under proposed section 92.302 include the existence and scope of such exemption in its required notices. It would be misleading and inaccurate to require entities to let participants beneficiaries and the public generally that the entity does not discriminate if the entity does in fact discriminate in certain circumstances and has been granted permission to do so.

[Bold: Notice] Notice is an essential part of due process. DRM supports the proposed rule's balanced response on notice requirements for Section 1557. Proposed § 92.10 requires covered entities to provide recurring annual notice of Section 1557 rights to people who currently participate in healthcare programs people who apply to those programs and members of the public.

Notice of Nondiscrimination [§ 92.10]We strongly support the notice requirements in section 92.10 and the Department's attempt to strike a balance so that covered entities are not overly burdened but that program participants and beneficiaries are aware of their rights. We note that the description of prohibited sex discrimination in this section differs from the language of section 92.101. While the differences are not extensive for the sake of clarity it would be preferable to use consistent language throughout the rule, the more expansive definition in 92.101 should be used.

Notice of Nondiscrimination[CC] Supports the requirements for providing a notice of nondiscrimination to beneficiaries participants enrollees and applicants and to members of the public.

We strongly support the requirements related to providing notice of nondiscrimination. Notifying individuals of their rights is fundamental to successful implementation of any civil rights law including Sec. 1557. After the 2019 rulemaking eliminated this provision individuals receiving health care and long-term services and supports (LTSS) were no longer made aware of their rights under Sec. 1557. This has been especially harmful to LEP older adults who do not know that they have a right to an interpreter or how to access other language access services and to people with disabilities who may not have the information they need to access necessary auxiliary aids and services. In addition without this notice people who experience discrimination may not know that they can file a complaint or even venue or how to do so. Providing notices of nondiscrimination has helped people know and understand their rights. For example even providing a sentence in LEP individuals' language has presented an opportunity for them to enforce their rights against discrimination.

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(b)(5) American Nurses Association

National Immigration Law Center

National Health Council

California Department of Health Care Services

(b)(5) AARP

American Psychological Association

Equitas Health

Disability Rights Maine

(b)(5) Color

Genesee County Legal Aid Society dba Center for Civil Justice

Center for Elder Law & Justice

raises First Amendment concerns. [Proposed § 92.8 requires training on the proposed nondiscrimination regulations while proposed § 92.10 requires notices of nondiscrimination. Both requirements could raise concerns under the First Amendment. The Sixth Circuit recently found that a teacher who was disciplined for not using a student's preferred title and pronouns was able to claim protection under the First Amendment. [Footnote 253: Meriwether v. Hartop, 992 F.3d 492 (6th Cir. 2021) (reversing dismissal of First Amendment free speech and free exercise claims by professor disciplined by university for not following university's gender identity nondiscrimination policy when he refused to address transgender identifying student by student's preferred title and pronouns and instead used only student's last name); see also Voluntarily dismissed sub nom. Meriwether v. Trustees of Shawnee State Univ., No. 1:18-cv-00753, [S.D. Ohio Apr. 14, 2021) (press release available at: https://adfmedia.org/case/meriwether-v-trustees-shawnee-state-university) (university agreed to pay teacher $400,000 plus attorneys' fees and agreed teacher has a right to choose when to use or avoid using honorifics or pronouns when referring to or addressing students, including when student requests preferred pronouns)]. HHS should clarify that under its proposed regulations medical professionals retain free speech protections and it will not be considered a discriminatory action based on the ability to acknowledge a patient's biological sex or choose not to use a person's preferred pronouns based on gender identity. Further, HHS should clarify whether it would be discriminatory to use the word "woman" or say that "there are only males and females." It is unclear whether such statements would be deemed discriminatory and whether signs or statements about for example pregnancy women would be permitted under the Proposed Rule. HHS should also clarify that its regulations do not prohibit talk therapy (sometimes mischaracterized as "conversion therapy") as it relates to discussing issues of gender or sexuality with a patient.

Bold and Italics: Notice of Nondiscrimination (§ 92.10) and Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (§ 92.11)

Bold: The AAMC supports proposals to reinstate and expand requirements that covered entities provide notices about and ensure access to nondiscrimination rights and language assistance services for individuals with limited English proficiency and auxiliary aids and services for individuals with disabilities. We opposed the repeal of the nondiscrimination notice and tagline requirements under the 2019 proposed rulemaking out of concern that it would impede access to critical language assistance services for millions of limited English proficiency individuals. We noted that such requirements would contribute to and exacerbate existing inequities related to health care access and utilization. [Footnote 14. Supra note 4]

A notice that clearly explains the breadth of Section 1557 rights and provides information on how to practically obtain those rights including contact information for the entity's 1557 coordinator is particularly important for people with disabilities because disabilities can be acquired at any point in life by individuals who may have little or no preexisting knowledge of disability rights. We know that there is still a significant number of people unaware of ADA and disability rights.

We ask that HHS include in the notice requirement that any entity receiving a religious exemption under proposed section 92.302 include the existence and scope of such exemption in its required notices. It would be misleading and inaccurate to require entities to tell participants and beneficiaries and the public generally that the entity does not discriminate if the entity does in fact discriminate in certain circumstances and has been granted permission to do so.

Bold: VII. The proposed rule affirms key requirements for a nondiscrimination notice as well as nondiscrimination protections for people with limited English proficiency and people with disabilities. A. The proposed rule's correct response on annual nondiscrimination notice. We strongly support the requirements related to a notice of nondiscrimination. The NPRM's proposed requirement that covered entities provide the notice on an annual basis and upon request is clearer than the prior requirement for notice in "significant" communications. [Footnote 118: Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824 (proposed August 4, 2022); See e.g. Nat'l Council of Asian Pacific Ams., Comment on Section 1557 NPRM, pp. 3-7 (Aug. 13, 2019) https://www.regulations.gov/comment/HHS-OCR-2019-0007-145953.]. The proposed requirement of informing the public by prominently posting the notice in the covered entity's physical location and on its website if applicable is clear, specific and comes at a low cost to entities. We also agree with the Department's assessment that the 2020 Rule failed to sufficiently account for some of the harmful effects of the provisions' absence on individuals or health care systems. Footnote 119: Id.] In addition to the proposed requirements we also recommend including a requirement that if a covered entity will deny certain services due to a religious belief that it must include that information on the notice, including in the required non-English languages.

Proper Notification of Nondiscrimination Protections: To ensure individuals are aware of steps being taken by covered entities to protect them from discrimination, covered entities will be required to notify the public of their nondiscrimination requirements as well as provide participants, beneficiaries, enrollees and applicants with a notice of nondiscrimination relating to its health programs and activities.

Bold: § 92.10 Notice of nondiscrimination. We thank HHS for re-establishing requirements to inform beneficiaries of their ability to obtain the services they need to access health care services. We are particularly glad to see that the notices must include details on how to file a complaint with HHS. We support the proposal for conspicuous location on the website and prominent physical location. Notices must be posted in physical locations on websites and sent with significant documents.

Bold: B. The proposed Notice of Nondiscrimination (§ 92.10) requirements are appropriate but should incorporate inclusion of any exemption under proposed section 92.302. We strongly support HHS's proposed notice requirements which are crucial to ensure program beneficiaries understand and can assert their rights and which do not overly burden covered entities. It is critical that such notices convey to program beneficiaries including LGBTQI+ beneficiaries the breadth of the ACA's sex discrimination and other protections. As with proposed section 92.8 above we urge HHS to fully align the description of prohibited grounds of discrimination in this section with that of section 92.101. For notice to beneficiaries to be meaningful, it cannot advise beneficiaries of nondiscrimination protections without qualification if the entity providing the notice intends not to fully comply with those protections in significant part and instead to rely on a religious exemption. Such an omission could be profoundly misleading to patients and their reliance on such incomplete notice could cause significant harms. Thus section 92.10 should require that any entity relying on a religious exemption under proposed section 92.302 identify the existence and scope of such exemption in its required notices.

Notice of Nondiscrimination [§ 92.10]: We strongly support the notice requirements in section 92.10 and the Department's attempt to strike a balance so that covered entities are not overly burdened but that program participants and beneficiaries are aware of their rights. We note that the description of prohibited sex discrimination in this section differs from the language of section 92.101. While the differences are not extensive it would be preferable to use consistent language throughout the rule, the more expansive definition in 92.101 should be used for a variety of reasons including those related to the intersex community (as noted above). We ask that HHS include in the notice requirement that any entity receiving a religious exemption under proposed section 92.302 include the existence and scope of such exemption in its required notices. It would be misleading and inaccurate to require entities to tell participants, beneficiaries and the public generally that the entity does not discriminate if the entity does in fact discriminate in certain circumstances and has been granted permission to do so.

The notice must include all the protected bases of nondiscrimination recognized under Section 1557 including limited English proficiency, sexual orientation and gender identity. It must also indicate that the covered entity will provide reasonable modifications, auxiliary aids and services and alternative formats to people with disabilities free of charge and in a timely manner when requested by people with disabilities to afford equal accessibility and an equal opportunity to health care.

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Ethics & Public Policy Center

Association of American Medical Colleges [AAMC]

Disability Rights Maine

SIECUS: Sex Ed for Social Change

(b)(5)

Center for Reproductive Rights

Covered California

National Disability Rights Network

InterACT: Advocates for Intersex Youth

Equitas Health

(b)(5)

Disability Rights Maine

(b)(5)

We ask that HHS include in the notice requirement that any entity receiving a religious exemption under proposed section 92.302 include the existence and scope of such exemption in its required notices. It would be misleading and inaccurate to require entities to tell participants and beneficiaries and the public generally that the entity does not discriminate if the entity does in fact discriminate in certain circumstances and has been granted permission to do so. We strongly recommend the agencies reverse their proposal to separate the notification requirements into two distinct documents with different distribution requirements. We believe the content of the Notice of Nondiscrimination and the Notice of Availability are so inherently interrelated that separating these notices would lead to the provision of incomplete information to our members. For example the provision of taglines in a separate document does not provide members with complete information on the plan's obligations regarding nondiscrimination as it relates to the provision of language assistance and auxiliary aids. Further the burden of administering two separate notices with different distribution requirements introduces significant administrative burden and financial cost on plans without a corresponding benefit to our members. In fact the issuance of two separate notices may actually result in member confusion or

The notice would also have to be given out upon request and must be clearly displayed on the entity's website and in clear and prominent physical locations where individuals seeking service from the health program or activity are able to read or hear the notice

require each covered entity to provide a notice of nondiscrimination relating to its health programs and activities annually and upon request to participants beneficiaries enrollees and applicants of its health programs and activities as well as members of the public. Notice can be provided through written translations in language required audio or video clips.Recommendations: • BCBSA supports the requirement to provide the notice of nondiscrimination annually and upon request. We recommend that HHS clarify that plans may comply with the requirement by including the notice with other routine annual mailings. • While the proposed rule identifies certain notices with which the nondiscrimination notice may be combined BCBSA recommends that this list of notices should be expanded further to include individual and group health plan documents that are annually distributed to enrollees and other annual notices that issuers are required to send (e.g. Part D creditable coverage CHIP Women's Health and Cancer Rights Act [WHCRA]). • BCBSA recommends that the final rule clarify that the notice of nondiscrimination may be provided in English if it is accompanied by the notice of availability of language assistance services. • BCBSA recommends that Medicare Advantage and Part D plans be deemed compliant if they meet standards set forth in 42 CFR §§ 422.2267(e) and 423.2267(e) as promulgated in the Contract Year 2023 Policy and Technical Changes Final Rule (CMS–4192–F CMS–1744–F and CMS–5401–F) published in the Federal Register on May 3 2022. This would facilitate use of the CMS model. • We strongly urge maximum possible consistency so that the same language tagline could be used for both MA/Part D and the Commercial business. • BCBSA recommends HHS provide the flexibility for electronic access or delivery such as website links QR codes emails or texts for enrollees to obtain in the right channels. Rationale Currently in the commercial market requiring the notice of nondiscrimination to be sent annually would increase costs significantly

Blue Cross Blue Shield Association

We believe that the proposed requirements for the notice of nondiscrimination with modification are closer to striking the right balance in providing members with the information needed to prevent discrimination and access to care issues while minimizing member confusion program cost and administrative burden. We believe that providing the information in a [underline]single combined notice[/] at the time of enrollment in the member handbook on the health plan's publicly available website annually and by request adequately informs members of their rights to obtain language assistance and auxiliary aids while reducing administrative burden program cost and member abrasion that would otherwise result from the repeated distribution of the notice multiple times in a single calendar year. [Bold: We recommend the agencies adopt the following notice distribution cadence for covered health plans: at the time of enrollment in the member handbook on the health plan's publicly available website annually and by request].

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The Health Plan of West Virginia, Inc

Sec. § 92.10 – Notice of nondiscrimination[We thank HHS for re-establishing requirements to inform beneficiaries of the ability to obtain the services they need to access health care services. We are particularly glad to see that the notices must include details on how to file a complaint with HHS. We support the proposal for conspicuous location on the website and prominent physical location. Notice must be posted in physical locations on websites and sent with significant documents.

National Disability Rights Network

The Health Connector supports the proposal to re-state and expand some current policies on notice requirements. OCR's proposal to re-state and expand some current policies on notice requirements will help individuals know that the Health Connector and any covered entity does not discriminate on bases prohibited by section 1557. The Health Connector supports making sure individuals are aware that national origin discrimination includes discrimination based on limited English proficiency and primary language while sex discrimination includes discrimination based on pregnancy sexual orientation gender identity or sex characteristics. In addition Health Connector staff appreciate the additional clarity the proposed rule provides regarding how entities should notify individuals about nondiscrimination.

Massachusetts Health Connector

While we support §§ 92.10 and 92.11 including a revised notice requirement that does not require a 1557 notification to be sent out with every patient/member contact and requires the notice of auxiliary services and supports in a specified list of significant communications we make the following additional recommendations to ensure that the proposed notice requirement is as effective as it is needed: • The § 92.10 and § 92.11 notices should be posted not only in locations where individuals seeking service will be able to see or hear it but also be posted prominently where frontline employees can see it and be trained to use it to communicate the rights described to those individuals with communication or cognitive disabilities who face inherent barriers to seeing hearing or understanding the notice without auxiliary aids or services or other means of assistance. • Covered entities must inquire about the communication needs of members/beneficiaries and record their needed auxiliary aid or service in the electronic health records so that they can consistently receive effective communication from the covered entity. • The § 92.11 Notice should be visually distinguishable through the use of large sans serif print that is a minimum of size 18 font. • The regulation itself should explicitly clarify that any request for all written communications to be rendered in alternative formats or in LEP languages necessarily include but are not limited to the first set of significant communications in subsection 92.11(c)(5). • The critical importance of clear communication in health care settings warrants the inclusion of a requirement that covered entities in determining what is an appropriate auxiliary aid or service should give primary consideration to the requests of the person with a disability.

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Disability Rights Maine

Finally the proposed regulation would require covered entities to provide notice of the accommodations under section 1557 for LEP and disabled patients. These requirements are similar to existing requirements for the general nondiscrimination protections of the section they must be provided on an annual basis upon request on the entity's website and posted in a clear and prominent physical location. These regulations will help ensure that patients are able to communicate effectively with their providers whether the potential for miscommunication stems from limited English proficiency or from a disability. Being unable to communicate effectively with a provider results in lower quality of care as well as less satisfaction with that care for both the patient and provider side [Footnote 21: Lisa Diamond et al. "A Systematic Review of the Impact of Patient–Physician Non-English Language Concordance on Quality of Care and Outcomes" Journal of General Internal Medicine 34 no. 8 (May 01 2019): pp. 1591–606 https://doi.org/10.1007/s11606-019-04847-5. Martinez Matthew and Glenn A. Martinez "Scoping Review: Definitions and Outcomes of Patient-Provider Language Concordance in Healthcare" Patient Education and Counseling 103 no. 10 (October 2020): pp. 1883–901 https://doi.org/10.1016/j.pec.2020.05.025]

The Century Foundation

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To improve the effectiveness and accessibility of this notice we recommend that covered entities be required to provide the notice in large print (18-point font minimum) and plain language. We also recommend that any entity that receives an exemption due to the application of a Federal constitutional or religious freedom law under § 92.302 be required to include the exemption in its notice of nondiscrimination. It is essential for individuals to have this information when choosing a provider.

We believe that the proposed requirements for the notice of nondiscrimination with modifications are closer to striking the right balance in providing members with the information needed to prevent discrimination and access to care issues while minimizing member confusion program cost and administrative burden. We believe that providing the information in a [underline]single combined but[/] at the time of enrollment in the member handbook on the health plan's publicly available website annually and by request adequately informs members of their rights to obtain language assistance and auxiliary aids while reducing administrative burden program cost and member duress that would otherwise result from the repeated distribution of the notice multiple times in a single calendar year. [Bold] We recommend the agencies adopt the following notice distribution cadence for covered health plans: at the time of enrollment in the member handbook on the health plan's publicly available website annually and by request[.]

[illegible] applications and medical diagnostic equipment. Plain language easy read and graphic language should always be used. Key aspects of [Hyperlink] plain language, https://www.plainlanguage.gov/about/definitions/[] include: use of active voice; brief sentences and paragraphs; common words and design features (i.e. – Lists headings and tables). [Hyperlink] Text in Easy Read; https://www.learningdisabilities.org.uk/learning-disabilities/a-to-z/e/easy-read[] is accessible to people with learning and other disabilities. Prevalent Easy Read rules are the use of brief sentences images representing each sentence simplified language large font simple fonts and minimal design elements. Easy Read documents tend to be longer than non Easy Read materials. Graphic illustrations can allow people with IDD to better understand concepts. [Bold] Steps HHS can take to help covered entities meet their language access and effective communication responsibilities[:][HHS should not just focus on Limited-English proficiency. [HHS should] use Plain Language and Easy Read. [S]hould also ensure that people with IDD can communicate in the way they would like [verbal AAC device care partner].

- Requires covered entities to provide a notice of nondiscrimination along with a notice of the availability of language assistance services and auxiliary aids and services 1) Specify wording of signage. Require wording that offers language services and interpreters as opposed to policy statements (i.e. "We respect all languages" "we respect all national origins" shall not substitute but may supplement language services information) or 2) Specify languages. Identify and utilize measures for determining which languages signage will be posted in [how to determine threshold languages]. 3. Specify places for posting. Clarify requirements such as posting "at all points of contact" (lobbies registration front desks waiting rooms entrances information booths). Clarify that signage is required as opposed to optional, akin to signs for "exit" and "fire extinguisher." Federally required interpreter services signage trumps organization decor or display preferences if policies are in conflict.

The Health Connector supports the proposal to reinstate and expand the nondiscrimination notice requirements. OCR's proposal to reinstate and expand the nondiscrimination notice requirements will help individuals know that the Health Connector and any covered entity does not discriminate on bases prohibited by section 1557. The Health Connector supports making sure individuals are aware that national origin discrimination includes discrimination based on limited English proficiency and primary language while sex discrimination includes discrimination based on pregnancy sexual orientation gender identity or sex characteristics. In addition Health Connector staff appreciate the additional clarity the proposed rule provides regarding how entities should notify individuals about nondiscrimination.

CCI suggests a requirement that if a covered entity will not provide certain services due to a religious belief that it must include that information on the notice and provide the notice in the required non-English languages.

No comments are associated with this issue.

Notice of Availability of Language Assistance Services:CCI supports this provision of the proposed rule. CCI agrees that LEP individuals often rely on community based organizations as the first line of support when they are unable to access other systems due to language barriers which should not be necessary.

We strongly support the proposal to require covered entities to provide a notice of availability of language assistance services and auxiliary aids and services and that this notice be translated. We agree with HHS's approach to clarifying the requirements for when this notice must be made available and providing individuals with the opportunity to opt out of receiving these notices.

To help ensure the notice of availability is as informative as possible we also suggest that HHS develop and provide covered entities with model notices that are tailored to the different types of communications they are included for. For example rather than having the same generic notice or a communications notice of availability should indicate that a response is required or that the communication contains information about one's rights or benefits.

compliance burdens resulting from the proposed 1557 compliance requirements will overwhelm providers' offices particularly small practices and solo practitioners that HHS seeks additional comment on. Specifically we are concerned about the resources needed to write and implement Section 1557 specific policies and procedures identify a Section 1557 Compliance Coordinator and train employees on new nondiscrimination standards. Pediatric physicians like other physician specialties are increasingly under-reimbursed for the patient care they provide particularly when compared to other types of health care providers and Medicare Advantage plans. Medicare payments to physicians have failed to keep up with inflation – which has recently hit record highs – and with the passage of the Medicare Access and CHIP Reauthorization Act of 2015 no longer incorporate inflation as a factor for determining annual payment updates. As a result of this and other structural challenges with the Medicare Physician Fee Schedule Medicare payment rates are scheduled for a third straight year of payment reductions in 2023. Moreover providers already face significant administrative burdens due to federal and state regulations and payer contract requirements for example related to audits and medical record reviews prior authorizations and quality reporting requirements. These requirements consume clinical and administrative staff time and attention and limit practices' ability to focus on delivering high quality care. Pairing this already overwhelming administrative burden with existing funding constraints and health care workforce challenges [which impair physicians' ability to simply hire additional staff to manage more] providers are already struggling and cannot afford another unfunded mandate in the current environment. Given the above APMA asks that HHS not finalize policies that would add to providers' administrative burden. If HHS chooses to finalize the rule with no changes APMA asks that it strive to minimize the burdens created by developing and making available free of charge

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Justice in Aging

The Health Plan of West Virginia, Inc.

Institute for Exceptional Care

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Massachusetts Health Connector

Genesee County Legal Aid Society dba Center for Civil Justice

Genesee County Legal Aid Society dba Center for Civil Justice

Center for Elder Law & Justice

Center for Elder Law & Justice

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American Podiatric Medical Association

(b)(5)

will be creative as a result of the proposed requirements for physicians' offices related to Section 1557 compliance. Specifically we are concerned about the resources needed to write and implement Section 1557 specific policies and procedures identify a Section 1557 Compliance Coordinator and train practice employees on new nondiscrimination standards. Rheumatology practices are grossly underreimbursed for the patient care they provide particularly when compared to other types of health care providers and Medicare Advantage plans. Since the inception of the resource-based relative value scale the Medicare Physician Fee Schedule (PFS) conversion factor has remained consistently flat. Add with passage of the Medicare Access and CHIP Reauthorization Act of 2015 physician payments no longer incorporate inflation which has reached record levels in recent months. In addition to unsustainable payments rheumatology practices face increasing administrative burdens primarily associated with utilization management such as prior authorizations step therapy and other tactics which divert clinical and administrative staff away from direct patient care and relative activities. This is on top of the punitive quality reporting and program integrity audits. Simply stated our practices cannot afford another unfunded mandate in the current environment. As such we ask the Department not to create additional administrative burdens on already overburdened physicians' offices. If the Department finalizes these requirements despite this concern then at a minimum [italicized] we seek your assistance in helping rheumatology practices with compliance. Specifically we request that HHS develop and make available free-of-charge to the following: • Template Section 1557 policies and procedures that rheumatology offices can incorporate into their existing compliance manuals as is; • Section 1557 educational materials and training resources including materials that would help practices test their employee understanding of the new requirements and how to comply; and • Patient

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Coalition of State Rheumatology Organizations (CSRO)

However we are deeply concerned with the [italicized] proposed requirement that providers including physicians must write and implement Section 1557–specific policies and procedures identify a Section 1557 Compliance Coordinator and train their employees on these new standards. Physicians' offices are overwhelmed by administrative tasks that stem from a multitude of federal regulators and requirements including quality reporting utilization management and medical review/audits. Indeed many allergy/immunology (A/I) practices are small and have limited administrative and clinical staff that can be diverted from patient care activities to manage yet another compliance program. Considering the year over year reductions in payments to Medicare physicians coupled with high overhead and extreme workforce challenges we are frustrated that the Department is proposing this unfunded mandate on physician offices. And while we support the intent of this new policy our practices simply lack the financial and staffing resources to properly comply. Should the Department proceed with finalizing this proposal HHS must develop template Section 1557 policies and procedures and compliance guidance that physician offices can easily incorporate into their existing compliance manuals. HHS should also develop educational materials that assist practices with training activities and with testing staff understanding of the policies. HHS should develop patient notices and other patient education materials for practices. These resources should be downloadable from the HHS website and made available free-of-charge to practices to help practices comply with the Section 1557 requirements. Practices should start with enhanced education and the provision of technical assistance so providers can come into compliance without ramifications or penalties.

American Academy of Allergy Asthma and Immunology (AAAAI

We support the 2022 proposed rule's restored provisions from the 2016 Final regulations regarding definitions for language assistance services required steps to provide meaningful access for Limited English proficient (LEP) individuals standards for video remote interpretation and provisions of notices to inform individuals of their rights. We do however see opportunities to clarify and strengthen these provisions.

Farmworker Justice

Justice in Aging strongly supports HHS's proposal only 87 11 to require covered entities to provide notice of availability of language assistance services and auxiliary aids and services. We agree with HHS that the 2020 rule did not appropriately consider the costs to individuals with LEP in eliminating the 2016 rule's tagline requirements and that the benefits of providing notice of availability of language access services outweigh the costs to covered entities. As HHS notes in the preamble and as was discussed in the litigation we filed challenging the 2020 rule eliminating these taglines was particularly harmful to older adults with LEP and community based organizations that provide language access services. Concrete 5 82 FR 42854, Comp. Children's Serv. Ctr. v. U.S. Dep't of Health & Human Servs. No. 1 21-cv-00331 (D.D.C. Feb. 5 2021)]. For example we learned about a recent incident where a Los Center staff for a Medicare Advantage plan were unfamiliar with the plan's own interpretation services. As a result a community based organization in Southern California spent many hours and made several attempts to access and schedule a qualified interpreter through the plan. The ordeal exacerbated the older adult's stress and their anxiety about their medical condition not knowing whether they would be able to communicate with their provider. This is a common experience for many older adults with LEP.

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Justice in Aging

In addition we encourage OCR to require that these notices be written at an accessible reading level. If a document's phrasing is too complex to be understood by a person likely to experience discrimination and poor health outcomes its value is extremely limited. [Footnote 18 Dewalt Darren et al. Literacy and Health Outcomes: A Systematic review of the literature" Journal of General Internal Medicine December 2004. https://pubmed.ncbi.nlm.nih.gov/15610334/] The American Academy of Family Physicians recommends that patient materials be written at no more than a 5th grade reading level. [Footnote 19 Safeer Richard and Jann Keenan "Health Literacy: The Gap Between Physicians and Patients" American Family Physician 2005 https://www.aafp.org/pubs/afp/issues/2005/0301/p463.html]

National Immigration Law Center

Notice of Availability of Language Assistance Services and Auxiliary Aids and Services [§ 92 11] We support the inclusion of the proposed notice of availability of language assistance services and auxiliary aids and services. This proposed notice provides easily accessible information to consumers about how to obtain services in their preferred language.

National Immigration Law Center

We support the notice of nondiscrimination requirements in Section 92.10 to help ensure that individuals receive information about their rights; know how to access interpreters auxiliary aids and services; and know how to file a complaint or a grievance. Greater notice and transparency of information available to patients and greater understanding of what is required of providers will help to improve overall patient experiences and health care outcomes.

The Leadership Conference on Civil and Human Rights

Language Support Services. BCBSA recommends the final rule ensures enrollees understand how to access language support services in a way that is effective administratively efficient and does not unnecessarily expand and complicate the communications going to members.

Blue Cross Blue Shield Association

Meaningful access to care also requires addressing and removing language barriers. AMCP supports the proposal to require covered entities to provide language assistance for limited English proficient individuals without charge and to offer a qualified interpreter when oral interpretation is necessary as these requirements further remove barriers to access. Similarly AMCP agrees with the proposal to require covered entities to send notices of nondiscrimination and notices of availability of language assistance services and auxiliary aids and services annually or on request as well as posting them on the covered entity's website and in physical locations. AMCP encourages HHS to be mindful of the potential administrative burden of these requirements and offer covered entities additional flexibility to find innovative ways of addressing language barriers.

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Academy of Managed Care Pharmacy (AMCP)

Brief Notice of Nondiscrimination (§92.10) We support the restoration of the brief notice of nondiscrimination requirements which were removed from the previous section 1557 rule in 2019. Lack of awareness of one's language access rights has long been a [Hyperlink: https://www.migrationpolicy.org/sites/default/files/language_portal/AwarenessofLanguageLaw_3.pdf] an obstacle for many patients and restoring the requirement for these notices is an essential step toward addressing this long-standing issue.

UnidosUS

Taglines. Notice of availability of language services] We strongly support this provision and the requirements for when this notice must be made available.

National Asian Pacific American Women's Forum

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Additionally we applaud the expanded notice of nondiscrimination and language access requirements included in the proposed rule that would require covered entities to provide a notice of nondiscrimination to participants beneficiaries enrollees and applicants of its health programs and activities as well as members of the general public. This transparency and consumer education element of the proposed rule will help to ensure that providers are held accountable to the provisions of Section 1557 while ensuring that all individuals know they are protected from discrimination under federal law.

In addition as we have suggested in previous comments developing a universally recognizable icon to convey that translation services are available would be helpful. Posting that symbol in various locations around the hospital and on the hospital's website could communicate quickly and effectively that translation services will be made available to the individual. We urge HHS to develop and seek international recognition of such an icon. In the meantime hospitals and health systems will continue to alert their communities that translation services are available through existing methods.

The Health Connector fully supports retaining requirements to ensure meaningful access for limited English proficiency (LEP) individuals. In Massachusetts 24% of residents speak a language other than English at home [Footnote 5: Source: U.S. Census 2016-2020 American Community Survey. Retrieved from U.S. Census Bureau QuickFacts: Massachusetts]. Tagline and language supports are critical to the health care access and overall well-being of those with limited English proficiency which is why the Health Connector continues to incorporate these requirements despite their removal from Section 1557 requirements several years ago. While not all of the 24 percent of Massachusetts residents who speak a language other than English at home may need support to engage meaningfully in English having tools commensurate with the size and diversity of non-English speakers is paramount. The Health Connector supports OCR's proposal to restore the requirement to provide clear and consistent notification of assistance in other languages by covered entities.

Mod: Notice of Availability of Language Assistance Services and Auxiliary Aids and Services [§92.11] We strongly support the requirement to provide notice of availability for language access services. In addition to the requirements described within the rule we urge OCR to make improvements involving the notice's content and placement the range of documents covered by the requirement and the languages encompassed by the notice.

Mod: Notice of Nondiscrimination/Notice of availability of language assistance services] We strongly support the provisions and requirements related to nondiscrimination and the notice of availability of language assistance services. LEP individuals are often unaware of their rights especially as they pertain to language access. Farmworkers tend to be isolated from the communities where they live and work with limited access to community resources including health and legal services. Due to fear of employer retaliation workers may be reluctant to ask about or assert their rights including those rights. A notice ensures that all individuals are aware of the language services available to them how to request these services and their rights when they face discrimination.

Mod and Italics: Notice of Nondiscrimination [§92.11] and Notice of Availability of Language Assistance Services and Auxiliary Aids and Services [§92.11]] Mod: The AAMC supports proposals to reinstate and expand requirements that covered entities provide notices about and ensure access to nondiscrimination rights and language assistance services for individuals with limited English proficiency and auxiliary aids and services for individuals with disabilities.] We oppose the repeal of the nondiscrimination notice and tagline requirements under the 2019 proposed rulemaking out of concern that it would impede access to critical language assistance services for millions of limited English proficient individuals. We noted that such impediments would contribute to and exacerbate existing inequities related to health care access and utilization. [Footnote 34: *supra* note 4]

We also recommend that if a covered entity operates across multiple states that the covered entity has to provide the notice in not merely the top 15 languages in the aggregate [that is across all the states] but rather a total of the top 15 languages in each state.

The direct attention to nondiscrimination on the basis of sex limited English proficient (LEP) individuals and people with disabilities and the clarification of the specific measures that are anticipated to comply with Section 1557 are welcome. Specifically we support the major clarifications in the rule: • The interpretation of Section 1557 to cover all health programs and activities administered by HHS; • The interpretation that provision of Medicare Part B assistance is federal financial assistance and that entities receiving Medicare Part B funds must comply with the Rule; • The application to health insurance issuers that receive federal financial assistance; • The clarification that the protections against discrimination on the basis of sex as including sexual orientation or a gender identity and a determination on the basis of sex stereotypes and the extension of these protections to CMS regulations; • The expectation that compliance will require implementing programs to develop maintain and communicate clear policies and train on the provision of language assistance services for limited English proficient [LEP] individuals and effective communication and reasonable modifications to policies and procedures for people with disabilities; • The requirement that implementing entities provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states.; • The expectation of nondiscrimination based on clinical algorithms; • The expectation that nondiscrimination extends to telehealth services and; • The development of clear processes for requesting exceptions from the expectation of compliance.

Mod: Notice of Availability of Language Assistance Services and Auxiliary Aids and Services [§92.11]] [Mod: TPCA strongly supports this provision and the requirements for when this notice must be made available.] We also recommend that if a covered entity operates across multiple states that the covered entity must provide the notice in not merely the top 15 languages in the aggregate [that is across all the states] but rather a total of the top 15 languages in each state. Since 2015 TPCA has advocated for covered entities operating across multiple states to provide notice in the top 15 languages in each individual state. TPCA recommends that covered entities provide the notice in the top 15 languages in each state in which they operate not just the top 15 languages across all of the states.

With regard to the translated notice we agree with the proposed approach of using the top 15 languages by state as the minimum standard. However we recommend clarifying that a covered entity which operates across multiple states must provide the notice in the top 15 languages in [italics: each] of those states. We also urge HHS to consider a more localized standard such as the standard for Medicare Advantage Plans and Prescription Drug Plans which considers the plan service area. Using service areas or counties rather than states could help ensure smaller language communities that are often concentrated in a particular area of a state are also receiving in-language notices. CEJ serves many refugees from Somalia who speak Somali. Somali is not within the top 15 languages in New York and therefore would not receive a translated notice demonstrating the need to utilize counties rather than states to better serve our community.

Notice of Availability of Language Assistance Services and Auxiliary Aids and Services [§92.11]WPHCA strongly supports this provision and the requirements for when this notice must be made available. We also recommend that if a covered entity operates across multiple states that the covered entity must provide the notice in not merely the top 15 languages in the aggregate (that is across all the states) but rather a total of the top 15 languages in each state. Since 2015 WPHCA has advocated for covered entities operating across multiple states to provide notice in the top 15 languages in each individual state. WPHCA also suggests that OCR develop and provide covered entities with model notices and translated information in the relevant languages that will be needed across the country. These notices should relate to the different types of publications they are included on, that is a notice would likely be different for a consent form versus information about a public health emergency versus a notice about one's rights or benefits.

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AARP

American Hospital Association

Massachusetts Health Connector

UnidosUS

Farmworker Justice

(b)(5)

Association of American Medical Colleges [AAMC]

National Asian Pacific American Women's Forum

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard [MRCT Center]

Tennessee Primary Care Association

Tennessee County Legal Aid Society dba Center for Civil Justice

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Center for Elder Law & Justice

Wisconsin Primary Health Care Association

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|Bold Notice of Availability of Language Assistance Services and Auxiliary Aids and Services |§92.11| MNACHC strongly supports the provision and the requirements for when this notice must be made available.| We also recommend that if a covered entity operates across multiple states that the covered entity must provide the notice in not merely the top 15 languages in the aggregate |that is across all the states| but rather a total of the top 15 languages in each state. True 2015 YOUR ORGANIZATION has advocated for covered entities operating across multiple states to provide notice in the top 15 languages in each individual state. |Bold MNACHC also suggests that OCR develop and provide covered entities with model notices and translated information on the relevant languages that will be needed across the country.] These notices should relate to the different types of publications they are included or: that is a notice would likely be different for a consent form versus information about a public health emergency versus a notice about one's rights or benefits.

require covered entities to provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states. Such notices must be provided:• In alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication• To participants, beneficiaries, enrollees and applicants and members of the public who are blind or have limited vision, on an annual basis to these persons and upon request at any time• In clear and conspicuous physical locations where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice; and In a conspicuous location on the covered entity's health program or activity website (if applicable)• Along with a specified list of electronic and written communications.The Proposed Rule provides alternative methods by which a covered entity would be deemed in compliance with this provision including providing individuals on an annual basis the option to opt out of receipt of the notice.Recommendations • BCBSA recommends that covered entities be given the option of distributing the Notice of Availability at the time of initial enrollment, upon request and in the following documents: • Individual health insurance contracts and group health plan booklet/certificates• The notice of nondiscrimination required by proposed § 92.10 is inconsistent with the annually required notices like WHCRA, etc.u The notice of Health Insurance Portability and Accountability Act (HIPAA) privacy practices described in 45 CFR 164.520(b) for claims forms and patient and member handbooks• BCBSA recommends that the Final Rule requires covered entities to provide notices with Explanations of Benefits (EOBs) that covered entities should be given the option to only including the notice of availability of language with those EOBs that notify individuals of a cost sharing responsibility while maintaining the safe harbor of

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Minnesota Association of Community Health Centers

Blue Cross Blue Shield Association

and the requirements. In particular, the Proposed Rule requires covered entities to notify the public of the availability of language assistance services along the "tagline" requirement with a Notice of Availability requirement that also requires a notice of the availability of auxiliary aids and services) in English and the top 15 most common languages spoken by LEP individuals in the relevant state or states. 87 Fed. Reg. at 47853-56 47915. But rather than provide the required notices for all "significant" communications or publications as required by the 2016 Rule, HHS proposes that the notice of nondiscrimination and notice of availability be provided on an annual basis displayed prominently on the covered entities' website and physical locations and upon request. HHS also proposes that the notice of availability be provided until specifically identified documents and communications, including for example application and intake forms. Health Insurance Portability and Accountability Act (HIPAA) notices, notices of denial or termination of eligibility benefits or services including Explanations of Benefits, notices of appeal and grievance rights, consent forms, communications related to a person's rights and benefits among others. 87 Fed. Reg. at 47855 (Table 16). This proposal strikes a reasonable balance between the 2016 Rule's efforts to improve access to health programs and services for LEP individuals and the 2020 Rule's concerns regarding cost and administrative burden. It also provides clear guidance to covered entities as to the information that must be conveyed under what circumstances notices must be provided and how the information must be provided or otherwise made available. Although the proposed Rule does not include the 2016 Rule's broad requirement that taglines be provided in all "significant" communications or publications the list of documents and communications to which the notice of availability must be provided is comprehensive. It reduces any ambiguity and confusion as to what constitutes a "significant" communication or publication and will help ensure that

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Attorneys General of California, New York, Massachusetts, and nineteen other States

We encourage OCR to require covered entities to translate their notice into the fifteen languages spoken by people with LEP in their service area to post the notice on the website to make the notice available upon request and to send the notice to individuals for whom a preferred written language is known. A notice in none or most or all in English provides minimal value for a person with LEP. Given that these notices must only be provided annually or on request this translation requirement should not pose a large burden on covered entities

National Immigration Law Center

claims that covered entities may aggregate the top fifteen languages across states they service by saying that the notice must be provided in English and at least the top 15 languages commonly spoken by LEP individuals in the relevant state or states." We urge OCR to instead have entities aggregate the languages within each of their areas of service to be defined no more broadly than a Core Based Statistical Area. Doing so would ensure that populations that are smaller at the national level but of significant size within a state or communities have information they need. For example discussing an example of communicating to Medicare beneficiaries in Michigan CMS states "if providers in Dearborn only post taglines in the top 15 non-English languages spoken in the state of Michigan they could very well neglect the needs of the Romanian Hmong and Hungarian speaking beneficiaries and expend resources on languages that are rarely spoken in the community." [Fuot note 20 "Understanding Communication and Language Needs of Medicare Beneficiaries" Centers for Medicare and Medicaid Services Apr. 2017 https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Issue-Briefs-Understanding-Communication-and-Language-Needs-of-Medicare-Beneficiaries.pdf] According to American Community Survey data the top languages spoken across all 50 states by people with LEP are Spanish Chinese Vietnamese Korean Tagalog Arabic Russian Haitian Portuguese French Amharic or Somali or other Afro Asiatic languages Polish Japanese Persian and Hindi. |Footnote 21 NILC review of 2020 five Year American Community Survey Data Table B16001.] For a person living in Michigan served by a health insurance company operating not-on-wide those are the languages they would receive taglines. However if they were served by an insurer operating only in Michigan the taglines would not include Bengali Ukrainian and German a population of about 20 thousand people in that state. In Minnesota nearly 30 thousand Hmong speakers would be excluded from taglines

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The COVID-19 pandemic emphasizes the need for covered entities to be able to serve the language needs of their local communities. For example one report found "The COVID-19 crisis has elevated the critical need to develop in-language outreach engagement and engagement materials. Many jurisdictions were accustomed to providing translation in threshold languages however the crisis has elevated the need to provide language support for community members who may not speak a County or City's threshold language." |Footnote 22 "Supporting Communities and Local Public Health Departments During COVID-19 and Beyond" Public Health Alliance of Southern California July 2022 https://7m15a7emh57413D.5vkaWg.wpengine.netdna-ssl.com/wp-content/uploads/2022/07/Public-Health-Alliance_Supporting-Communities-and-LHDs-Report_July-2022.pdf.

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Communities|With respect to languages required the MAPD regulations and proposed § 92.11 also differ. The MAPD regulations require the notice in the top 15 languages in the U.S. |Footnote 11 The top 15 languages nationwide are Spanish Chinese Tagalog French Vietnamese German Korean Russian Arabic Italian Portuguese French Creole Polish Hindi and Japanese.| as well as any other language that meets a five percent service area threshold. [Footnote 12 42 C.F.R. § 422.2267(e)(31)(i). 42 C.F.R. § 423.2267(e)(35)(i) | The proposed § 92.11(b) requires the notice of availability in top fifteen languages per state or relevant states. [Build: We urge HHS to revise § 92.11|b| to clarify that in addition to the top 15 languages in each state covered entities be required to provide the notice of availability in any additional languages meeting the five percent service area threshold as is required in Medicare Advantage and Part D. The additional five percent service area threshold trigger is important because it captures smaller more geographically isolated language communities who might not otherwise rise to the top fifteen languages in a particular state. It is more localized standard recognizes the racialized segregation in America's residential communities and the clustering of specific language communities. It also would likely capture those languages that HHS has already identified under the top 15 standard. Although HHS is understandably concerned about the burden on covered entities to provide the notices in an abundance of languages MAPD plans have been providing the inserts in these languages for many years. Any reduction in the number of languages from those identified in the MAPD regulations will only potentially harm Medicare beneficiaries especially those in smaller language communities who may no longer receive important information about their language access rights. Therefore if HHS is not going to add a service area threshold in § 92.11|b| we recommend HHS retain the current MAPD requirements for which languages the notices must be provided in the MAPD

Seal: B. The NPRM's proposed notice of language services requirement is essential for people with limited English proficiency and should be given additional emphasis.' We strongly support the provision of notice of language assistance services and the requirements for when this notice must be made available. We also recommend that if a covered entity operates across multiple states that the covered entity must provide the notice in not merely the top 15 languages across all the states but rather in the top 15 languages for each state. We also recommend that covered entities be required to provide the notice in large print at least 18 point font. This will assist individuals with vision impairments to understand the importance of the notice. As the Office of Civil Rights (OCR) has previously done we also recommend that OCR develop and provide covered entities with model notices and translated information in the relevant languages that will be needed across the country. We also recommend a requirement that this notice must be provided at the beginning or on the first page of any document. Unfortunately many documents in which this notice will be required can be lengthy. We do not believe a person with limited English proficiency would look through a multi-page English-language document to find the notice at the end of the document. Given the importance of this notice we believe it should be the first page that everyone sees. This will benefit LEP individuals who will immediately see in their language that language assistance services are available and will also benefit individuals with disabilities who will see information in large print up front as well.

The Colorado Health Foundation also supports the sections of the proposed rule that would advance health equity by requiring digital access and access for persons with disabilities. Specifically the Foundation supports the proposed rule requirement that covered entities take reasonable steps to provide meaningful access to language services in the 15 most common languages spoken by individuals with limited English proficiency in each state. Such a requirement is a crucial step in helping close gaps in access to linguistically appropriate care

The AHA supports the proposed regulations emphasis on ensuring that those who are less proficient in English know that they can access translation services to aid in their care. We are concerned however that the proposal to reinstate the blanket mandate to provide translations in 15 different languages regardless of the languages spoken in the communities served requires a great deal of resources for services that may not be required in every community. Because such a large commitment of resources could be difficult for some hospitals particularly in the current financial environment in which hospitals are operating we suggest a change to replace that blanket mandate with a more flexible standard permitting a precise focus on languages spoken in the particular communities served. This change would enable the many hospitals especially in rural areas that serve communities in which many fewer languages are spoken to more effectively devote their resources to translation services that are most meaningful for the patients they serve.

We also recommend that if a covered entity operates across multiple states it must provide the notice in not merely the top 15 languages in the aggregate [that is adding to the top 15 languages across all the states] but rather the top 15 languages in each state.

Notice and Availability of Language Assistance Services and Auxiliary Aids and Deadline. Notice of Availability of Language Assistance Services and Auxiliary Aids and Services [§ 92.11]To best utilize resources NACDS requests that OCR consider a minimum population threshold for a specific language before requiring the Notice of Availability be provided for that language in a particular state. In addition we request that OCR consider a national list as opposed to state by state lists. In 2016 when OCR supplied the taglines for 64 languages it did not provide covered entities with the top 15 languages for each state which complicated compliance efforts because many resources differed on this matter. Should OCR finalize this rule with the state by state requirement then we strongly urge OCR to provide the top 15 languages for each state and to provide updates from time to time.

Notice of Availability of Language Access Services and Auxiliary Aids and Services § 92.11 requires that the Notice of Availability be provided in English and at least the 15 most common languages spoken by Limited English Proficiency (LEP) individuals in the relevant state or states. In its comments on the 2020 rule the ADA estimated that dental offices had spent $240 million on these requirements. We continue to be concerned about these costs and think that given the small staff size of most dental offices it would be more effective for them to concentrate on providing information in the language(s) other than English that are spoken among their patients or potential patient pool. This is widely variable across the country with some dental offices never encountering patients who do not speak English while others may encounter patients who speak languages not listed in the state's top 15 chosen languages. And while we appreciate that the Department tried to propose alternative optional methods we think that these alternatives would be just as burdensome. Putting the burden on the dental offices to offer their patients on an individual basis the opportunity to opt out and requiring documentation of that opt out would be confusing for dental offices and patients alike.

Removing Preferences for Limited English Proficient Individuals. HHS proposes to require covered entities to provide in person access to language services in the 15 most common languages spoken by individuals with limited English proficiency in each state. Covered entities would also be required to develop and implement written language access procedures to support compliance with the meaningful access requirement. To ensure participants beneficiaries enrollees and applicants are aware of these language access services covered entities will be required to inform them with a notice that these services exist.

We recommend that OCR require covered entities that operate across multiple states to not merely provide the notice of language assistance services in the top 15 languages in the aggregate [across all of the states where the entity operates] but rather a total of the top 15 languages in each state.

The Health Connector also supports notifying individuals of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP individuals in Massachusetts. Providing this information to individuals promotes equitable access to coverage and health care services across the Commonwealth.

(b)(5)

Justice in Aging

Center for Reproductive Rights

The Colorado Health Foundation

(b)(5)

American Hospital Association

National Health Council

National Association of Chain Drug Stores

American Dental Association

(b)(5)

Covered California

Farmworker Justice

Massachusetts Health Connector

(b)(5)

Last y in terms of languages encompassed by this require me nt instead of requiring the notices be made ava la ble in the top 15 languages "in a state or states" We d: we urge OCR to require covered entities to prov de notice in the top 15 languages "in a state," rather than allow ng aggregation across mult ple states served by an ent ty wh ch would potentially jeopard ze access for speakers of smaller languages

We st ong y rec mmend that OCR allow covered entities the flexibility to separate the not fica on requ rements into two d stinct documents with different distribution requirements We believe the content of the Notice of Nond scrimination and the Not ce of Availab ty are so inherent y interrelated that separating these notices would lead to the prov s on of incom plete information to our members. For exam ple the prov s on of taglines in a separate document does not provide members with com plete information on the scope of obligations regarding nond scr m nat on as it relates to the prov s on of language assistance and auxiliary aids. Further the burden of administering two separate notices with different d str bution requirements introduces significant admin st at ve burden and financial cost on plans without a corresponding benefit to our members. In fact the issuance of two separate notices may actua y result in member confus on

Bcbsf: TPCA also suggests that OCR develop and provide covered entities with model notices and translated nformat on in the re evant languages that will be needed across the country | These notices should relate to the different types of publicat ons they are included on; that is a notice would likely be different for a consent form versus information about a pub c health emergency versus a notice about one's rights or benefits

The Health Plan of West Virginia, Inc.

Tennessee Primary Care Association

to require covered ent ties to prov de notice of the availab ty of language ass stance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states These notices must be prov ded:• In a te nate formats for ind v dua s with disabilities who require aux liary aids and services to ensure effective com munication• To part cipants beneficiar es enrollees and applicants and members of the public w ttten trans ations or recorded audio or video r pts• On an annual bas s to these persons and upon request at any time• In clear and prom nent physical locations where it is reasonable to expect individuals seeking service from the health program or act vity to be able to read or hear the not ce and In a conspicuous locat on on the covered entity's hea th program or activity website (if applicable)• Along with a specified list of e ectronic and w tten communications The Proposed Rule prov des alternative methods by which a covered entity would be deemed in comp iance with this prov s on including prov ding individuals on an annual bas s the option to opt out of rece pt of the not ce. Recommendations • BCBSA recommends that covered ent ties be given the option of distributing the Notice of Availab ty at the time of in tial enrollment upon request and in the follow ng documents: o Individual hea th insurance contracts and group health plan booklet/certificates• The notice of nond scr m nat on required by proposed § 92.10 incorporated with the annually required notices like WHCRA notices The notice of Health Insurance Portability and Accountab ty Act H PAA privacy practices described in 45 CFR 164.520• Complaint forms and patient and membe handbooks• BCBSA recommends that if the Final Rule requires covered entities to provide not ces with explanations of benefits (EOBs) that covered entities should be given the option of any including the notice of ava ability of language with those EOBs that notify ind v duals of a cost-sharing responsibility while maint ining the safe harbor of

Blue Cross Blue Sh eld Associat on

and tag ne requirements. In particular the Proposed Rule requires covered entities to not fy the public of the ava ability of language assistance services through the "tagline" requirement with a Not ce of Availab ty requirement that also requires a notice of the availab ty of auxiliary aids and services) in English and the top 15 most common anguages spoken by LEP individuals in the relevant state or states. 87 Fed. Reg. at 47854 Sk 47915. But rather than prov de the required not ces n all "significant" communications or publications as required by the 2016 Rule HHS proposes that the notice of nond scrimination and not ce of availab ty be provided on an annual basis e splayed prom nent y on the covered ent ties' website and physica locations and upon request. IIIIS also proposes that the notice of ava ability be provided on specifica y identified documents and communications nc uding for example application and Inform ation's Health Insurance Portab lity and Accountab ty Act (HIPAA) notices notices of denial or termination of eligibi ty benefits or services including Exp anations of benefits notices of appeal and grievance rights consent forms comm un cations related to a person's rights and benefits among others 87 Fed Reg at 47855 47915 16 This proposal strikes a reasonable balance between the 2016 Rule's efforts to im prove access to hea th programs and services for LEP individuals and the 2020 Rule's concerns regarding cost and adm nistrative burden. It also prov des clear gu dance to covered entities as to the in formation that must be conveyed under what circumstances not ces must be provided and how the information must be prov ded or otherwise made available Although the Proposed Rule does not include the 2016 Rule's broad requirement that taglines be provided in a l "significant" communicat ons or pub cations the sc of documents and communications n which the not ce of availab ty must be prov ded s com prehensive reduces am biguity and confusion as to what constitutes a "significant" communication or pu blication and will he p ensure that We agree with HHS's general approach to clarify ng the requ rements for when this notice must be made available and providing individuals with the opportunity to opt out of rece iving these notices

Attorneys General of California, New York Massachusetts, and nineteen other States

Lat ce in Aging

Bcbsf: B. The NPRM's proposed notice of language services requirement is essential for people with lim ited English proficiency and should be given additional emphasis. We strong y support the provision of notice of language ass stance services and the requirements for when not ces must be made available We also recommend that if a covered entity operates across mult ple states that the covered entity must provide the not ce in not more y the top 15 languages across all the states but rather in the top 15 languages for each state. We also recommend that covered ent ties be requ red to provide the notice in large print at least 18 point font This will assist individuals with vision impairments to understand the im portance of the notice As the Office of Civil Rights (OCR) has previously done we also recom mend that OCR develop and prov de covered entities with model not ces and translated nformation in the relevant languages that will be needed across the country.We also recommend a requirement that this notice must be provided at the beginning or on the first page of any document Unfortunately many documents in which this not ce will be requ red can be lengthy We do not be eve a person with lim ited English proficiency would look through a mult page English language document to find the notice at the end of the document Given the importance of this notice we be eve it should be the first page that everyone sees This will benefit LEP ind v duals who w immed ately see in their language that language assistance services are available and will a so benefit individuals with d sabilities who see nform at on in large print up front as well.

(b)(5)

Center for Reproductive Rights

Nation's Association of Chain Drug Stores

(b)(5)

UnitedUS

The Health Plan of West Virginia, Inc.

Tennessee Primary Care Association

Blue Cross Blue Sh eld Associat on

Attorneys General of California, New York Massachusetts, and nineteen other States

Lat ce in Aging

Center for Reproductive Rights

Nation's Association of Chain Drug Stores

(b)(5)

IIIIS proposes that the notice of availab ty would have to accompany certain other documents Although some covered entities may be able to provide the Not ce of Availab ity with certain documents such as the Notice of Privacy Pract ces or Medicare documentation others may find it nearly impossible to prov de it with other documents such as with a consent form Moreover having to prov de the Notice of Availability with every other listed document would likely lead to overcommunicating such informat on to patients. We believe a more reasonable approach would be for OCR to require the Notice of Availabi ty to accompany similar types of documents such as the not ce of nond scr m nat on Finally we request that OCR clarify the requ rement that the Not ce of Availab ity accompany "com m un cations related to a public hea th emergency." Cons dering the need to commu nicate rapid y and eff ciently in t mes of emergency we urge OCR to clarify that the Notice of Availability would not be required to accompany text messages to pat ents concerning a pu blic health emergency

(b)(5)

The Proposed Rule Improves Communication Access Requirements and Processes We applaud HHS's restoration and expansion of communication access requirements processes and training which would allow LEP individuals and people with disabilities to better access health care The proposed rule would require covered entities to provide a notice of rights on an annual basis and upon request and outlines requirements for available language services and reasonable modifications for LEP individuals and people with disabilities [Footnote 11: 87 Fed Reg at 47852 47915 (Proposed § 92 10)] Further the proposed rule adds a definition and new requirements for machine translations and updates standards for video remote interpretation [Footnote 12: Id at 47912-13 (Proposed § 92.4)]. Language access for individuals with limited English proficiency (language access is essential to ensuring effective communication between individuals and the health care system without which individuals with limited English proficiency (LEP) may not enroll in programs for which they are eligible may not receive timely or comprehensive health care and may not know their rights to free timely and competent language services For individuals who are not proficient in English language differences often compound existing barriers to accessing appropriate care LEP often makes it difficult to navigate an already complicated health care system or understand medical or insurance terminology. For these reasons we strongly support the provision relating to notice of language assistance services We recommend that OCR specify that this notice must be provided at the beginning or on the first page of any document Unfortunately many documents in which this notice will be required can be lengthy. We do not believe a person with LEP would look through multiple pages of a document to find a short notice only at the end. As OCR has previously done we also suggest that OCR develop and provide covered entities with model notices and translated information in the relevant languages that will be needed across the country We also support the inclusion of a definition of machine translation and relocation that machine translation of critical information must be reviewed by a qualified human translator to ensure accuracy and comprehension According to census data between 2012 and 2016 approximately half a million Massachusetts residents speak limited English. Our organizations hear firsthand the difference linguistically appropriate assistance makes to populations with LEP. The HCFA Helpline provides health insurance enrollment and education services in English Spanish Portuguese Haitian Creole and French Over half the calls handled on the Helpline are taken in a language other than English Access to coverage and care for limited English speakers creates additional challenges to an already

- Restoring Protections for Limited English Proficient Individuals HHS proposes to require covered entities to provide meaningful access to language services in the 15 most common languages spoken by individuals with limited English proficiency in each state. Covered entities would also be required to develop and implement written language access procedures to support compliance with the meaningful access requirement To ensure participants beneficiaries enrollees and applicants are aware of these language access services covered entities will be required to inform them with a notice that these services exist

While we support §§ 92 10 and 92 11 including a revised notice requirement that does not require a 1557 notification to be sent out with every patient/member contact and requires the notice of auxiliary services and supports in a specified list of significant communications we make the following additional recommendations to ensure that the proposed notice requirement is as effective as intended • The § 92 10 and § 92 11 notices should be posted not only in locations where individuals seeking service will be able to see or hear it but also be posted prominently where frontline employees can see it and be trained to use it to communicate the rights described to those individuals with communication or cognitive disabilities who face evident barriers to seeing hearing or understanding the notice without auxiliary aids or services or other means of assistance. • Covered entities must inquire about the communication needs of members/beneficiaries and record their needed auxiliary aid or service in the electronic health record so that they can consistently receive effective communication from the covered entity • The § 92 11 Notice should be visually distinguishable through the use of large sans serif print that is a minimum of size 18 font • The regulation itself should explicitly clarify that any request for all written communications to be rendered in alternative formats or in LEP languages necessarily include but are not limited to the list of significant communications in subsection 92 11(c)(5) • The critical importance of clear communication in health care settings warrants the inclusion of a requirement that covered entities in determining what is an appropriate auxiliary aid or service should give primary consideration to the requests of the person with a disability. To inform people with vision impairments of their rights and help them access these services we recommend that HHS require covered entities to also provide a large print notice of availability (minimum of 18-point font)

Brief TPCA also suggests that OCR develop and provide covered entities with model notices and translated information in the relevant languages that will be needed across the country | These notices should be able to the different types of publications they are included in; that is a notice would likely be different for a consent form versus information about a public health emergency versus a notice about one's rights or benefits

- Tennessee Primary Care Association

to require covered entities to provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states These notices must be provided: • In alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication • To participants beneficiaries enrollees and applicants and members of the public who listen translations or recorded audio or video scripts • On an annual basis to these persons and upon request at any time • In clear and prominent physical locations where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice and • As a conspicuous oral on on the covered entity's health program or activity website (if applicable)• Along with a specified list of electronic and written communications The Proposed Rule provides alternative methods by which a covered entity would be deemed in compliance with this provision including providing individuals on an annual basis the option to opt out of receipt of the notice Recommendations • BCBSA recommends that covered entities be given the option of distributing the Notice of Availability at the time of initial enrollment upon request and in the following documents • Individual health insurance contracts and group health plan booklet/certificates • The notice of nondiscrimination required by proposed § 92.10 incorporated with the annually required notices like WHCRA notice • The notice of Health Insurance Portability and Accountability Act HIPAA privacy practices described in 45 CFR 164 520(c Complaint forms and patient and member handbooks • BCBSA recommends that if the Final Rule requires covered entities to provide notices with explanations of benefits (EOBs) that covered entities should be given the option of only including the notice of availability of language with those EOBs that notify individuals of cost-sharing responsibility while maintaining the safe harbor of

(b)(5)

- Senate Democrats
- Health Care For All
- Covered California

(b)(5)

- Disability Rights Maine
- Center for Elder Law & Justice

(b)(5)

- Blue Cross Blue Shield Association

(b)(5)

the Notice of Availability taglines as a single document] The proposed rule requires the Notice of Availability to accompany the following documents: (i) the notice of nondiscrimination; (ii) the notice of privacy practices; (iii) application and intake forms; (iv) notices of denial or termination of eligibility for benefits or services including explanations of benefits (EOBs) and notices of appeal and grievance rights; (v) communications relating to a person's rights eligibility benefits or services that require or request a response from a participant beneficiary enrollee or applicant; (vi) communications related to a public health emergency; (vii) consent forms and instructions related to medical procedures or operations medical power of attorney or living will; (viii) discharge papers; (ix) complaints forms; and (x) patient and member handbooks. We recognize and appreciate the agencies' proposal to provide optional methods in which a covered entity may be deemed to be compliant with these requirements including the option for individuals to opt out of receipt of the Notice of Availability and the documentation of the individual's primary language and any appropriate auxiliary aids and services. We are however concerned that the compliant administration of these optional methods could be administratively difficult to operationalize and prone to errors that could potentially cause members not to receive the appropriate notifications as intended. We further recognize that in certain settings such as in the provider setting more frequent distribution of the content of these notices may be necessary to prevent barriers to access to care. Health plans however have a long-term and ongoing relationship with their members. In addition once we learn of a member's need for language assistance and/or auxiliary aids often at the time of enrollment we are able to address those needs in future communications with the member. Consequently in the health plan setting we believe the proposed distribution requirements of the Notice of Availability taglines far exceed what is needed to

(b)(5)

The Health Plan of West Virginia, Inc.

and tagline requirements. In particular the Proposed Rule requires revenue penalties to notify the public of the availability of language assistance services replacing the "tagline" requirement with a Notice of Availability requirement that also requires a notice of the availability of auxiliary aids and services) in English and the top 15 most common languages spoken by LEP individuals in the relevant state or states. 87 Fed. Reg. at 42853-54, 47815. But rather than provide the required notices in all "significant" communications or publications as required by the 2016 Rule HHS proposes that the notice of nondiscrimination and notice of availability be provided on an annual basis displayed prominently on the covered entities' website and physical locations and upon request. HHS also proposes that the notice of availability be provided in specifically identified documents and communications including for example application and intake forms Health Insurance Portability and Accountability Act (HIPAA) notices notices of denial or termination of eligibility benefits or services including Explanations of Benefits notices of appeal and grievance rights consent forms communications relating to a person's rights and benefits among others. 87 Fed. Reg. at 42854-47915-16. This proposal strikes a reasonable balance between the 2016 Rule's efforts to improve access to health programs and services for LEP individuals and the 2020 Rule's concerns regarding cost and administrative burden. It also provides clear guidance to covered entities as to the information that must be conveyed under what circumstances notices must be provided and how the information must be provided or otherwise made available. Although the Proposed Rule does not include the 2016 Rule's broad requirement that taglines be provided in all "significant" communications or publications the list of documents and communications in which the notice of availability must be provided is comprehensive. Ventures ambiguity and confusion as to what constitutes a "significant" communication or publication and will help ensure that

(b)(5)

Attorneys General of California, New York, Massachusetts, and nineteen other States

Medicare Beneficiaries with LEP] The MAPD regulations also differ from proposed § 92.11 with respect to which documents plans are required to provide the notices. The MAPD regulations include 20 plus documents that must provide the insert while proposed § 92.11(c)(5) identifies only ten types of documents. In cross referencing both lists we believe the vast majority of documents under the MAPD regulations would be included in the proposed ten categories but there are some ambiguities. For example provider directories and drug formularies are identified in the MAPD regulations, however it is unclear whether and where these critical documents would be encompassed under 92.11(c)(5). [Footnote 10: This depends on whether HHS's interpretation of § 92.11(c)(5)(x) "patient and member handbooks" is inclusive of these types of directories. If it is we recommend HHS clarify this in the regulatory text by adding these specific documents.] Similarly the MAPD regulations include documents specific to the Medicare program and Medicare plans like the Annual Notice of Change (ANOC). [Bold: For provider directories and prescription drug formularies we recommend HHS enumerate those in § 92.11(c)(5) of the final rule.] These are documents that are not unique to Medicare and are some of the most useful and important documents to understanding health coverage. [Bold: We also recommend HHS review all of the documents identified in the MAPD regulations and cross walk any that are not included under the current § 92.11(c)(5) to the final implementing regulation for Sec. 1557.] HHS should enumerate any additional documents in the final rule that are not specific to Medicare as well as provide MAPD plans with the final cross-walk to explain that the lists in the MAPD regulations and in Sec. 1557 are not in conflict. MAPD plan members should continue to receive critical information about the availability of key consumer protections or vital plan documents that list of documents should not be reduced because HHS has implemented a separate regulation with a similar

(b)(5)

Justice in Aging

OCR requests comment about the proposed list of documents that the notice must accompany. We believe this list strikes an appropriate balance though we emphasize that it should be seen as a minimum rather than a maximum in terms of covered entities' obligation to inform consumers about the availability of language access services. The 2016 rule did not have a list of documents but rather noted that they should be appended to "significant documents" and we are aware that this led to divergent interpretations by covered entities who attached taglines to documents that were not necessarily significant to most consumers. Therefore we support the proposed list with a requested addition below but note the OCR continue to clarify that covered entities can and in some circumstances should go beyond the list. We encourage OCR to add communications about access to medical services to the documents required to include the notice of availability. Specifically we believe that information related to drug formularies or provider networks should include the notice. This information is vital for the ability of people with LEP to access the medical care they need whether it is understanding what drugs are available to them at what cost as well as how to find a doctor that best meets their needs.

(b)(5)

National Immigration Law Center

8. Clarify that Section § 92.11 Notice of availability of language assistance services and auxiliary aids and services applies to participation in clinical research. Specifically section § 92.11(c)(5)(iv) should be revised to read: Consent forms and instructions related to medical procedures or operations] and clinical research participation] medical power of attorney or living will (with an option of providing only one notice for all documents bundled together.) Currently clinical research commonly excludes people with limited English proficiency from clinical trials without explanation or just flat out resulting in discrimination. [Footnote 5: Muthukumar AV Morrell W Bierer BE. Evaluating the frequency of English language requirements in clinical trial eligibility criteria. A systematic analysis using ClinicalTrials.gov. PLoS Med. 2021 Sep 14;18(9):e1003758.]

(b)(5)

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard. [MRCT Center.]

We also suggest that OCR develop and provide covered entities with model notices and translated information in the relevant languages that will be needed across the country. These notices should relate to the different types of publications they are included in: that is a notice would likely be different for a consent form versus information about a public health emergency versus a notice about one's rights or benefits.

National Health Council

(b)(5)

In terms of the range of documents covered by the requirement we believe the list of written communications to which this particular notice applies is comprehensive and we are pleased to see the proposed rule's specificity. People with LEP will not receive the full benefits of any communication if it does not contain this notice so it is important not to leave "loopholes" allowing important communications to skip this notice.However we urge OCR to expand the list of covered communications by making clear that [the] provider directories must contain these notices | Otherwise LEP consumers who are selecting a plan may not be able to absorb the information they require to choose a plan that meets their needs The likely inadvertent failure of the proposed rule to add provider directories to the list of covered documents illustrates a broader problem [Build: The final rule should add a catch all category requiring that every document that a covered entity is legally required to provide shall include this notice] prominently displayed on the document's first page Otherwise people with LEP will be denied equal access to the benefits that policymakers sought to provide when they promulgated the requirement.

(b)(5) UnidosUS

While we support §§ 92.10 and 92.11 including a revised notice requirement that does not require a 1557 notification to be sent out with every patient/member contact and requires the notice of auxiliary services and supports in a specified list of significant communications we make the following additional recommendations to ensure that the proposed notice requirement is as effective as intended:• The § 92.10 and § 92.11 notices should be posted not only in locations where individuals seeking services will be able to see or hear them but also be posted prominently where friendly employees can see them and be trained to use them to communicate the rights described to those individuals with communication or cognitive disabilities who face evident barriers to seeing hearing or understanding the notice without auxiliary aids or services or other means of assistance.• Covered entities must inquire about the communication needs of members/beneficiaries and record their needed auxiliary aid or service in the electronic health record so that they can consistently receive effective communication from the covered entity.• The § 92.11 Notice should be visually distinguishable through the use of large sans serif print that is a minimum of size 18 font.• The regulation itself should explicitly clarify that any request for all written communications to be rendered in alternative formats or in LEP languages necessarily include but are not limited to the first set of significant communications in subsection 92.11(c)(2).• The critical importance of clear communication in health care settings warrants the inclusion of a requirement that covered entities in determining what is an appropriate auxiliary aid or service should give primary consideration to the requests of the person with a disability

(b)(5) Disability Rights Maine

to require covered entities to provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states These notices must be provided:• In alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication• To plan participants beneficiaries enrollees and applicants and members of the public in alternate formats on recorded audio or video tapes• On an annual basis to these persons and upon request at any time• In clear and prominent physical locations where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice and in a conspicuous location on the covered entity's health program or activity website (if applicable)• Along with a specified list of electronic and written communications.The Proposed Rule provides alternative methods by which a covered entity would be deemed in compliance with this provision including providing individuals on an annual basis the option to opt out of receipt of the notice Recommendations • BCBSA recommends that covered entities be given the option of distributing the Notice of Availability at the time of initial enrollment upon request and in the following documents:• Individual health insurance contracts and group health plan booklet/certificates • The notice of nondiscrimination required by proposed § 92.10 incorporated with the annually required notices like WHCRA notice The notice of Health Insurance Portability and Accountability Act (HIPAA) privacy practices described in 45 CFR 164.520• Complaint forms and patient and member handbooks• BCBSA recommends that if the Final Rule requires covered entities to provide notices with Explanations of Benefits (EOBs) that covered entities should be given the option of only including the notice of availability of language with those EOBs that notify individuals of a cost-sharing responsibility while maintaining the safe harbor of

(b)(5) Blue Cross Blue Shield Association

the Notice of Availability taglines as a single document] The proposed rule requires the Notice of Availability to accompany the following documents: (i) the notice of nondiscrimination; (ii) the notice of privacy practices; (iii) application and intake forms; (iv) notices of denial, termination, or of eligibility benefits or services including explanations of benefits (EOBs) and notices of appeal and grievance rights; (v) communications relative to a person's rights eligibility benefits or services that require or request a response from a participant beneficiary enrollee or applicant; (vi) communications related to a public health emergency; (vii) consent forms and instructions related to medical procedures or operations medical power of attorney or living will; (viii) discharge papers; (ix) complaints forms; and (x) patient and member handbooks We recognize and appreciate the agencies' proposal to provide optional methods in which a covered entity may be deemed to be compliant with these requirements including the option for individuals to opt out of receipt of the Notice of Availability and the documentation of the individual's primary language and any appropriate auxiliary aids and services We are however concerned that the compliant administration of these optional methods could be administratively difficult to operationalize and prone to errors that could potentially cause members not to receive the appropriate notifications as intended.We further recognize that in certain settings such as in the provider setting more frequent distribution of the content of these notices may be necessary to prevent barriers to access to care Health plans however have a long-term and ongoing relationship with their members In addition once we learn of a member's need for language assistance and/or auxiliary aids often at the time of enrollment we are able to address those needs in future communications with the member. Consequently in the health plan setting we believe the proposed distribution requirements of the Notice of Availability taglines far exceed what is needed to

(b)(5) The Health Plan of West Virginia, Inc.

OCR requests comment on whether the notice of availability could be limited to any accompany explanations of benefits (EOB) in which consumers may owe a portion of the cost We do not support this proposal which could be confusing to people with LEP. An EOB is not a bill and does not have the primary purpose of informing consumers of their cost sharing responsibilities An EOB with no cost sharing is still an opportunity for patients to understand what care they received and how much was paid for it including any future payment obligations For example if a patient receives an EOB for services that are fully covered because they have reached their deductible in the next calendar year they may have to pay the full cost with their deductible reset. If an EOB is a significant document it should make no difference whether cost sharing may be required in the context of whether a person should understand their options for language assistance However we would support approach that allows for covered entities to omit the notice of availability on repeated services with recurring charges such as a required monthly visit for an ongoing course of treatment In those cases the EOB is duplicative and the notice of availability would have little value add for the consumer.

National Immigration Law Center

2. Expand on "availability of language assistance services and auxiliary aids and services" to include plain language and screen reader capabilities Information pertaining to health is not typically provided in an easily understood format which leads to confusion when accessing and utilizing health care services The use of plain language in healthcare should be at the forefront of all healthcare communication. For the more all information presented on a virtual platform needs to be accessible for a screen-reader Understanding health information is critical for people with disabilities to fully access accurate health care We agree with HHS's general approach to clarifying the requirements for when this notice must be made available and providing individuals with the opportunity to opt out of receiving these notices

The Arc of Pennsylvania

Justice in Aging

(b)(5)

(b)(5)

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(b)(5)

We support the pathways for covered entities to opt out of the notice through an explicit opt-in process by consumers or by providing all information in a person's preferred language and recorded in the patient's medical record. We encourage OCR to conduct robust oversight to ensure that covered entities are not encouraging or pressuring people to opt-out. We also encourage OCR to clarify what it means for an entity "provides all materials and communications in that individual's primary language" using robust standards for how materials and communication are delivered in these circumstances.

(b)(5)

Italics Opt Out Provision Properly Balances the Importance of the Notices with Minimizing Unnecessary Costs]Finally the MAPD regulations do not contain an opt out provision as is proposed in § 92.11(d)(1). We believe the proposed opt out provision properly balances the importance of providing individuals with LEP and people with disabilities with critical information about their rights and the potential burdens on covered entities large and small to provide such information. This is particularly true if HHS adds a five percent service area threshold trigger until the languages required and includes the MAPD regulations' documents under 92.11(c)(5) as doing so potentially increases the number of languages and documents that require the notices of availability. Therefore for simplicity, Bold we support including the proposed opt out provision in the final rule and applying it to Medicare plans as well. In addition providing an opt-out with appropriate guardrails for all healthcare consumers will be easier to administer and minimize confusion for consumers who may not understand why they can opt out of such notices in one context but not in Medicare. With respect to how the opt-out provision operates we appreciate the clarity around individuals who opt out retaining the right to ask for translated documents on a case by case basis. We also appreciate that the opt out not filed or and process be required annually. We recommend HHS similarly clarify in the final rule that an individual can opt back in to receiving the notice of availability or a relevant documents at any time (not only annually).

National Immigration Law Center

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availability of auxiliary aids and services within the language not be required under proposed § 92.11. In general research on health and healthcare outcomes when people with communication disabilities such as speech, language voice and/or hearing don't receive effective communication is not as well-developed as research on the impact on LEP individuals often do not receive health and health care information in the language they use. Nonetheless the Joint Commission has long recognized people with communication disabilities among patient groups that require additional support and effective communication to achieve equitable access to healthcare. The National Health Interview Survey did not even include a specific question about communication disabilities until 2012. When that data was analyzed in 2019 the authors concluded that people with communication disabilities "represent 10% of the US population have high rates of healthcare utilization and experience significant disparities in health and healthcare outcomes." Another study is currently recruiting subjects to investigate the efficacy of two interventions for alleviating poor patient-provider communication that contribute to the healthcare inequities experienced by people with communication disabilities. The growing body of research coupled with existing complaints and litigation certainly warrants having language notices in significant communications that are consistent with inclusive of people with disabilities and increases their ability to receive effective communication in healthcare thereby ensuring healthcare inclusive and their health and economic consequences. The key is making sure that notices are sufficiently brought to the attention of people who have disabilities that can interfere with typical ways of reading and understanding the content of the notice. Covered entities need to have active obligations to notify members and beneficiaries of their right to request effective communication and auxiliary aids and services including recording granular information about disability function and accommodation needs in electronic

Justice in Aging

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No comments are associated with this issue

Disability Rights Maine

The Notice of Availability taglines as a single document]. The proposed rule requires the Notice of Availability to accompany the following documents: (i) the notice of nondiscrimination, (ii) the notice of privacy practices, (iii) application and intake forms, (iv) notices of denial or termination of eligibility benefits or services including Explanations of Benefits (EOBs) and notices of appeal and grievance rights; (v) communications related to a person's rights eligibility benefits or services that require or request a response from a participant beneficiary enrollee or applicant; (vi) communications related to a public health emergency, (vii) consent forms and instructions related to medical procedures or operations medical power of attorney or living will; (viii) discharge papers; (ix) complaint forms; and (x) patient and member handbooks. We recognize and appreciate the agencies' proposal to provide optional methods in which a covered entity may be deemed to be compliant with these requirements including the options for individuals to opt out of receipt of the Notice of Availability and the documentation of the individual's primary language and any appropriate auxiliary aids and services. We are however concerned that the compliant administration of these opt out methods could be administratively difficult to operationalize and prone to errors that could potentially cause members not to receive the appropriate notifications as intended. We further recognize that in certain settings such as in the provider setting more frequent distribution of the content of these notices may be necessary to prevent barriers to access to care. Health plans however have a long term and ongoing relationship with their members. In addition once we learn of a member's need for language assistance and/or auxiliary aids often at the time of enrollment we are able to address those needs. In future communications with the member. Consequently in the health plan setting we believe the proposed distribution requirements of the Notice of Availability taglines far exceed what is needed to

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The Health Plan of West Virginia, Inc

Italics The Benefits of Providing Notice Outweigh the Costs] The greater purpose of Sec. 1557 and these regulations is to prevent discrimination in the first place and ensure meaningful access to high-quality necessary health care and 1755. We agree with HHS that benefits of this rule include reducing obstacles to accessing care by requiring covered entities to provide language and communications access and train their employees on policies and procedures. Without meaningful access individuals with LEP and/or disabilities are more at risk of negative health outcomes. In addition to this real harm to individuals which must not be minimized in considering the costs of the rule erroneous diagnoses poorer health outcomes and inefficiencies (e.g. more time rescheduling appeals) imposes costs on the entire healthcare system like providers and payers including those subsidized under Medicare and Medicaid. It takes time to educate the public on any type of law or regulation. The best way to ensure that effective education is through repetition. When an older adult receives a notice that a gender-affirming service has been denied for example or is told that the clinical tests showed nothing is wrong or is misunderstood because a qualified interpreter was not offered they will probably be frustrated and feel wronged but they may not recognize what they experienced as discriminatory or understand their right to challenge it as such. The proposed notice of nondiscrimination and notice of availability are key in filling this information gap for individuals and to enforcement of the law. Someone who is aware of their rights because they have been repeatedly notified can both proactively enforce those rights and challenge violations. This enforcement in turn is key to better health care for the individual and to ending systemic discrimination and the disparities it produces.

Justice in Aging

Notice of Availability of Language Assistance Services and Auxiliary Aids and Services §92.11]WPHCA strongly supports the provisions and the requirements for when this notice must be made available. We also recommend that if a covered entity operates across multiple states that the covered entity must provide the notice in not merely the top 15 languages in the aggregate ((that is across all the states) but rather a total of the top 15 languages in each state. Since 2015 WPHCA has advocated for covered entities operating across multiple states to provide notice in the top 15 languages in each individual state. WPHCA also suggests that OCR develop and provide covered entities with model notices and translated information in the relevant languages that will be needed across the country. These notices should relate to the different types of publications they are included on, that is a notice would likely be different for a consent form versus information about a public health emergency versus a notice about one's rights or benefits.

Wisconsin Primary Health Care Association

The notice should also be in large print for people with visual impairments. CLI suggests that OCR develop and provide covered entities with model notices and translated information in the relevant languages that will be needed across the country. CLI recommends that the rule require the notice be provided at the beginning or on the first page of any document

to require covered entities to provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states. Those notices must be provided: • In alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communications. • To plan participants, beneficiaries, enrollees, and applicants and members of the public, via telephone, translations of recorded audio or video clips, on an annual basis to these persons and upon request at any time. • In clear and conspicuous physical locations where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice and in a conspicuous location on the covered entity's health program or activity website (if applicable). • Along with a specified list of electronic and written communications. The Proposed Rule provides alternative methods by which a covered entity would be deemed in compliance with this provision, including providing individuals on an annual basis the option to opt out of receipt of the notice. Recommendations: • BCBSA recommends that covered entities be given the option of distributing the Notice of Availability at the time of initial enrollment, upon request, and in the following documents: ○ Individual health insurance contracts and group health plan booklet/certificates. ○ The notice of nondiscrimination required by proposed § 92.10. Incorporated with the annually required notices like WHCRA etc. ○ The notice of Health Insurance Portability and Accountability Act (HIPAA) privacy practices described in 45 CFR 164.520. ○ Explanation of benefit forms and patient and member handbooks. • BCBSA recommends that if the Final Rule requires covered entities to provide notices with explanations of benefits (EOBs), then covered entities should be given the option to carry out this requirement by including the notice of availability of language assistance with those EOBs that would be sent to individuals of cost-sharing responsibility while maintaining the safe harbor of

In addition to more detailed recommendations below to ensure consistency and the strongest available protections for people with Medicare, BCBSA recommends that HHS require covered entities to also include a large print notice of availability (minimum of 18-point font) in English at the beginning of any document listed in proposed § 92.11(c)(5). | To help ensure the notice of availability is as informative as possible and to assist covered entities in complying with this section, we also suggest that HHS develop and provide covered entities with model notices that are tailored to the different types of communications they are included in. For example, a notice of availability should include a statement that a response is required or that the communication contains information about one's rights or benefits.

[redacted] under the requirements of § 92.11 or related authorities in the Medicare Advantage program and harmonize potential inconsistencies with policies that are most protective of the individual with LEP." |Footnote 6: Although our discussion centers on harmonizing proposed § 92.11 with Medicare Advantage and Part D regulations, we encourage HHS to review other federal regulations already in effect that may overlap with § 92.11 and other parts of the proposed Sec. 1557 implementing regulations.| Over 53 million older adults and people with disabilities are enrolled in a Medicare Advantage or Medicare Part D plan (MAPD). |Footnote 7: CMS, Medicare Advantage Last Page, Demand Prescription Drug Plan Monthly Contract Summary Report | Data from Sep. 2022 | available at www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareadvpartdenrolldata/monthly-contract-summary-2022-09.| The MAPD regulations (42 C.F.R. §§ 422.2267(e)(31) and 423.2267(e)(33)) mandate that these plans provide a multi-language insert (MLI) notifying enrollees that the plan provides free interpreter services. |Footnote 8: 42 C.F.R. § 422.2267(e)(31) governs Medicare Advantage and 42 C.F.R. § 423.2267(e)(33) governs Medicare Part D plans. The MLI states: "We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks [language] can help you. This is a free service." It must be provided in 15 languages as well as any additional language that meets a five percent (5%) service area threshold. |Footnote 9: The required languages are Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.| Plans also have the discretion to include the MLI in additional languages below the threshold. The MLI is required for over 20 documents as set forth under 42 C.F.R. § 422.2267(e)(31) and § 423.2267(e)(33), including the Evidence of Coverage, Explanation of Benefits, Formulary, Provider/Pharmacy

There are at least four key ways the proposed notice of availability differs from what is currently required by MAPD regulations: (a) the content of the insert/notice, (b) on what documents the notice/insert is required, (c) what languages the insert/notice is made available and (d) the availability of an opt-out mechanism. We believe that the MLI can be subsumed within the Sec. 1557 notice of availability in a way that is still protective of individuals with LEP, while also reducing confusion and easing compliance efforts for MAPD plans. We make recommendations to address each of the specific differences below. | Rules Subsuming the MLI in the Notice of Availability Is Appropriate Given the Overlapping Content | By assuming the MLI with the notice of availability makes sense because of their overlapping content. The MLI does not require information about the availability of appropriate auxiliary aids and services a key improvement between proposed § 92.11 and what was previously required in the 2016 tagline requirement. Awareness of the availability of auxiliary aids and services is critical to ensuring effective communication and access to services for older adults and people with disabilities. In contrast, the availability of language assistance services is part of both the MLI and proposed § 92.11. Therefore, we believe that HHS should clarify that MAPD plans should be deemed compliant with both Sec. 1557 and the MAPD regulations as long as they are providing notices of availability that contain the contents as set forth in proposed § 92.11(a). Doing so will alleviate the burden on both consumers and plans. Consumers will not be flooded with partially overlapping notices and MAPD plans can follow Sec. 1557 notice requirements while also fulfilling essentially what is required under 422.2267(e)(31) and 423.2267(e)(33). This approach also comports with the notion that Sec. 1557 is an anti-discrimination rule for health programs and activities.

[redacted] Medicare Beneficiaries with LEP | The MAPD regulations also differ from proposed § 92.11 with respect to which documents plans are required to include the notices. The MAPD regulations include 20 plus documents that must include the insert while proposed § 92.11(c)(5) identifies only ten types of documents. In cross-referencing both lists we believe the vast majority of documents under the MAPD regulations would be included in the proposed ten categories but there are some anomalies. For example provider directories and drug formularies are identified in the MAPD regulations, however it is unclear whether and where these critical documents would be encompassed under 92.11(c)(5). |Footnote 10: This depends on whether HHS's interpretation of § 92.11(c)(5)(x) "patient and member handbook" is inclusive of these types of directories. If it is we recommend HHS clarify this in the regulatory text by adding these specific documents. | Similarly the MAPD regulations include documents specific to the Medicare program and Medicare plans like the Annual Notice of Change (ANOC). |Build: For provider directories and prescription drug formularies we recommend HHS enumerate those in § 92.11(c)(5) of the final rule. | These are documents that are not unique to Medicare and are some of the most useful and important documents to utilizing health coverage. |Build: We also recommend HHS review all of the documents identified in the MAPD regulations and crosswalk any that are not included under the current structure of § 92.11(c)(5) to the final implementing regulation for Sec. 1557. HHS should enumerate any additional documents in the final rule that are not specific to Medicare as well as provide MAPD plans with the final crosswalk to explain that the lists in the MAPD regulations and in Sec. 1557 are not in conflict. MAPD plan members should continue to receive critical information about the availability of key consumer protections or vital plan documents that list of documents should not be reduced because HHS has implemented a separate regulation with a similar

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Blue Cross Blue Shield Association or

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barriers owning and accessing the taglines that were required under the 2016 rule which resonable this notice. First covered entities often placed tagl nes at the end of letters some of which exceeded ten pages. As a result people with LEP would often only see the first page of the document written in English and discard it. We heard this with respect to notices received by consumers during the ACA enrollment process notifying them of data match errors or potential termination of coverage due to nonresponse or nonpayment of premiums. Therefore we request that OCR require covered entities to either place the notice on the first page of any document and in the case of physical mail on the envelope. Combined with our recommendation that taglines be more specific and actionable prominent placement would be expected to lead to action by the recipients rather than hidden at the end. We also heard that consumers were frustrated by the lack of information contained in the taglines about what the document related to and the immediacy of its urgency. For example OLR's current model tagline provides no context about the document it is accompanying but rather just notes the availability of language services and associated telephone number. [Footnote 23 "Sample Covered Entity Tagline Informing individual with Limited English Proficiency of Language Assistance Services" Department of Human Services Office for Civil Rights https://www.hhs.gov/sites/default/files/sample-notice-tagline-english.pdf. Because consumers received frequent mailings from doctors and insurance companies without context a person with LEP would be unable to know which require action and which are primarily informational and can be discarded without negative consequences. Therefore we believe that OLR should require that notices should not be static across all covered entities' communications but rather provide some context as to the documents' contents or action requested. For example a notice that will result in termination of coverage without action should say as

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Overall we encourage OCR to work with consumers covered entities and other federal agencies to develop additional efficient ways to inform individuals with LEP about their language access rights and options. For example visual cues are extremely important for people with lower literacy levels. In fiscal year 2022 Congress funded the Office of Minority Health [OMH] to "do research develop and test methods of informing limited english proficient [LEP] individuals about their rights and the availability of language access services." [Footnote 24 H.R. 4502 "Departments Of Labor Health And Human Services And Education And Related Agencies Appropriations Bill 2022" Report 117-96 117th Congress https://www.congress.gov/117/crpt/hrpt96/CRPT-117hrpt96.pdf] In its proposed fiscal Year 2024 Health and Human Services funding bill the House clarifies the intent of this research is to "develop a universal symbol that accompanies only a phone number or similar information could be prominently placed on consumer-facing documents websites and notices about the availability of language access services." [Footnote 25 H.R. 8295 "Departments Of Labor Health And Human Services And Education And Related Agencies Appropriations Bill 2024" H. Rept. 118-403 118th Congress https://www.congress.gov/118/crpt/hrpt403/CRPT-118hrpt403.pdf]. We strongly encourage OCR to work with OMH to develop this new symbol as another option beyond the proposed notice of availability to inform people with LEP of the availability of language access services.

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large print at least 18 point font as well as the top 15 languages. This would assist individuals with vision impairments to understand the importance of the notice. As OCR has previously done we also suggest that OCR develop and provide covered entities with model notices and translated information in the relevant languages that will be needed across the country. We also recommend that OCR specify that this notice must be provided at the beginning or on the first page of any document. Unfortunately many documents in which this notice will be required can be lengthy. We do not believe a person with LEP would look through multiple pages of a document in English if the notice is only at the end. Given the importance of this notice we believe it should be the first page that everyone sees. This will benefit LEP individuals who will see information in their language and also individuals with disabilities who will see information in large print up front as well. We also suggest that OCR develop and provide covered entities with model notices and translated information in the relevant languages that will be needed across the country. These notices should be tailored to the different types of publications they are included in. That is a notice would likely be different for a consent form versus information about a public health emergency versus a notice about one's rights or benefits AAPI women often face [Hyperlink: multiple barriers to care, https://www.kff.org/racial-equity-and-health-policy/fact-sheet/health-coverage-of-immigrants/#:~:text=Barriers%20to%20Health%20Coverage%20Men%20enrollment%20among%20eligible%20individuals.] beyond language access. Long work hours caregiving responsibilities and household finances can often take precedence over health care especially when communication is an additional burden. Clear and transparent notices of available language services in clinics and health care programs lifts a large burden off of AAPI women with LEP and gives them the confidence to seek health care without the fear of miscommunication. We also recommend that OCR require covered entities to require the notice include a large print statement in at least 18-point font in addition to the top 15 languages. This will assist individuals with vision impairments to understand the importance of the notice.

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National Asian Pacific American Women's Forum

A primary goal of the Affordable Care Act and Massachusetts's own health reform law Chapter 58 of the Acts of 2006 was to expand coverage to individuals that had previously struggled to obtain and maintain health insurance coverage including many immigrants and people for whom English is not a first language. OCR's proposal to restore meaningful access for LEP individuals will promote access to information about how to enroll in health coverage and how to navigate the health care system.

National Health Council

Language access for individuals with limited English proficiency. Language access is essential to ensuring effective communication between individuals and the health care system without which individuals with limited English proficiency (LEP) may not enroll in programs for which they are eligible may not receive timely or comprehensive health care and may not know their rights to free timely and competent language services. For individuals who are not proficient in English language differences often compound existing barriers to accessing appropriate care. LEP often makes it difficult to navigate an already complicated health care system or understand medical or insurance terminology. For these reasons we strongly support the provision relating to notice of language assistance services. We recommend that OCR specify that this notice must be provided at the beginning or on the first page of any document. Unfortunately many documents in which this notice will be required can be lengthy. We do not believe a person with LEP would look through multiple pages of a document in English if the notice is only at the end. As OCR has previously done we also suggest that OCR develop and provide covered entities with model notices and translated information in the relevant languages that will be needed across the country. We also support the inclusion of a definition of machine translation and recognition that machine translation of critical information must be reviewed by a qualified human translator to ensure accuracy and comprehension. According to census data between 2012 and 2016 approximately half a million Massachusetts residents speak limited English. Our organizations hear firsthand the difference linguistically appropriate assistance makes to populations with LEP. The HCFA Helpline provides health insurance enrollment and education services in English Spanish Portuguese Haitian-Creole and French. Over half the calls handled on the helpline are taken in a language other than English. Access to coverage and care for limited English speakers creates additional challenges to an already

Massachusetts Health Connector

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Health Care For All

Beyond barriers of notice content and placement we urge OCR to require that these notices be made available on the first page of each of the documents described. We routinely hear from our community based affiliates about challenges that individuals with LEP face navigating through English language forms or reading through English language paperwork to locate critical information in Spanish. We also urge [the] OCR to require tailored notices depending on the type of document to make clear when failing to respond to the communication could cause serious harm. For example among the written communications required to provide notices are those "related to a person's rights eligibility benefits or services that require or request a response" from an individual. OCR should develop model notices for different types of written communications and make these available to covered entities.

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Finally the NHC requests that CMS engage affected communities including patients and their representatives to codevelop understandable information and identify the best ways to communicate rights and responsibilities in ways that meet them where they are and in a manner that will be useful.

Further we recommend that OCR specify the notice or tagline be provided at the top or on the first page of any document. Many documents under this provision will be lengthy. We believe that less LEP patients will see through multiple pages of a document in English and therefore may not see a notice about language assistance services that is placed at the end. For those who live in areas where there are a lower percentage of non-English speakers the availability of taglines at the top of the document ensures that all individuals know where to access information in the language they feel the most comfortable

covered entities to collect additional data beyond those required by the referenced statutes and their regulations or race ethnicity language sex gender gender identity sexual orientation disability and age in part so that such entities could better plan how to meet the needs of those populations. Specifically HHS seeks comment on whether covered entities are already collecting disaggregated demographic data in their health programs and activities and if so for which categories of data through what systems and at what cost. And finally HHS seeks comment on how a civil rights data collection requirement could impact current data collection efforts either positively or negatively. HHS seeks comment on whether the adoption of a regulatory standard for a recurring civil rights data collection would benefit civil rights enforcement as well as how frequently the data should be submitted. STS is deeply committed to the elimination of bias and disparities in healthcare in general and specifically in cardiothoracic surgery. Equitable access to cardiothoracic surgical care is fair just and would optimize patient outcomes across all patient demographics. STS appreciates the goal of HHS to reduce healthcare disparities to advance health equity. However we believe there are significant barriers to data collection that produces clear usable data. At this time there are no widely adopted national industry standards for the collection of race ethnicity and language (REAL) data or social determinants of health (SDOH) data. For example the Office of Management and Budget (OMB) classifies race as "White Black/African American American Indian/Alaska Native Asian Native Hawaiian/other Pacific Islander" and ethnicity as Hispanic/Latino or Non-Hispanic/Latino. While our organization utilizes the standards set by the Office of Management and Budget (OMB) in our own data collection efforts we feel this limiting and in need of modernization. OMB leading advocates have pointed out that existing standards do not account for the variation that exists within groups. As a result racial and ethnic group disaggregation has been limited. Demographic data collection. The collection of language data especially disaggregated data is important both for developing effective policies and procedures to provide language access and assure civil rights enforcement. A growing number of farmworkers are from indigenous communities in Mexico and Guatemala. Each community speaks a distinct language but there is little information about the prevalence of indigenous languages in rural communities. To ensure covered entities are providing services equitably OCR must require the collection of demographic data from program participants to monitor goals and address disparities.

comment on the data collection piece WPCA encourages HHS to utilize existing data collection systems to minimize provider burden. The request for information mentions whether some covered entities as recipients of Federal financial assistance are already collecting disaggregated demographic data in their health programs and activities and in what systems as well as at what cost. A FQHCs are required to submit data through an annual reporting system called the Uniform Data System (UDS). FQHCs report data on utilization patient demographics insurance status managed care prenatal care and birth outcomes diagnoses and financing.Beginning in 2024 HRSA will implement an enhanced UDS system UDS+ to allow Community Health Centers to submit CY2025 data. UDS+ will move from patient-oriented tables aggregated at the Community Health Center level to more patient level data. The data will show the breakdown of most outcomes by demographics and incorporate social drivers for the need for social services by demographics. Community Health Centers will continue to report data that includes race ethnicity language gender gender identity sexual orientation and age which are suggested in this data collection section. While disability status is not currently slated to be collected in UDS+ we know that HRSA is working closely with ONC on data standards and that disability is one of the elements in United States Core Data for Interoperability v3 [embedded hyperlink text [https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#uscdi-v3)]. It is unclear in the future if would satisfy the data ONC wants in its goals to improve equity in terms of reporting burden Community Health Centers are happy to provide this data to HRSA which takes approximately 288 total hours [embedded hyperlink text [https://omb.report/icr/202305-0915.001)] a year to fully complete the UDS report. Besides reporting these data Community Health Centers are ensuring they come into compliance with Fast Healthcare Interoperability Resources [FHIR] to allow healthcare information to be easily

request for comment on the data collection piece [Red TPCA encourages HHS to utilize existing data collection systems to minimize provider burden.] The request for information mentions whether some covered entities as recipients of Federal financial assistance are already collecting disaggregated demographic data in their health programs and activities and in what systems as well as at what cost. A FQHCs are required to submit data through an annual reporting system called the Uniform Data System (UDS). FQHCs report data on utilization patient demographics insurance status managed care prenatal care and birth outcomes diagnoses and financing.Beginning in 2024 HRSA will implement an enhanced UDS system UDS+ to allow Community Health Centers to submit CY2025 data. UDS+ will move from patient-oriented tables aggregated at the Community Health Center level to more patient level data. The data will show the breakdown of most outcomes by demographics and incorporate social drivers for the need for social services by demographics. Health centers will continue to report data that includes race ethnicity language gender gender identity sexual orientation and age which are suggested in this data collection section. While disability status is not currently slated to be collected in UDS+ we know that HRSA is working closely with ONC on data standards and that disability is one of the elements in United States Core Data for Interoperability v3 [embedded hyperlink text [https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#uscdi-v3)]. It is unclear in the future if would satisfy the data ONC wants in its goals to improve equity in terms of reporting burden health centers are happy to provide this data to HRSA which takes approximately 288 total hours [embedded hyperlink text [https://omb.report/icr/202305-0915.001)] a year to fully complete the UDS report. Besides reporting these data Community Health Centers are ensuring they come into compliance with Fast Healthcare Interoperability Resources [FHIR] to allow healthcare information to be easily exchanged between by implementing

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Farmworker Justice

The Society of Thoracic Surgeons

Farmworker Justice

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Mountain Primary Health Care Association

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Tennessee Primary Care Association

request for comment on the data collection piece | Rod: MNACHC encourages HHS to utilize existing data collection systems to minimize provider burden.": The request for information inquires whether some covered entities as recipients of Federal financial assistance are already collecting disaggregated demographic data in their health programs and activities and in what systems as well as at what cost. All FQHCs are required to submit data through an annual report ng system (also called the Uniform Data System (UDS). FQHCs report data on utilization patient demographics insurance status managed care prenatal care and birth outcomes diagnoses and financing. Beginning in 2024 HRSA will implement an enhanced UDS system UDS+ to allow health centers to submit CY2023 data. UDS+ will move from pattern-oriented tables aggregated at the health center level to more patient level-data. The data will show the breakdown of most outcomes by demographics and incorporate social drivers for the need for social services by demographics. Health centers will continue to report data that includes race ethnicity language gender gender identity sexual orientation and age which are suggested in this data collection section. While disability status is not currently slated to be collected in UDS+ we know that HRSA is working closely with ONC on data standards and that disability is one of the elements in [underlined/grey: United States Core Data for Interoperability v1]. Its inclusion in the future would satisfy the data ONC wants in its goals to improve equity in terms of reporting burden health centers are happy to provide these data to HRSA which [underlined/grey: takes approximately 238 total hours] a year to fully complete the UDS report. Besides reporting these data health centers are ensuring they come into compliance with Fast Healthcare Interoperability Resources [FHIR] to allow healthcare information to be easily exchanged between by implementing electronic health records [EHR] platforms. Given these considerations we appreciate HHS to allow FQHCs to opt out of submitting data and encourage OCR

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Minnesota Association of Community Health Centers

In response to the Department's inquiry we encourage the Department to require covered entities to collect and report comprehensive disaggregated data to ensure civil rights enforcement and allow for better resources to address health disparities and inequities [Footnote 36: Id. at 47856]. Data collection should include, race ethnicity language age disability sex sexual orientation gender identity and pregnancy status. As these data can reveal deeply sensitive information we urge the Department in consultation with relevant agencies such as the National Institute of Standards and Technology and Federal Trade Commission to require that data collection use storage and sharing is consistent with best practices for sensitive data and adopts the principles of privacy and security by design in order to ensure providers and patients are protected from data breaches and are not targeted for civil criminal or immigration enforcement. We also urge the Department to share any gaps or limitations they encounter in creating and implementing such requirements.

Senate Democrats

Democratic Data Collection or DCD recommends that the proposed rule require covered entities collect demographic data on program participants to monitor gaps and disparities. The collection of language data is important to the development of policies and procedures to provide language access. The establishment of demographic data collection as a function of civil rights monitoring is critical.

Genesee County Legal Aid Society dba Center for Civil Justice

The population groups that experience significant health disparities. They engage in preventive care at lower rates than recommended and report unmet healthcare needs. They may or may not go without recommended care for a variety of reasons including disability related access barriers such as provider inaccessibility lack of accessible medical diagnostic equipment and lack of necessary accommodations in healthcare settings. Health and healthcare disparities are compounded when disability intersects with race ethnicity gender identity and age. The prevalence of disability increases with age and is especially high where age intersects with multiple marginalized identities reflecting other systemic and historic barriers to healthcare experienced by these groups. Disability like race ethnicity and gender identity is a bona fide demographic category. Therefore health plans and providers should be collecting disability status information voluntarily provided by patients as a core demographic data element. This collection of data will serve at least three critical goals which are not necessarily listed here in order of priority. First for the purposes of Section 1557 and clearly identified in the preamble to the proposed rule disaggregated service delivery and complaint data is vital to ensuring civil rights compliance. Second collecting disability status using granular functional limitation questions will allow for better measurements of health equity the relationship between disability and social determinants of health and more comprehensively support efforts to achieve health equity for this demographic group. And third functional limitation information in Electronic Health Records [EHRs] will help providers to identify patients' need for accommodations during clinical visits and hospitalizations. Ideally increasing the likelihood that accommodations needed for equally effective healthcare will be provided in a timely and consistent way. The Maine CDC will be collecting data for other demographic categories does not collect data for those with disabilities. For disability data the "how" of obtaining data is

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Disability Rights Maine

1.0 Data Collection [Preamble]: The Preamble notes that HHS considered but did not include a provision requiring covered entities to collect additional civil rights data such as data on sex gender gender identity and sexual orientation from patients and health care providers. The Preamble requests comments on a range of issues related to such a data collection requirement. Recommendation: BCBSA appreciates HHS's recognition of current challenges around accurate SOGI data at this time and recommend that HHS support industry standard data collection efforts across all healthcare stakeholders prior to any mandated compliance requirements. Rationale: Today the collection of social determinants of health (SDOH) data elements including SOGI data varies greatly based on available data sets and line[s] of business. The development of national standards and technical implementation guides are necessary to drive care management efficiency and leverage clinical data to improve patient outcomes. To foster the deployment of digital analytics and tools to further this effort BCBSA and BCBS Plans are actively engaged in industry-led efforts such as the HL7 Gravity Project a multi-industry effort to reduce current barriers to integration and interoperability of social risk data into clinical decision making to improve health outcomes while increasing safeguards and privacy protections to enhance the appropriate use of sensitive consumer information.

Blue Cross Blue Shield Association

availability of disaggregated demographic data supports the Department's enforcement efforts. We therefore commend the Department for recognizing the critically important role demographic data plays in recognizing understanding and addressing discrimination and health disparities. However we are concerned the Department does not at minimum require covered entities to collect disaggregated demographic data. Better national standards and uniform data collection practices could have an outsized impact on efforts to narrow health disparities. HHS must require demographic data collection based on multiple demographic variables including sex race ethnicity primary language age gender identity sexual orientation and disability status. At the community and population levels these variables both individually and in combination can reveal health disparities. For example racial and ethnic minority women receive poorer quality care than racial and ethnic minority men who receive poorer care than White men. Spanish-speaking Hispanics experience poorer quality care than English-speaking Hispanics who experience poorer care than non-Hispanic Whites. Compared to women without disabilities women with disabilities are more likely not to have regular mammograms or Pap tests. Racial and ethnic minorities with disabilities experience greater disparities in diagnoses and utilization of assistive technology. Within the AANHPI designation there are innumerable variations in health status across disease categories languages and variances in the impact of social determinants of health. At minimum data disaggregation between Asian American Native Hawaiians and Pacific Islanders should be standardized for covered entities. American Indians and Alaskan Native demographic data also needs to be standardized; there is a false perception that these groups exclusively access care in rural and/or tribal settings but a significant proportion of American Indians and Alaskan Natives are in urban areas as well. While investigations of alleged discrimination sometimes focus on variations based on a single

(b)(5)

Alliance of Multicultural Physicians

(b)(5)

We support continued efforts to encourage covered entities to collect data on care to protected populations to ensure compliance and prioritize effective program planning. We share HHS's understanding that high quality and comprehensive data is critical to measure disparities, adequately tailor health care services and ensure that covered entities comply with the statute. We urge HHS to continue to emphasize the importance of data collection to covered entities, encourage them to collect data as part of routine compliance and program design, and when necessary, request data from covered entities to evaluate their compliance.

(b)(5) — U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

[Bold: Demographic Data Collection is Critical to Civil Rights Enforcement.] The Proposed Rule acknowledges that demographic data collection and civil rights enforcement are inextricably linked. We agree and recommend that HHS adopt a demographic data collection requirement and establish demographic data collection as a function of civil rights monitoring. Demographic data collection requirements should align with the demographic characteristics enumerated within the rule (race, ethnicity, language, disability, age, sex, sexual orientation, gender identity, pregnancy status, and sex characteristics) and allow for intersectional analysis. HHS should incorporate existing data collection practices and engage in additional research where necessary. While covered entities should be required to request demographic data, individuals' responses must be voluntary and should be self-reported to ensure accuracy and privacy. HHS must also ensure that data collected is maintained safely and securely by the appropriate entities and implement strict standards to make clear that data cannot be used for negative actions such as immigration or law enforcement, redlining, or targeting of specific groups. Additionally, HHS should provide appropriate training and technical assistance resources to programs and grantees, including training on how to explain why data is being collected. These protections will help to ensure that data collected can be best utilized to prevent discriminations and disparities in healthcare and access.

Center for Elder Law & Justice

of disaggregated demographic data supports the department's enforcement efforts. We commend the department for recognizing the critically important role demographic data plays in addressing discrimination and health disparities. [Footnote 18: Fed. Reg. at 47856-7.] However, we are concerned the department does not at minimum require covered entities to collect disaggregated demographic data. Better national standards and uniform data collection practices could have an outsized impact on efforts to narrow health disparities. HHS must require demographic data collection based on multiple demographic variables, including sex, race, ethnicity, primary language, age, gender identity, sexual orientation, or disability status. At the community and population levels, these variables both individually and in combination can reveal health disparities. For example, racial and ethnic minority women receive poorer quality care than racial and ethnic minority men who receive poorer care than White men. [Footnote 19: Rosaly Correa-de-Araujo et al. Gender differences across racial and ethnic groups in the quality of care for acute myocardial infarction and heart failure associated co-morbidities. Women's Health Issues 44 (2008); Ann F. Chou et al. Gender and racial disparities in the management of diabetes mellitus among Medicare patients. Women's Health Issues 150 (2007).] Spanish-speaking Hispanics experience poorer quality care than English-speaking Hispanics who experience poorer care than non-Hispanic Whites. [Footnote 20: Eric M. Cheng, Alex Chen & William Cunningham. Primary language and receipt of recommended health care among Hispanics in the United States. J. General Internal Medicine 283 (2007). C. Annette DuBard & Ziya Gizlice. Language spoken and differences in health status, access to care, and receipt of preventive services among U.S. Hispanics. Am. J. Public Health 2073 (2008).] Compared to women without disabilities, women with disabilities are more likely not to have regular mammograms or Pap tests. [Footnote 21: Marguerite E. Diab & Mark V. Johnston. Relationships between level

The Leadership Conference on Civil and Human Rights

Data Collection: The NPRM HHS acknowledges that demographic data collection and civil rights enforcement are inextricably linked. We agree. Therefore, we recommend that HHS adopt a demographic data collection requirement and establish demographic data collection as a function of civil rights monitoring. Demographic data collection requirements should align with the demographic characteristics enumerated within the rule (race, ethnicity, language, disability, age, sex, sexual orientation, gender identity, pregnancy status, and sex characteristics) and allow for intersectional analysis among multiple demographic characteristics. We support the more detailed comments on data collection submitted by the National Health Law Program.

(b)(5) — Justice in Aging

[Bold: Making DD Visible in Healthcare Data.] [Hyperlink: Currently https://www.iecare.org/making-idd-visible] many people with IDD are poorly identified (or "not visible") in typical healthcare data such as insurance claims or electronic medical records and charts. Based on our preliminary data of national insurance claims and Epic's Cosmos database of electronic health records, the observable prevalence of IDD in typical healthcare data is a fraction (~10-25%) of what would be expected based on monitoring data from the Centers for Disease Control and Prevention (the National Health Interview Survey and other surveys of adults. This is likely due to a combination of factors (under-screening and diagnosis, lack of self-disclosure among adults and loss of clinical history during care transitions such as adolescence into adulthood.) These data gaps pose a foundational barrier to: [1] addressing disparities in access and quality of care, [2] measuring and improving quality of care; (3) understanding true national cost and outcome patterns among people with IDD; (4) effectively targeting services and supports (some unlabeled "people with" DD hence currently manifest as "high cost high need" patients because their underlying needs aren't being met); [5] creating credible business cases for stakeholder investments in IDD care, and [6] drawing sustained clinical attention to this large and growing population.

Institute for Exceptional Care

= SOGI Data Collection: BCBSA supports HHS's recognition of current challenges around accurate gender sexual orientation and gender identity (SOGI) data at this time, but not mandating their collection.

Blue Cross Blue Shield Association

Data Collection: We encourage OCR to consider provisions requiring the collection of data on individuals' preferred written and spoken language in the Final rule. This data is important for both providing meaningful access for individuals with LEP as well as for OCR policymakers and advocates to understand potential trends in the provision of services that may indicate discrimination. Covered entities will find it difficult to develop language access protocols if they do not have an assessment of their current population's language preferences both for written and oral communication. As discussed above because patients may have companions who are LEP this data should also be collected in the case of agencies accepting applications for health coverage such as Exchanges and state Medicaid agencies. Language information should be collected about all household members not just the primary applicant as is the practice today. Data on a person's written language preferences would also be required by an entity that wishes to opt out of the proposed notice (if available) by providing all communications in language. We encourage OCR to require covered entities to maintain and report disaggregated data on the language preferences of their users. The COVID-19 pandemic has revealed the layers of failure in our public health system when it comes to demographic data collection including the lack of systematic policies. In particular in the event of a potential civil rights discrimination investigation OCR should be able to require covered entities to identify trends in their services by language preferences. For example if people whose preferred language is not English are not utilizing interpreters or appointments that may indicate a provider's failure to inform individuals about their language access options.

(b)(5) — National Immigration Law Center

[Bold and Underline: Data Collection] NACDS urges OCR not to move forward with a requirement for covered entities to collect additional demographic data. Collecting and transmitting data is costly and burdensome to organizations. As OCR recognizes in the proposed rule the federal government is already collecting a wide variety of demographic data through various reporting requirements. Considering the razor thin margins on which pharmacies must operate we have serious concerns about the feasibility of pharmacies collecting and transmitting additional patient demographic data especially in light of the fact that much of the same data is most likely already being collected by various federal agencies.

National Association of Chain Drug Stores

(b)(5)

[Bold: Request for Information re: Data Collection]We appreciate HHS' attention to this important issue of data collection. We believe that comprehensive and stratified data collection on HCBS would be invaluable and we recommend that HHS adopt a demographic data collection requirement and establish demographic data collection as a function of civil rights monitoring.Another way for HHS to better systematically collect data on disability status in health care is to address the need for standard disability data elements in electronic health records (EHRs). The electronic health record (EHR) is an essential tool in linking demographic and clinical data within and across health care systems and public health databases. Data collected within the EHR is crucial to understanding and addressing inequities that negatively impact health and health care outcomes of marginalized communities including people with disabilities. The lack of standardized collection of patients' disability status within EHRs has obscured our understanding of health inequities for people with disabilities and inhibited solutions.

3) Data Collection. Data is foundational to achieving any population-based behavioral health or health equity goal, maximizing as well as ensuring civil rights compliance by covered entities. Better national standards and uniform data collection practices could have an outsized impact on efforts to narrow health disparities. Yet complete data collection remains largely unavailable for many groups at risk of greater risk of discrimination in healthcare settings and insurance coverage. HHS has an opportunity to enhance cross-agency data-sharing, analysis and reporting that are essential to the agency's core public health functions. Such information can aid efforts to better understand the nexus between social determinants of health, civil rights compliance and health equity. APA commends HHS for recognizing the critically important role demographic data plays in addressing discrimination and health disparities [Footnote 14: Fed. Reg. at 47856]. However we are concerned the final rule does not require covered entities to report disaggregated demographic data. The Department considered including such a provision but instead chose to create a dynamic and responsive civil rights data collection structure through the Office of Civil Rights using existing authorities [Footnote 15: Page 47857]. We urge the Department to reconsider this decision. At minimum the final rule should require disaggregated race ethnicity and disability data collection and reporting by covered entities. The Department should consult with these groups on effective strategies for ensuring the availability and dissemination of data that all agree is crucially needed to protect civil rights and achieve health equity.

Accordingly APA recommends that HHS develop an action plan to enhance data collection relevant to effective Section 1557 enforcement that includes the following elements:o Prioritization of meaningful engagement of external stakeholders professional associations and members of communities that have experienced historic social and economic marginalization.o Integration of behavioral health indicators and analysis into the newly established data collection.o Collaboration with health equity offices across HHS as well as with federal agencies responsible for safety net programs to ensure adequate collection of data to inform policies that address underlying social determinants of health.

HHS require covered entities to collect standardized data on race ethnicity language sex gender gender identity sexual orientation disability status and age. As HHS noted in its request for comments effective data collection can play a vital role in ensuring civil rights compliance yet that data remains largely unreflected for many demographic subgroups. HHS has further noted the potential difficulty in requiring covered entities to collect such sensitive data. Covered California welcomes the chance to comment on this proposal from the perspective as an active partner with extensive experience balancing the administrative and financial burdens on QHP issuers with the benefits of collecting and utilizing demographic data. Specifically Covered California is focused on increasing the accuracy and completeness of its demographic data in order to enable and assess health care disparity interventions.Covered California would welcome this data collection requirement as a first step to streamlining our special data collection. While Covered California is committed to collecting a range of demographic data elements to inform our health equity work the manner in which we do so is disjointed and confusing to our consumers due to constraints from federal law and guidance. Currently Covered California provides individuals who apply for coverage through the single streamlined application the ability to answer [optional] questions identifying their race and ethnicity but is prohibited from requiring the questions [Footnote 11: 42 U.S.C. 18081(g) currently limits the collection of information from applicants to only the information strictly necessary to authenticate identity determine eligibility and determine the amount of credit or reduction]. The optional nature of this question results in unreliable response rates and incomplete data. Covered California also has limited ability to collect information on an applicant's disability status which we are only able to collect if an applicant is applying for financial assistance in order to determine if they may qualify for Medi-Cal coverage for a reason outside of. Comments associated with this issue are included in the subsections below.

The Colorado Health Foundation is a private foundation committed to improving the health and well being of all Coloradans. We are guided by a vision of making Colorado the healthiest state in the nation through grantmaking public policy initiatives available or private sector engagement and communications outreach. The Foundation supports the nondiscrimination provisions in this proposed rule as an important step toward eliminating the limitations that were placed on 1557 protections in 2020 reinstating protections that were previously in place and further strengthening them in order to ensure that all individuals are free from discrimination when accessing health care services.

[Bold and Italics: Discrimination Prohibited §92.101(a)(Italic: The AAMC strongly supports the proposal to restate the core objective of Section 1557 to generally prohibit discrimination on the basis of race color national origin sex age or disability against any individual seeking to participate in or receive benefits of [a] covered entity's health program or activity."] [Footnote 2: Id. at 47857 58]

Furthermore we support consistency with Federal civil rights law and civil rights enforcement as cited by HHS that such protections prohibit discrimination based upon a person's actual or perceived race color national origin sex age or disability.

3) HHS must finalize provisions without delay that protect against discriminations in health care programs and activities. In the above-captioned rule HHS is proposing several provisions that would reinstate safeguards that protect against discrimination in covered health care programs and activities as outlined in Section 1557 of the ACA. These proposed provisions include reinstating the scope of Section 1557 clarifies application to health insurance issuers receiving federal financial assistance prohibits discrimination in clinical algorithms used to support decision-making and that nondiscrimination provisions are applicable to services offered through telehealth technologies. HHS is right to propose these provisions and ANA urges the agency to finalize this proposed rule.ANA is an informed and active stakeholder in the implementation of health care policy. ANA sees the proposed rule effectively undoing what we saw as the 2020 rulemaking instituting a fundamental change in direction that is antithetical to our principles of health system transformation namely universal access to health care coverage for all citizens and residents. We are pleased that HHS would return key definitions and protection mechanisms that make Section 1557 meaningful, to all especially to people who otherwise face discriminatory barriers to care. This is acutely important as nurses and the health care delivery system focus on achieving health equity and identify approaches to overcome health disparities.We believe that existing regulations for Section 1557 and other HHS programs fulfill the intent of Congress to protect people from discrimination in health care that denies their access.Section 1557 should be implemented in a manner that promotes access for those who are subject to discrimination. [Bold: As such HHS must finalize proposed Section 1557 provisions that protect against discrimination in health care programs and activities. We urge HHS to act expeditiously on this rulemaking]

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National Disability Rights Network

(b)(5)

American Psychological Association

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American Psychological Association

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Covered California

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The Colorado Health Foundation

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Association of American Medical Colleges (AAMC)

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American Nurses Association

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Cincinnati Children's Hospital Medical Center

American Academy of Family Physicians

Colorst

Alliance of Multicultural Physicians

Genesee County Legal Aid Society dba Center for Civil Justice

38 Members of Congress

Eating Disorders Coalition for Research, Policy & Action

(b)(5)

Alliance of Multicultural Physicians

Justice in Aging

Center for Reproductive Rights

(b)(5)

National Immigration Law Center

(b)(5)

Chairs fighting diversity equity and inclusion (DEI) and living out every day is fundamental to who we are at Cincinnati Children's. More importantly it's who we aspire to be a place where everyone feels welcome safe valued and respected.These proposed changes would restore and strengthen nondiscrimination protections and improve access to care for millions of people If these proposed changes are adopted they will promote the health equity of Black Indigenous and people of color and increase access to coverage and care for those historically underserved because of race ethnicity language age disability and sex Discrimination has no place in health care and it is critical that you move forward with these protections to secure access to care free from any discrimination or prejudice.

Prohibited Discrimination (§ 92.101) and Application (§ 92.2)Under the rule protections against discrimination extend to a person's actual or perceived race color national origin sex age and/or disability. HHS is proposing to clarify that discrimination on the basis of sex includes the basis of sex stereotypes characteristics including intersex traits pregnancy or related conditions sexual orientation and gender identity [Bold: The AAFP agrees with this definition of prohibited discrimination and the clarification that sex-based protections include sexual orientation gender identity sex stereotypes and pregnancy related conditions]

Subpart B—Nondiscrimination Provisions] Discrimination Prohibited (§ 92.101)It is encouraging to see the Department recognize in the preamble to the NPRM that people may experience discrimination on the basis of sex in health care on more than one basis. It would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. We propose the following change to section 92.101(a)[1]:"Except as provided in Title I of the ACA an individual must not on the basis of race color national origin sex age or disability [bold underline or any combination thereof] be excluded from participation in be denied the benefits of or otherwise be subjected to discrimination under any health program or activity operated by a covered entity." This language should also be added to sections 92.207[a] [b][1] and [b][2].

The Proposed Rule Addresses Various Forms of Systemic Racism in Health Care The Department properly notes that racial health disparities in the United States are directly attributable to "persistent bias and racism" in the healthcare system. Both intentional and unintentional race discrimination serve as barriers to care lead to lower quality care and drive worse health outcomes for communities of color. Discrimination in health care is often systemic — deeply embedded within the policies procedures and practices of covered entities to say nothing of the social determinants of health outside of healthcare systems. The Proposed Rule addresses several major drivers of systemic racism including anti-discrimination policies and procedures algorithmic discrimination and discriminatory health insurance networks. Each of these are a critical step toward addressing the ways in which racism manifests systemically in health care.

Discrimination ProhibitedCCJ supports the intersectional nature of Section 1557 (a) [Bold: Clarifying how the Department will handle intersectional claims] Some claimants will have intersecting claims of discrimination in healthcare. We encourage the Department to unambiguously state the inclusion of protections for intersectional cases in section 92.101(a)(1) and sections 92.207(a) [b][1] and [b][2].

Discrimination Prohibited [§ 92.101](It is encouraging to see the Department recognize in the preamble to the NPRM that people may experience discrimination in health care on more than one basis. It would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. We propose the following change to sect.or 92.101(a)(1):"Except as provided in Title I of the ACA an individual must not on the basis of race color national origin sex age or disability [bold/underlined: or any combination thereof] be excluded from participation in be denied the benefits of or otherwise be subjected to discrimination under any health program or activity operated by a covered entity."This language should also be added to sections 92.207(a) [b][1] and [b][2].

The Proposed Rule Addresses Discriminatory Conduct that Disproportionately Impacts Communities of Color Federal law has prohibited race discrimination in health care since the passage of Title VI of the Civil Rights Act of 1964. However Title VI does not apply to all healthcare related activities and programs nor does it apply to all forms of discrimination in health care. Section 1557 therefore fills in a critical gap by extending anti-discrimination protections to patients at the intersection of multiple identities. The Proposed Rule prescribes many forms of discrimination that amplify the impacts of racism and subject people to due discrimination. For example the Proposed Rule seeks to eliminate discrimination against Limited English Proficient (LEP) individuals and people living with disabilities — groups that are predominately comprised of people of color. Likewise Section 1557 proscribes sex discrimination in health care and the Proposed Rule clarifies that "sex discrimination" includes discrimination on the basis of sexual orientation and gender identity. Both cisgender women of color and LGBTQI+ people of color face racism in healthcare that is amplified by their gender sexual orientation or gender identity. As discussed further below the Proposed Rule restricts discriminatory conduct against these groups thus improving health care access for people of color with multiple systemically marginalized identities. Protection of people's rights can only occur when we see and understand their diverse selves and the Proposed Rule recognizes this.

Discrimination Prohibited [§ 92.101](We strongly support this proposed section nullifying specific forms of discrimination that are prohibited. Below we discuss the importance of these protections for older adults and recommend changes to further strengthen this provision

[Bold: VIII. The proposed rule restores the proper scope of Section 1557's nondiscrimination protections.' We support the proposed rule's restoration of the scope of application of Section 1557's nondiscrimination protections which were severely curtailed by the 2020 rule. The 2020 Rule narrowed its scope of application of nondiscrimination protections to the narrowest possible set of entities falling short of its statutory authority in its interpretation of section 1557 and jeopardizing patient access to care. The Department should restore application of Section 1557's nondiscrimination protections to its original scope ensuring that a greater number of patients will be able to benefit from Section 1557's nondiscrimination protections.

Discrimination Prohibited [§ 92.101](We support the restoration of protections against sexual orientation and gender identity discrimination including protections against discrimination on the basis of association and in the provision of gender affirming care. We endorse the comments on the topic submitted by the National Center for Lesbian Rights and write separately to highlight intersectional concerns affecting LGBTQI+ immigrants LGBTQI+ people face persecution in many countries where their identities may be criminalized. Many are survivors of sexual or other violence and they are often persecuted or rejected by their families. Compared with asylum seekers who report persecution for other reasons asylum seekers who report persecution due to the LGBTQI+ identity are more likely to have experienced sexual violence persecution as children persecution by family and suicidal ideation. Many LGBTQI+ immigrants to the U.S. are survivors of torture based on their sexual orientation or gender identity.1 These experiences result in both physical and mental health needs that can be exacerbated by experiences of discrimination and social isolation in the U.S Like other LGBTQI+ individuals immigrants frequently confront stigma and discrimination in accessing health care. These barriers are compounded by restrictions on immigrants' eligibility for health care affordability programs and limited access to culturally competent and identity affirming care. One study of older adults found that LGBTQI+ individuals who were foreign-born experienced more socioeconomic disadvantage and more barriers to accessing health care than those born in the U.S. Protecting LGBTQ + immigrants from discrimination based on all aspects of their intersectional identities is an essential step in promoting culturally competent care that improves access quality of care and ultimately health outcomes

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We also support strong enforcement of section 1557 and the Department's recognition in the preamble that the law protects people who experience intersectional discrimination. This encompasses individuals who experience health care discrimination at the intersection of two or more protected characteristics (for example some combination of sexism (e.g. people who are pregnant or capable of pregnancy or LGBTQI+) racism xenophobia (e.g. people with limited English proficiency (LEP)) ableism or ageism. We urge the Department to provide greater clarity in the final rule regarding the protections and enforcement mechanisms available for intersectional discrimination under section 1557. For example the Department should amend the proposed regulatory text at § 92.101(a)(1) to clarify that intersectional discrimination is prohibited. Specifically we recommend the provision to be amended as follows: [a] Rules. General. (1) Except as provided in Title I of the ACA an individual must not on the basis of race color national origin sex age disability or any combination thereof be excluded from participation in be denied the benefits of or otherwise be subjected to discrimination under any health program or activity operated by a covered entity. In addition §92.301 should ensure that the Department will have clear and accessible procedures for individuals to file and the agency to investigate and remediate discrimination complaints including intersectional discrimination complaints. The Department should also make clear throughout the final rule that Section 1557 creates a health-specific anti-discrimination cause of action that is subject to a single standard regardless of a plaintiff's protected class or classes.

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Center for Reproductive Rights

[Bold: C. Proposed § 92.101 appropriately codifies the broad sweep of the ACA's sex discrimination prohibition. [Bold: 1. We strongly support proposed § 92.101's broad approach and encourage HHS to affirm these clarifications. We strongly support the broad yet express but not exhaustive description of covered grounds of discrimination including sex-based discrimination in proposed section 92.101. We suggest two clarifications to this language [and related language in other provisions]. In section 92.101(a)(1) add the phrase "or any combination or thereof" after "disability." In section 92.101(a)(2) Add the phrase "including termination of pregnancy" after "related conditions." -- Add the phrase "transgender status" after "sexual orientation."

InterACT Advocates for Intersex Youth

The addition of intersectional discrimination is much appreciated and we feel it would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. We propose the following change to section 92.101(a)(1):[1] "Except as provided in Title I of the ACA an individual must not on the basis of race color national origin sex age or disability [would or any combination thereof] be excluded from participation in be denied the benefits of or otherwise be subjected to discrimination under any health program or activity operated by a covered entity."

Howard Brown Health

[Bold: § 92.101 Discrimination Prohibited: Proposed § 92.101(b)(1)] It applies regulations implementing Section 504 of the Rehabilitation Act to health programs or activities that receive federal financial assistance State Exchanges and Federally Facilitated Exchanges. Specifically the proposed section incorporates by reference 45 C.F.R. Parts 84 and 85 regulations pertaining to program accessibility. We support HHS' general goal of explicitly incorporating into paragraph [a] the specific prohibitions on discrimination found in each of the civil rights laws on which Section 1557 is grounded. We think this approach is prudent given that some health care entities may not be readily familiar with the specific regulatory standards and obligations that apply to them under Section 504 and the Americans with Disabilities Act ["ADA"]. However care must be taken not to incorporate standards that do not fully reflect the requirements of Section 1557 or the changes the ACA brought to nondiscrimination in health care. We are specifically concerned that the incorporation of 45 C.F.R. § 84.22 85.42 Section 504's regulations pertaining to the accessibility of existing facilities will create inconsistencies regarding the obligations of covered entities. Additionally we object to the incorporation of § 84.23(c) which applies an outdated standard [the Uniform Federal Accessibility Standards] to new construction.

National Disability Rights Network

It is encouraging to see the Department recognize in the preamble to the NPRM that people may experience discrimination that is simultaneously related to multiple identities. However I would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. As such we propose the following change to section 92.101[a][1]:"Except as provided in Title I of the ACA an individual must not on the basis of race color national origin sex age or disability [should or any combination thereof] be excluded from participation in be denied the benefits of or otherwise be subjected to discrimination under any health program or activity operated by a covered entity." Should this addition be adopted this new sex language should also then be added to sections 92.207(a) (b)(1) and (b)(4) to ensure consistency.

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Equitas Health

No comments are associated with this issue.

We appreciate the rule's specificity regarding sex discrimination on the basis of sex which is proposed to include discrimination on the basis of sex stereotypes sex characteristics including intersex traits pregnancy or related conditions sexual orientation or and gender identity.

JRAC

The direct attention to nondiscrimination on the basis of sex limited English proficient (LEP) individuals and people with disabilities and the clarification of the specific measures that are anticipated to comply with Section 1557 are welcome. Specifically we support the major clarifications in the rule. • The interpretation of Section 1557 to cover all health programs and activities administered by HHS. • The interpretation that provision of Medicare Part B assistance is federal financial assistance and that entities receiving Medicare Part B funds must comply with the Rule. • The application to health insurance issuers that receive federal financial assistance. • The clarification that the protections against discrimination on the basis of sex as including sexual orientation and gender identity and discrimination on the basis of sex stereotypes and the extension of these protections to CMS regulations. • The expectation that compliance will require implementing programs to develop maintain and communicate clear policies and train on the provision of language assistance services for limited English proficient (LEP) individuals and effective communication and reasonable modifications to policies and procedures for people with disabilities. • The requirement that implementing entities provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states. • The expectation of nondiscrimination based on clinical algorithms. • The expectation that nondiscrimination extends to telehealth services and • The development of clear processes for requesting exceptions from the expectation of compliance.

Multi Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard [MRCT Center]

Championing diversity equity and inclusion [DEI] and living our every day is fundamental to who we are at Cincinnati Children's. More importantly it's who we aspire to be—a place where everyone feels welcome safe valued and respected. These proposed changes would restore and strengthen nondiscrimination protections and improve access to care for millions of people. If these proposed changes are adopted they will promote the health equity of Black Indigenous and people of color and increase access to coverage and care for those historically underserved because of race ethnicity language age disability and sex. Discrimination has no place in health care and it's critical that you move forward with these protections to secure access to care free from any discrimination or prejudice.

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Cincinnati Children's Hospital Medical Center

Discrimination Prohibited: (1) supports the intersectional nature of Section 1557.

Genesee County Legal Aid Society dba Center for Civil Justice

We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law including Titles: Price Waterhouse v. Hopkins and Bostock v. Clayton County] makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity including transgender status. It is essential that this rule track those decisions to provide assurance to participants beneficiaries and enrollees and not cause covered entities that those bases are inadequately included. We also support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex-based.

Eating Disorders Coalition for Research Policy & Action

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Dispariti es for LGBTQ+ Older Adu lts|We strongly su pport the proposed broad regulatory language to prohibit discri mination on the basis of sex that specifi cally includes discrimination on the basi s of sex stereotypes sex characteri stics including intersex traits sexual ori entation and gender identity [Sec. 92.101] LGBTQI+ older adults experience pronounced health disparities and higher poverty rates compared to their heterosexual and cisgender peers due in large part to historical and ongoing discri mination. Among LGBT+ over the age of 50 more than one in ten have been denied healthcare or were provided with inferior care; forty-seven percent of these older adults have a disabili ty. [Footnote 8: LGBT Health Ratio Disparities and Aging by the Numbers SAGE https://sti.u.com/lgbtag sgcenter/docs/sage_equity_infographic [2013].]There is signi ficant evide nce that discrimination in health care contri butes to these disparities. LGBTQ+ older adults may be deni ed care or provided inadequate care or they may be afraid to seek necessary care for fear of mistreatment. For exam ple many LGBTQ+ elders and their loved one's experience discri mination in long term care facilities rang ng from verbal and physical harassment to being de nied basic care such as a shower to visi ting restrictions and isolation to being improperly discharged or refused admission. Transgender older adults in particular experience discrimination in coverage of medically necessary care related to gender transition as well as in coverage of laboratory tests and treatments associated with one's gender. Transgender people of color face signi ficant barriers to health care access from denials of gender affirming care to medical abuse. [Footnote 9: Protecting and Advancing Health Care for Transgender Adult Communities The Center for American Progress https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/ [2017].] Few physicians have the requisite knowledge and comfort level to provide transgender treatment because it is not

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Center for Elder Law & Justice

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Center for Reproductive Rights

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Pennsylvania Health Insurance Exchange Authority d/b/a Penn

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Academy of Managed Care Pharmacy (AMCP)

Association of American Medical Colleges (AAMC)

prevent a retrogression of rights |Retrogression is a backwards step in law or policy that impedes or restricts the enjoyment of a right. The principle against retrogression is given effect on the obligation of governments to ensure constant forward progress in realizing rights. |Footnote 110: International Covenant on Economic Social and Cultural Rights adopted Dec. 16 1966 art. 2 para. 1 G.A. Res. 2200A (XXI) U.N. GAOR 21st Sess. Supp. No. 16 U.N. Doc. A/6316 (1966) 993 U.N.T.S. 3 [entered into force Jan. 3 1976].] In the context of sexual and reproductive health in particular the Committee on Economic Social and Cultural Rights ("CESCR") – the Committee overseeing implementation of International Covenant on Economic Social and Cultural Rights ("ICESCR") – has provided specific examples of measures which would be retrogressive. "Footnote 111 Committee on Economic Social and Cultural Rights General comment No. 22 (2016) on the right to sexual and reproductive health (article 12 of the International Covenant on Economic Social and Cultural Rights) para. 48 U.N. Doc. E/C.12/GC/22 (2016).' These include "legal and policy changes that reduce oversight by States of the obligation of private actors to respect the right of individuals to access sexual and reproductive health services." |Footnote 112: Id. Other examples of retrogressive measures include the removal of sexual and reproductive health medications from national drug registries; laws or policies revoking public health funding for sexual and reproductive health services; imposition of barriers to information on goods and services relating to sexual and reproductive health; and enacting laws criminalizing certain sexual and reproductive health conduct and decisions.|The United States is currently experiencing a retrogression of reproductive rights of which the overturn of [Italics: Roe] is just the latest and most extreme example. Over the last decade states across the country have engaged in a retrogression of abortion rights. This has occurred within the context of a retrogression of civil rights overall. For exa

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Center for Reproductive Rights

Boston Children's Hospital has always been and always will be committed to providing the best care for all of our patients including patients of all gender identities and sexual orientations. The belief that all patients deserve the opportunity to live grow and thrive with love and support is foundational to who we are and what we do. We strongly support the Administration's proposal to strengthen protections for LGBTQ+ people by providing clear protections on the basis of sexual orientation and sex characteristics and improving protections on the basis of gender identity.

Boston Children's Hospital

provisions relating to discrimination on the basis of sex. HHS is proposing to ensure equal access to health care programs or the basis of sex and prohibit discrimination based on marital family and parental [including termination of pregnancy] status along with gender identity and sexual orientation. ANA holds that these protections are vital and urges the Agency to finalize these provisions. At the same time ANA encourages HHS to utilize nurses and their expertise to ensure compliance with these important protections. ANA and its members strongly believe that discrimination has no place in nursing practice education or research. There is no place in health care and nurses strongly believe that all patients be treated equally respectfully and with civility.[Footnote 2: The Nurse's Role in Addressing Discrimination: Protecting and Promoting Inclusive Strategies in Practice Settings Policy and Advocacy. American Nurses Association. 2018. https://www.nursingworld.org/~4ab207/globalassets/practiceandpolicy/nursing-excellence/ana-position-statements/social-causes-and-health-care/the-nurses-role-in-addressing-discrimination.pdf. Accessed September 2022] This is especially important to safeguard access for people who often face multiple barriers to care. Including LGBTQI+ individuals. For these individuals sex discrimination may have specific harm in health care such as coverage limitations and encounters with providers who deny them care based on their gender identity or sex-stereotyped characteristics. ANA is in the process of issuing a statement on gender affirming care which demonstrates the association's strong position against policies that restrict or criminalize care to this vulnerable patient population. [Footnote 3: American Nurses Association. American Nurses Association Opposes Restrictions on Transgender Healthcare and Criminalizing Gender-Affirming Care. 2022. Unpublished Statement]. We thus these protections providers and payers can deny care to transgender persons and to other LGBTQI+ patients based on sex stereotyping. This crucial work complements

American Nurses Association

[Bold: VIII. The proposed rule restores the proper scope of Section 1557's nondiscrimination protections.] We support the proposed rule's restoration of the scope of application of Section 1557's nondiscrimination protections which were severely curtailed by the 2020 rule. The 2020 Rule narrowed its scope of application of nondiscrimination protections to the narrowest possible set of entities falling short of its statutory authority in its interpretation of Section 1557 and jeopardizing patient access to care. The Department should restore application of Section 1557's nondiscrimination protections to its original scope ensuring that a greater number of patients will be able to benefit from Section 1557's nondiscrimination protections.

Center for Reproductive Rights

The proposed rule will reduce barriers and increase access to health care for LGBTQI+ individuals who have long faced discrimination in health care settings. We strongly support HHS's clarification in the proposed rule that discrimination on the basis of sex includes discrimination on the basis of sexual orientation or gender identity. LGBTQI+ people face both health disparities and barriers to accessing health care reporting poorer overall health being more likely to acquire a disability and experiencing refusal of care or blame for their condition from health care providers [Footnote 2: National Academies of Sciences Engineering and Medicine. Understanding the Well-Being of LGBTQI+ Populations [Oct. 21 2020]; Lambda Legal. When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV [2010].] Studies have found such discrimination to be associated with mental and physical health harms for LGBT people. [Footnote 3: Cornell University. What Does the Scholarly Research Say about the Effects of Discrimination on the Health of LGBT People? (2013); https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-scholarly-research-say-about-the-effects-of-discrimination-on-the-health-of-lgbt-people/] (accessed Sept. 26 2022).] Discrimination on the basis of sexual orientation and gender identity is considered a form of sex-based discrimination under the Supreme Court's Bostock v. Clayton County decision and formally incorporating Bostock into the final rule will increase access to health care and lead to improved health outcomes. [Footnote 4: Bostock v. Clayton County Georgia 590 U.S. 140 S. Ct. 1731 (2020).] We urge HHS to finalize this provision adopting a uniform more expansive description of prohibited sex discrimination (such as the proposed § 92.101)

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U.S. House Committees on Energy and Commerce Ways and Means and Education and Labor

c. [Bold: Intersectional Discrimination] As discussed above one of Section 1557's most groundbreaking aspects was its creation of protections against intersectional discrimination. While we appreciate HHS's focus on unlawful intersectional discrimination in the preamble HHS must clarify Section 1557's intersectional protections throughout the regulatory text. HHS should strengthen the text of proposed § 92.101(a)(1) to the effect.RECOMMENDATION: Amend the text of proposed § 92.101(a)(1) to read as follows: Except as provided in Title I of the ACA an individual must not on the basis of race color national origin sex age [Italics: or] disability [Italics: or any combination thereof] be excluded from participation in be denied the benefits of or otherwise be subjected to discrimination under any health program or activity operated by a covered entity.

Physicians for Reproductive Health

Accordingly APA recommends that HHS and short on to the definition of prohibited sex discrimination at § 92.101(a)(2) as follows: "Discrimination on the basis of sex includes but is not limited to discrimination or the basis of sex stereotypes; sex characteristics including intersex traits; [Italics: and]: pregnancy or related conditions including termination of pregnancy and transgender status]."

American Psychological Association

prohibited sex discrimination under Section 1557. [We urge the Department to affirm in the final rule that Section 1557 prohibits discrimination against those seeking contraception generally as well as specific types of contraception. Denial of contraceptive care is a free form of sex discrimination, and the [Mecos Dobbs] decision has opened the door to further attacks on contraception. It has emboldened some health care providers and entities to refuse to provide or counsel on certain types of contraceptive care and caused public confusion about the continued legality of contraception especially as some are openly calling for reversing the constitutional right to contraception. [Footnote 46: See e.g. Oriana Gonzalez Post Dobbs Birth Control Fight Heads to College Campuses AXIOS [Sept. 30 2022] https://www.axios.com/2022/09/30/dobbs-roe-abortion-university birth-control; Rebecca Boone Idaho Universities Disallow Abortion Contraception Referral Idaho News [Sept. 28 2022] https://idahonews.com/news/local/idaho-universities-disallow-abortion-contraception-referral.] Some of these attacks are rooted in a deliberate misrepresentation of contraceptive care and how it works. For example some forms of emergency contraception are mislabeled as abortion care ignoring the science and medical consensus that emergency contraception prevents pregnancy and is not effective if pregnancy has already occurred. [Footnote 47: See e.g. WORLD HEALTH ORGANIZATION Emergency Contraception Fact Sheet [Nov. 9 2021] WHO https://www.who.int/news-room/fact-sheets/detail/emergency-contraception; American College of Obstetricians and Gynecologists FAQs on Emergency Contraception ACOG [Nov. 2021] https://www.acog.org/womens-health/faqs/emergency-contraception.] Given the growing threats to contraceptive access post [Italics: Dobbs] the Department should clearly specify that Section 1557's sex discrimination protections for pregnancy related care include contraceptive care. On July 15 2022 the Department issued guidance to retail pharmacies about Section 1557 protections

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Center for Reproductive Rights

proposes in this rule to expand the definition of sex by incorporating the new definition in the Department of Education's proposed Title IX rule. The proposed rule defines [Italics: sex] to include "pregnancy or related conditions; sexual orientation; and gender identity" contrary to the original intent of the law [4/9/58]. By incorporating this language the proposed HHS rule would force health care providers and insurers to cover abortions and sex reassignment procedures drugs and surgeries. In section 92.2 it prohibits discrimination on these bases "in every health program and activity any part of which receives Federal financial assistance directly or indirectly from the Department" posing a serious threat to the religious liberty of Christian institutions. [4/931] If the rule is applied to all institutions regardless of religious belief the First Amendment right of schools to operate according to their biblical beliefs will be violated by this rule. Institutions that do not comply with the Department's standards for sex discrimination will be forced either to deny their deeply held beliefs or lose the ability to provide needed health insurance and other care to their employees and students. The Department's actions create a practical and legal dichotomy that violates recent court rulings such as Franciscan Alliance v. Becerra [2021] and Christian Employers Alliance v. Equal Employment Opportunity Commission [2022] that upheld the conscience and religious liberty rights of health care providers to decline participating in procedures that violate the sincerely held beliefs. HHS acknowledges the conflict these cases reveal between its proposed rule and fundamental conscience and religious liberty rights but rather than provide clear protections of Americans' constitutional rights HHS only gives vague reassurances that those rights will be protected. Further in the [Italics: Franciscan Alliance] case the government appealed the lower court's basis for to the Fifth Circuit Court of Appeals indicating the Department's unwillingness to respect the constitutional rights of health care providers. So we ask how will the department protect

American Association of Christian Schools

expand sex discrimination is based upon an erroneous application of the Bostock ruling and a failure to protect doctors and patients alike from compelled speech and action. In what seems to be an ideologically motivated move the Department also fails to acknowledge the controversy surrounding and the harms caused by so called gender transition. Instead of providing clarity the Department muddies the waters by simultaneously failing to define sex while expanding its meaning to include non observable subjective preferences that obscure its application the sexual difference that is the basis for Title IX itself. All people deserve to be treated with dignity and respect. Contrary to its express goal this proposed rule would greatly multiply discrimination and harm within federally funded educational programs and activities and beyond. The Department cites the Supreme Court's decision in [Italics: Bostock v. Clayton County] as justification for its expansion of sex discrimination to include sexual orientation gender identity and other categories. As we have argued before the administration's application of [Italics: Bostock] which exclusively focused on employment discrimination to Title IX is erroneous. In [Italics: Bostock v. Clayton County] the Supreme Court's ruling proceeded on the assumption that "sex" signified what the employers suggest referring only to biological distinctions between male and female." [Footnote 7: Bostock v. Clayton County 590 U.S. 140 S. Ct. 1731 (2020)] The ruling dealt with discrimination on the basis of sex in matters of employment according to Title VII of the Civil Rights Act. It did not redefine sex to include gender identity and sexual orientation. It also did not apply its ruling to any other part of the Civil Rights Act beyond Title VII. Notably the Bostock court used the term "transgender status" [Italics: not] "sexual orientation and gender identity" as HHS erroneously posits. Bostock is limited to employment nondiscrimination and "did not adopt gender identity as a protected basis." [Footnote 8: R. Morrison "HHS's Proposed Nine Sex Rules Impose Transgender Mandates on Health Care"

The Heritage Foundation

Body: C. Neither Title IX nor Section 1557 were amended by [Italics: Bostock] and [Italics: Bostock] does not support the need for regulatory action.]In support of its proposal HHS cites to the Supreme Court's 2020 [Italics: Bostock v. Clayton County] decision several federal court decisions that favor its position and various "notice[s] of interpretation" and "guidance" documents by HHS and the Department of Justice. [Footnote 57: 87 Fed. Reg. 47847 47848.] HHS alleges that Bostock held Title VII's prohibition against sex discrimination in employment prohibits discrimination on the basis of sexual orientation and gender identity" [even though Bostock used the term "transgender status" and did not adopt gender identity as a protected basis]. [Footnote 58: 87 Fed. Reg. 47827.] According to HHS because Title VII's and Title IX's prohibitions against sex discrimination are similar the Bostock Court's reasoning "applies to Title IX and by extension to Section 1557." [Footnote 59: 87 Fed. Reg. 47858.] Thus Section 1557 also prohibits discrimination based on "sexual orientation and gender identity." [Footnote 60: 87 Fed. Reg. 47830.]

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Ethics & Public Policy Center

Bostock, the Supreme Court held that under [Italics: Title VII of the Civil Rights Act of 1964] "an employer who fires someone simply for being homosexual or transgender has discharged or otherwise discriminated against that individual 'because of such individual's sex.'" [Footnote 64: 140 S. Ct. at 1737.] Title VII is the federal law that prohibits sex [and race color religion and national origin] discrimination in employment a completely different context from education and Title IX. Notably [Italics: Bostock]'s Title VII analysis does not apply to Title IX [and thus Section 1557] because Title IX has a different sex-specific structure and unlike Title VII specifically uses language based on a biological binary as detailed below.The Majority in [Italics: Bostock] used the term "transgender status" and did not adopt "gender identity" as a protected class. HHS recognizes in the Proposed Rule that "transgender" is not the same thing as "gender identity." [Footnote 65: 87 Fed. Reg. 41532.] Thus HHS cannot rely on [Italics: Bostock] to support the inclusion of the term "gender identity" within the definition of "sex discrimination." The [Italics: Bostock] Court premised its decision on the assumption that "sex" refers only to the "biological distinctions between male and female." [Footnote 66: Id. at 1739.] The Proposed Rule tries to explain this away: "[Italics: Bostock] demonstrated with respect to Title VII even accepting that definition of 'sex' would not preclude Title IX's coverage of these forms of discrimination." [Footnote 67: 87 Fed. Reg. 41538.] To be consistent with [Italics: Bostock,' HHS must assume "sex" refers to "biological distinctions between male and female" [which it purports to do] [Italics: and] that "sex" is incompatible with a gender specific fluid or subjective self-definition [which is promoted in the Proposed Rule]. As a federal district court judge just explained HHS "misread Bostock by making 'status' and 'conduct' into one and each protected class covering all conduct correlating to 'sexual orientation and gender identity.' Justice Gorsuch expressly did not do that." [Footnote 68: Texas v. Equal Emp't

Ethics & Public Policy Center

further [Italics: Bostock] was a limited holding. The Supreme Court specifically cabined its decision to the hiring and firing context under Title VII stating "I was not addressing other Title VII issues such as sex-specific bathrooms, locker rooms and dress codes or other laws. [Footnote 70: 140 S. Ct. at 1753.] While the Court acknowledged concerns by some that its decision could make sex-segregated bathrooms, locker rooms and dress codes "unsustainable" and "sweep beyond Title VII to other federal or state laws that prohibit sex discrimination," the Court did not address those concerns. [Footnote 71: Id. at 1753.] The Court explained that such questions were for "future cases" and the Court would not prejudge any such questions because "none of [those other laws were] before [them]." [Footnote 72: Id.] Likewise HHS should not prejudge those questions that the Court left unanswered especially as it relates to sex-segregated spaces in the health care context. The Supreme Court was clear that [this case: Bostock] did not decide any issue beyond hiring and firing under Title VII and it is arbitrary and capricious for HHS to ignore [Italics: Bostock]'s limitations and claim Bostock requires its regulatory action. As the Sixth Circuit recently put it "Bostock extends no further than Title VII." [Footnote 73: Pelcha v. MW Bancorp, Inc., 988 F.3d 318, 324 (6th Cir. 2021).]

The Proposed Rule states "Since [Italics: Bostock] two Federal courts of appeals have held that the plain language of Title IX's prohibition on sex discrimination or it must be read similarly." [Footnote 74: 87 Fed. Reg. 47829.] In support HHS cites to a Ninth Circuit and Fourth Circuit case. [Footnote 75: 87 Fed. Reg. 47829.] This is a far cry from consensus. HHS further mentions DOJ has taken the same position in Title IX litigation. [Footnote 76: 87 Fed. Reg. 47829.] While citing to a brief DOJ filed in an Eleventh Circuit case it fails to acknowledge that court rejected DOJ's position. In [Italics: Adams v. School Board of St. Johns County], the Eleventh Circuit granted rehearing [Italics: en banc] and vacated the panel's 2-1 decision that aligns with the Department's interpretation. [Footnote 77: Adams v. Sch. Bd. of St. Johns Cnty., No. 18-13592, [11th Cir. Aug. 23 2021].] The vacated panel majority had held that [Hecox/Bostock]'s reasoning that Title VII with its "sterdy broad terms" forbids discrimination against transgender people "applies with the same force to Title IX's equally broad prohibition on sex discrimination." [Footnote 78: Adams v. Sch. Bd. of St. Johns Cnty., 968 F.3d 1286, 1305 (11th Cir. 2020) vacated, No. 18-13592 (11th Cir. Aug. 23 2021).] Given that the [Italics: en banc] Eleventh Circuit has not issued its opinion [Footnote 79: Oral argument was held February 22 2022.] it would be arbitrary and capricious for HHS to ignore the impending decision and rely on its partisan litigation position over the court's actions. To the extent HHS is relying on [Italics: Bostock] as the legal impetus for its rulemaking that basis is deficient. [Italics: Bostock] requires no such regulatory action. It is arbitrary and capricious and contrary to law for HHS to claim that [Italics: Bostock] requires HHS's expansion of sex discrimination under Section 1557 and provides grounds to support its rulemaking.

This Proposed Rule is especially timely given the proliferation of bills and laws especially at the state level that have made or enable discrimination in health care or that could make health care access more difficult for LGBTQIA people. Transgender children have been the primary targets of these bills leading to tremendous challenges for them their families and health care providers trying to provide medically appropriate care.

Supreme Court case law including [Italics: Price Waterhouse v. Hopkins] and Bostock v. Clayton County [makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity including transgender status.

[Bold: In the wake of Dobbs v. Jackson Women's Health Organization, HHS must clarify the scope of Section 1557's protections against discrimination related to pregnancy and for LGBTQ+ people]. a. [Bold: LGBTQ+ Discrimination] PRH welcomes the explicit recognition that Section 1557's prohibition on sex discrimination includes discrimination on the basis of sex stereotypes, sexual orientation, gender identity, and sex characteristics, including intersex traits. This follows settled federal law and it is critical that the final rule consistently includes these bases. While the terms "gender identity" and "transgender status" are often used interchangeably, there have been instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between the two concepts. Therefore explicit language is needed to prevent this discrimination and consistency throughout the final rule is important. We recommend also including "transgender status" in § 92.206(b)(1)(i), (b)(4), and (c) and in § 92.207(b)(3)(i). RECOMMENDATION: Include "transgender status" after "sexual orientation" in § 92.101(a)(2) as follows: Discrimination on the basis of sex includes but is not limited to discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy; [Bold: or related conditions including termination of pregnancy]; sexual orientation; [Bold/Italics: transgender status]; and gender identity.

On June 15 2020 the Supreme Court ruled in Bostock v. Clayton County that existing laws prohibiting sex discrimination protect against both sexual orientation discrimination and gender identity discrimination. [Footnote 18: Bostock v. Clayton County, 590 U.S. _ (2020).] This proposed rule would align the protections under section 1557 with the Bostock ruling ensuring that LGBTQ patients receive the protections they deserve. Recent research by the Center for American Progress highlights the need for these protections. Nearly one in five LGBQ patients surveyed reported concerns over being denied good care if they disclosed their sexual orientation and half of transgender or nonbinary patients surveyed reported similar concerns. If they disclosed their gender identity. [Footnote 19: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," Center for American Progress, 14 September 2022, https://www.americanprogress.org/article/advancing-healthcare-nondiscrimination-protections-for-lgbtqi-communities/.]

discrimination on the basis of sex and it is important to ensure that sex discrimination captures discrimination related to sex assigned at birth gender expression gender identity and sexuality [both actual and/or perceived]. Our agency is particularly pleased to see this explanation in the proposed rule given that extensive case law has demonstrated the applicability of prohibitions against sex discrimination to members of the LGBTQI+ community. As HHS is aware case law from the Supreme Court of the United States (SCOTUS) including Price Waterhouse v. Hopkins [1989] and Bostock v. Clayton County [2020] makes clear that federal non-discrimination law provides protections from both sex stereotyping and sex discrimination including discrimination against people because of the actual and/or perceived sex assigned at birth gender expression gender identity and/or sexuality. And of course it is important to affirm that the case law established in Bostock v. Clayton County (2020) builds upon previous decisions from lower courts. These include Macy v. Holder [2012] – which held that discrimination against a transgender person due to their gender identity and/or "transgender status" is a form of sex discrimination that is outlawed under Title VII – and Baldwin v. Dept. of Transportation [2015] – which held that discrimination against someone on the basis of their sexuality necessarily involves sex discrimination [as the person has been discriminated against because of assumptions related to their sexuality based upon the their sex assigned at birth and gender identity] In relation to this ruling and the associated case law mentioned above we advise HHS to incorporate the following key suggestions: 1) It is essential that the proposed rule track those decisions to provide assurance to participants beneficiaries and enrollees. It is also essential that HHS provides notice to covered entities which will help to ensure that this rule's non discrimination provisions related to access to healthcare and insurance coverage or benefits for LGBTQI+ persons are clearly and unequivocally

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|Bold: Nondiscrimination Provisions| |Italics: Discrimination Prohibited|Health centers have long been trusted health care settings for the LGBTQ community. In 2021, 39% of health centers served 762,000 patients that identify as bisexual, gay, lesbian or another sexual orientation. Furthermore, 26% of health centers served patients who identified as transgender. Several health centers specialize in serving LGBTQ patients and provide services such as gender affirming surgeries, mental health care needs resources for unstable housed LGTBQ youth and HIV treatment and prevention. Health centers are committed to providing patient-centered care and investing in workforce training to ensure staff understand best practices to provide informed and inclusive care. TPCA appreciates OCR's clarification in paragraph [all 2] of §92.101) that prohibits discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions, sexual orientation, and gender identity. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have just fled it by pressing distinctions between the two concepts. Therefore explicit language is needed to prevent this discrimination and consistency throughout the final rule is important.

Tennessee Primary Care Association

|Bold: Nondiscrimination Provisions| |Italics: Discrimination Prohibited| Health centers have long been trusted health care settings for the LGBTQ community. In 2021, 39% of health centers served 762,000 patients that identify as bisexual, gay, lesbian or another sexual orientation. Furthermore, 26% of health centers served patients who identified as transgender. Several health centers specialize in serving LGBTQ patients and provide services such as gender affirming surgeries, mental health care needs resources for unstable housed LGTBQ youth and HIV treatment and prevention. Health centers are committed to providing patient-centered care and investing in workforce training to ensure staff understand best practices to provide informed and inclusive care. MNACHC appreciates OCR's clarification in paragraph [all 2] of §92.101) that prohibits discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions, sexual orientation, and gender identity. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have just fled it by pressing distinctions between the two concepts. Therefore explicit language is needed to prevent this discrimination and consistency throughout the final rule is important.

Minnesota Association of Community Health Centers

We strongly support the agency's clarification that Section 1557 unequivocally prohibits discrimination on the basis of sexual orientation or gender identity and sex characteristics, including intersex traits. These forms of discrimination have long been part and unchecked in our medical system. This outright discrimination flies in the face of the very foundation of civil rights that our nation has proudly stood for over the past decades. This rule will help to ensure that Section 1557 is properly interpreted and enforced to prohibit these forms of discrimination with a view to ensure

38 Members of Congress

WPHCA appreciates OCR's clarification in paragraph [all 2] of §92.101) that prohibits discrimination on the basis of sex stereotypes, sex characteristics, including intersex traits, pregnancy or related conditions, sexual orientation, and gender identity. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have just fled it by pressing distinctions between the two concepts. Therefore explicit language is needed to prevent this discrimination and consistency throughout the final rule is important. WPHCA recommends also including "transgender status" in §92.206(b)(1) (b)(2) and (b)(4) and in §92.207(b)(4)

Wisconsin Primary Health Care Association

prohibited discrimination based on sex characteristics. While codifying this protection is crucial and welcome the final rule or its preamble should provide greater guidance for covered entities in the form of illustrative examples. Due to social stigma, lack of public visibility and a cornerstone of prior case law guidance or enforcement examples covered entities may struggle to completely understand their responsibilities with regard to preventing or addressing discrimination against people with variations in their sex characteristics. Likewise intersex persons and their families may not be aware of their own rights and what forms of unwelcome conduct may be remediable under the ACA. Providing specific examples of prohibited discrimination that intersex people may face is essential. We encourage HHS to include the following examples:[Underline Example 1 | A nursing school administrator subjects a student to sexual harassment of invasive personal questions about their body or sexuality in relation to their intersex traits and thereby causes emotional distress and adversely affects the individuals' educational opportunities. This may constitute sex-based discrimination. [Underline Example 2:] A hospital administrator because he believes a patient's intersex traits presents an "interesting" case invites additional staff or students to observe or participate in a medical examination without a clinical purpose for doing so and without the patient's informed consent. This may constitute sex-based discrimination. [Underline Example 3 | A primary care physician practice refuses to accept a patient who seeks primary care services because they are "uncomfortable" with the patient's sex characteristics. This may constitute sex-based discrimination.] [Underline Example 4 | A specialty clinic intentionally provides false information to an adolescent patient about the existence or nature of their intersex traits and the reasons for recommending specific treatments thereby limiting the patient's ability to make informed decisions and causing emotional distress. It is may

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InterACT: Advocates for Intersex Youth

We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law including Price Waterhouse v. Hopkins and Bostock v. Clayton County makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity, including transgender status. It is essential that OCR's rule track those decisions to provide assurance to participants, beneficiaries and enrollees and notice to covered entities that these bases are adequately included. We also support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex-based.

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|Bold: Protecting LGBTQ individuals from unlawful discrimination| The proposed Rule correctly recognizes that discrimination "on the basis of sex" necessarily includes discrimination based on sex stereotypes, sex characteristics, sexual orientation, and gender identity. 87 Fed. Reg. at 47858. [Footnote 13: It is settled law that federal civil rights statutes forbid discrimination on the basis of sex stereotypes and sex characteristics. Price Waterhouse v. Hopkins, 490 U.S. 228, 240 [1989] ("[G]ender must be irrelevant to employment decisions."). It is also settled law that "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex," because "homosexuality and transgender status [is] inextricably bound up with sex." Bostock, 140 S. Ct. at 1741.] The States welcome this correction to the 2020 Rule and applaud HHS's return to proper statutory interpretation.

Attorneys General of California, New York, Massachusetts, and nineteen other States

A |Build: Provide explicit examples of prohibited discrimination based on sex characteristics.| Providing explicit examples of prohibited forms of discrimination will ensure that covered entities understand their obligations to intersex patients. Helpful examples of prohibited discrimination would include a medical school subjecting students or faculty to invasive personal questions about the intersex traits a provider refuses to accept an intersex patient because they are uncomfortable with their sex characteristics; providers providing false information about the existence or nature of intersex traits and a hospital having a general policy of limiting the performance of sterilizing procedures or major surgeries on people with intersex traits for infants but not following this policy for intersex infants.

38 Members of Congress

We are pleased that the department has articulated a clear and expansive explanation of discrimination on the basis of sex. We support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex-based.

The Leadership Conference on Civil and Human Rights

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Department recognize in the preamble to the NPRM that people may experience discrimination in health care on more than one basis. It would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. We propose the following change to sec. 92.101(a)(1): "Except as provided in Title I of the ACA, an individual must not on the basis of race, color, national origin, sex, age or disability, [Bold] or any combination thereof[] be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity operated by a covered entity." This language should also be added to sections 92.207(a), (b)(1) and (b)(2). This addition is incredibly important as similar to the importance of understanding the intersectionality of race and sexuality with a comprehensive sex education, factoring for intersectional discrimination within the various forms of discrimination that LGBTQIA+ youth can experience within the medical system is necessary. According to Rockefeller Institute of Government of SUNY [embedded hyperlink text (https://rockinst.org/blog/understanding-and-addressing-the-challenges-faced-by-lgbtq-people-of-color-poc-in-accessing-mental-healthcare/)] LGTBQIA+ youth of color are vulnerable to risk of suicide and poor mental health due to mistrust of mental health providers and fear of discrimination. We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law, including [Italics: Price Waterhouse v. Hopkins,] and [Italics: Bostock v. Clayton County,] makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity, including transgender status. It is essential that this rule track those decisions to provide assurance to participants, beneficiaries and enrollees and notice to covered entities that these bases are unequivocally included. We also support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex-based.

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IECUS Sexuality Education for Social Change

We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law including [Italics: Price Waterhouse v. Hopkins and Bostock v. Clayton County,] makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity, including transgender status. It is essential that this rule track those decisions to provide assurance to participants, beneficiaries and enrollees and notice to covered entities that these bases are unequivocally included. We also support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex-based.

ating Disorders Coalition for Research, Policy & Action

[Bold] The NPRM's proposal to restore protections for the LGBTQI+ community are essential and align with federal law and international human rights norms. A. The NPRM's proposed restoration of protections against discrimination for the LGBTQI+ community is essential. We strongly support the Department's recognition in the proposed rule that sex discrimination includes discrimination on the basis of sex stereotypes, sexual orientation, gender identity, and sex characteristics, including intersex traits. LGBTQI+ people frequently experience discrimination in accessing care. In a 2015 study, one in five LGBTQI+ people, including 33 percent of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. [Footnote 67: Shabab Ahmed Mirza & Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care (2018), CTR. FOR AMER. PROGRESS, https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445118/discrimination-prevents-lgbtq-people-accessing-health-care/. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41 percent reporting that it would be very difficult or impossible to find an alternative provider. [Footnote omitted.]]

Center for Reproductive Rights

Discrimination against intersex people is also inherently sex-based. For that reason, the proposed rule's explicit inclusion of discrimination on the basis of sex characteristics, including intersex traits, is essential and should be retained in the final rule. As of 2016, intersex individuals made up approximately 1.7 percent of the world population. [Footnote 70: 81 Fed. Reg. 31375, 31389 (May 18, 2016).] Adults with intersex conditions report facing discrimination in health care settings and denial of care once their atypical anatomy is known. [Footnote 71: Providing Ethical and Compassionate Health Care to Intersex Patients: Intersex-Affirming Hospital Policies, INTERACT & LAMBDA LEGAL (2018), https://www.lambdalegal.org/sites/default/files/publications/downloads/resource2018RD73_hospital_policies_intersex.pdf.] Studies have shown that up to 80 percent of intersex patients have changed their care based on discomfort with their medical providers. [Footnote 72: Id.]

Center for Reproductive Rights

[illegible] consistent with federal law and international human rights norms.[] The proposed rule's inclusion of sex stereotypes, sexual orientation, gender identity, and sex characteristics is consistent with settled federal law governing sex discrimination. Supreme Court jurisprudence, including the decisions in [Italics: Price Waterhouse v. Hopkins] and Bostock v. Clayton County,[] makes clear that federal sex discrimination laws prohibit discrimination on the basis of sex stereotypes, sexual orientation, and gender identity. We also note that the proposed rule's consistent interpretation of sex discrimination based on sex stereotypes, sexual orientation, and gender identity is in keeping with international human rights norms. [Footnote 73: Convention on the Elimination of All Forms of Discrimination Against Women, adopted Dec. 18, 1979, art. 5, G.A. Res. 34/180, U.N. GAOR, 34th Sess., Supp. No. 46, at 193, U.N. Doc. A/34/46 (1980); U.N.T.S. 13 [entered into force Sept. 3, 1981] [hereinafter CEDAW]. CEDAW Committee General Recommendation No. 28 on the core obligations of States parties under article 2 of the Convention on the Elimination of All Forms of Discrimination against Women, para. 3, U.N. Doc. CEDAW/C/GC/28 (2010) [hereinafter CEDAW Committee Gen. Recommendation No. 28]. CEDAW Committee General Recommendation No. 33 on women's access to justice, para. 7, U.N. Doc. CEDAW/C/GC/33 (2015), see also ESCR Committee General Comment No. 20, at para. 27; Convention on the Rights of Persons with Disabilities, adopted Dec. 13, 2006, art. 8, para. 1(b), G.A. Res. A/RES/61/106, U.N. GAOR, 61st Sess., U.N. Doc. A/61/611 (2006) [entered into force May 3, 2008].] The UN High Commissioner for Human Rights has affirmed that all people, including LGBT persons, are entitled to enjoy the protections provided by the right to be free from discrimination. [Footnote 74: United Nations High Commissioner for Human Rights, Discriminatory Laws and Practices and Acts of Violence Against Individuals Based on Their Sexual Orientation and Gender Identity, para. 5, U.N. Doc. A/HRC/19/41.]

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Center for Reproductive Rights

In addition, the provisions clarifying anti-discrimination provisions for specific populations are necessary and welcome, including provisions to: • Affirm gender-based and disability and accessibility anti-discrimination policies; • Clarify language access requirements; and • Include sex characteristics or orientation in coverage and restore coverage for gender identity or stereotype and pregnancy in addition to that "sex."

National Health Council

[Bold/italics: Support for NPRM's Reinstatement of Provisions from the 2016 Final Rule.] Given the existing state law framework and our shared values, Call HHS strongly supports the NPRM's principal objective to restore nondiscrimination and equal access policies to those promulgated under the 2016 Final Rule. This includes: • Expanding forms of sex discrimination to include discrimination on the basis of sex stereotypes, sex characteristics, including intersex traits, pregnancy and related conditions, sexual orientation and gender identity; • Clarifying that nondiscrimination policies extend to associational bases.

California Department of Health Care Services

(b)(5)

• More Explicitly Prohibiting Discrimination HHS focuses much of this rule on restoring nondiscrimination protections that were eliminated in the 2020 rule. HHS reiterates that Section 1557 provides a general prohibition on discrimination on the basis of race sex national origin age or disability under health programs or activities. Additionally HHS clarifies that the term "on the basis of sex" includes sex stereotypes sex characteristics including intersex traits pregnancy or related conditions sexual orientation and gender identity [Footnote 7. Consistent with legal conclusions reached in Price Waterhouse v. Hopkins 490 U.S. 228 (1989) (sex discrimination "occurs if sex stereotyping based on sex stereotypes") and Bostock v. Clayton County 140 S.Ct. 1731 1742 (2020) (sex discrimination includes discrimination based on sexual orientation and gender identity)." This broader definition will require covered entities to provide equal access to health programs and activities without the threat of discrimination on the basis of sex and will be prohibited from denying or limiting health services for gender-affirming care or the basis of an individual's sex assigned at birth gender identity or gender otherwise recorded. This clarification will also prohibit discrimination on the basis of sex race color national origin age and disability in the provision and administration of health insurance coverage.

Additionally we support the proposed rule's explicit language around discrimination "on the basis of sex" that clarifies application to sex stereotypes sex characteristics [including intersex traits] pregnancy or related conditions sexual orientation and gender identity.

Italic: Explicit prohibition of discrimination on the basis of sexual orientation gender identity and sex characteristics. We also strongly urge to clearly state that gender identity includes trans status. We applaud expansive explanation of discrimination on the basis of sex. Supreme Court case law including Price Waterhouse v. Hopkins and Bostock v. Clayton County makes clear that federal sex discrimination law includes sex stereotypes sexual orientation and gender identity including transgender status. The explicit inclusion of sexual orientation is a welcome addition to the Obama Section 1557 rule. We also support the explicit inclusion of discrimination based on sex characteristics including "intersex traits" as such discrimination is inherently sex based. Health disparities among intersex populations are primarily driven by stigma and discrimination especially with the lack of data around the experiences and needs of intersex people [Footnote 10: Medina Caroline Mahowald Lindsay. "Key Issues Facing People with Intersex Traits." Center for American Progress 22 Aug. 2022 www.americanprogress.org/article/key-issues-facing-people-intersex-traits/]. A 2018 survey of intersex individuals found that 43% of adult intersex individuals reported their physical health was fair or poor while 53% reported their mental health was fair or poor. [Footnote 11: Ibid]

Overall we support the proposed rule's explicit language around discrimination "on the basis of sex" that clarifies application to sex stereotypes [including intersex traits] pregnancy or related conditions sexual orientation and gender identity.

(b)(5)

Covered California

AARP

Howard Brown Health

Proposed § 92.101 explicitly recognizes that the non-discrimination on the basis of sex characteristics including intersex traits is especially important. We especially applaud the Department's clarification in the proposed rule that sex discrimination "includes discrimination on the basis of sex characteristics including intersex traits. The Department correctly observes that "discrimination based on anatomical physiological sex characteristics [such as] gonadal sex chromosomes and hormone function[] is inherently sex-based" and that "[d]iscrimination based on intersex traits is rooted in perceived differences between an individual's specific sex characteristics and those that are considered typical for their assigned sex at birth." [Footnote 12:

Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance 87 FR 41390 (Jul. 12 2022).] Discrimination against intersex people is invariably motivated by sex-based considerations whether related to how these individuals are sorted between binary sex categories or to how their bodies vary from stereotypes or expectations associated with binary sex categories.

InterACT Advocates for Intersex Youth

The Proposed Rule recognizes various forms of sex discrimination that disproportionately impact BIPOC and Latinx communities. The Proposed Rule clarifies discrimination on the basis of sex including but not limited to discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions, sexual orientation, and gender identity. As discussed further below prescribing discrimination on these bases will improve health care access for LGBTQ + people of color in particular. However the Department must further clarify discrimination on the basis of pregnancy or related conditions in order to ensure access to vital health care services to pregnant people.

Alliance of Multicultural Psychiatrists

discrimination on the basis of sex and it is important to ensure that sex discrimination captures discrimination related to sex assigned at birth gender expression gender identity and sexuality [both actual and/or perceived]. Our agency is particularly pleased to see this explanation in the proposed rule given that extensive case law has demonstrated the applicability of prohibitions against sex discrimination to members of the LGBTQI+ community. As HHS is aware case law from the Supreme Court of the United States (SCOTUS) – including Price Waterhouse v. Hopkins (1989) and Bostock v. Clayton County (2020) – makes clear that federal non-discrimination law provides protections from both sex stereotyping and sex discrimination, including discrimination against people because of the actual and/or perceived sex assigned at birth gender expression gender identity and/or sexuality. And of course it is important to affirm that the case law established in Bostock v. Clayton County (2020) builds upon previous decisions from lower courts. These include Macy v. Holder (2012) – which held that discrimination against a transgender person [due to their gender identity and/or "transgender status"] is a form of sex discrimination that is outlawed under Title VII – and Baldwin v. Dept. of Transportation (2015) – which held that discrimination against someone on the basis of their sexuality necessarily involves sex discrimination [as the person has been discriminated against because of assumptions related to their sexuality based upon their sex assigned at birth and gender identity]. In relation to this action and the associated case law mentioned above we advise HHS to incorporate the following key suggestions: 1) It is essential that the proposed rule trace those decisions to provide assurance to participants beneficiaries and enrollees. It is also essential that HHS provides notice to covered entities which helps to ensure that this rule's non-discrimination provisions related to access to healthcare and insurance coverage/benefits for LGBTQI+ persons are clearly and unequivocally

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Alliance of Multicultural Psychiatrists

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The Proposed Rule Strengthens Protections for LGBTQIA+ Individuals. We applaud HHS's proposed rule for making explicit that Section 1557's protections against discrimination on the basis of sex "includes gender identity which is consistent with the interpretation of the Supreme Court decision in Bostock and federal anti-discrimination laws. We support the proposed rule for clarifying that discrimination on the basis of sex in health care programs and activities includes sex stereotypes sexual orientation gender orientation gender identity and sex characteristics including intersex traits and "marital parental or family status. Footnote 22: Id. at 47816 [Proposed § 92.101)]. Sex stereotypes such as expectations about how people should present or communicate have historically created barriers to equitable health care access and services. We also support the intention of enforcement of protections against discrimination on the basis of association which should protect LGBTQ A+ couples who may be turned away from care [Footnote 23: Id. at 47918 (Proposed § 92.209)].

Equitas Health

LGBTQI+ peopleTransgender people of color face significant barriers to health care access. 65 percent of transgender people of color report experiencing some form of discrimination and 46 percent of transgender people report having their health insurance deny gender affirming care. Furthermore some transgender people report experiencing such hostile discrimination that doctors have refused to treat conditions such as asthma or diabetes. Proposed Section 92.206 requires equal program access on the basis of sex and addresses the conditions that lead to health disparities among transgender people more broadly. Under this section health care providers may not deny or limit health services based on their sex. This serves to ensure access to necessary health care services especially reproductive and gender-affirming care. For example transgender men face barriers to pap smears necessary for cervical cancer screenings as well as breast cancer screenings. Cisgender gay and lesbian people also face egregious denials of care such as refusal to provide infertility treatments.

Senate Democrats

Alliance of Multicultural Psychiatrists

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The proposed rule [RIN 0945-AA17] is a violation of the conscience rights of health care professionals and entities that seek to Do No Harm and to offer practical and life-giving care to the people they serve. Health care providers and insurers should not be coerced to perform or cover abortions or transgender procedures. It is improper and illogical to conflate sex discrimination with the issues of abortion and transgenderism. Provisions of the proposed rule that can be construed to require the providing for or coverage of such procedures violate rights of conscience and religious freedom as reflected in current federal conscience laws including the Weldon Amendment. For these reasons I oppose the abortion and gender identity provisions of the proposed rule.

If you are going to constitute sex discrimination in terms of coverage for abortion and sex transition surgery then by all means you need to also allow fertility treatments to be covered benefits to make it a level playing field for every human being. Not everyone that WANTS children gets children due to infertility issues. The cost for fertility treatments is astronomical but I would think that gender reassignment surgery is just as expensive so why discriminate against those with fertility issues who chose a sex unwanted and cause psychological physical spiritual and emotional distress?

[Bold: Nondiscrimination Provisions] - [Italics: Discrimination Prohibited] Health centers have long been trusted health care settings for the LGBTQ community. In 2021 99% of health centers served 762000 patients that identify as bisexual gay lesbian or another sexual orientation. Furthermore 96% of health centers served patients who identified as transgender. Several health centers specialize in serving LGBTQ patients and provide services such as gender affirming surgeries mental health care needs resources for unstable housed LGTBQ youth and HIV treatment and prevention. Health centers are committed to providing patient-centered care and investing in workforce training to ensure staff understand best practices to provide informed and inclusive care. TPCA appreciates OCR's clarification in paragraph [all 2) of [§92.101) that prohibits discrimination on the basis of sex stereotypes; sex characteristics including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between the two concepts. Therefore explicit language is needed to prevent this discrimination and consistency throughout the final rule is important.

Tennessee Primary Care Association

[Bold: Nondiscrimination Provisions] - [Italics: Discrimination Prohibited] Health centers have long been trusted health care settings for the LGBTQ community. In 2021 99% of health centers served 762000 patients that identify as bisexual gay lesbian or another sexual orientation. Furthermore 96% of health centers served patients who identified as transgender. Several health centers specialize in serving LGBTQ patients and provide services such as gender affirming surgeries mental health care needs resources for unstable housed LGTBQ youth and HIV treatment and prevention. Health centers are committed to providing patient-centered care and investing in workforce training to ensure staff understand best practices to provide informed and inclusive care. MNACHC appreciates OCR's clarification in paragraph [all 2) of [§92.101) that prohibits discrimination on the basis of sex stereotypes; sex characteristics including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between the two concepts. Therefore explicit language is needed to prevent this discrimination and consistency throughout the final rule is important.

Minnesota Association of Community Health Centers

CLI submits this comment because it opposes the proposed change to the interpretation of Title IX's prohibition of discrimination "on the basis of sex" and Section 1557's incorporation of that prohibition to include "termination of pregnancy" which we are concerned will be used to force healthcare providers to participate in the brutal and abhorrent practice of abortion.

Charlotte Lozier Institute

including abortion services is critical to the overall health and well-being of adolescents and young adults and ensures that young people are able to make informed decisions about their health and their future. As such we urge HHS to ensure that the final rule protects access to comprehensive reproductive health care for adolescents and young adults to the greatest extent possible. Sex discrimination related to pregnancy and related conditions pervasive in our health care system. Access to sexual and reproductive health care such as contraception fertility care abortion gender affirming care and maternity care is often barred by discriminatory policies or practices. For example pregnant Black Indigenous Hispanic Asian American and Pacific Islander and all people of color and others who live at the intersections of Section 1557's protected identities are often subjected to discrimination throughout pregnancy and the postpartum period including during labor and delivery. In light of the importance of comprehensive reproductive health care to adolescents and young adults the Academy recently reaffirmed its support for adolescents to receive factually accurate nonjudgmental pregnancy options counseling and confidential care when considering abortion. [Footnotes 4 and 5]

https://publications.aap.org/pediatrics/article/150/3/e2022058787/188540/Options-Counseling-for-the-Pregnant-Adolescent,

https://publications.aap.org/pediatrics/article/150/3/e2022058780/186339/The-Adolescent-s-Right-to-Confidential-Care-When] Medical issues are best decided by patients and families in consultation with their physicians and interference by the government into that decision process is inappropriate and dangerous. Laws that prevent physicians from providing the full spectrum of comprehensive health care can have life-threatening consequences. Certain pregnancy complications like ectopic pregnancy or premature rupture of membrane can lead to severe adverse health effects permanent disability and death when essential care is

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American Academy of Pediatrics

Pregnant peoplePeople of color whose access to health care is already inhibited by racial discrimination will be disproportionately impacted by restrictions or bans on abortion and reproductive health care. The Department must clarify that conduct prohibited for "pregnancy-related conditions" and specify that the denial of care based upon the need for or past use of abortion care is considered sex discrimination. Since the Court permitted states to criminalize abortion in Dobbs v. Jackson Women's Health there have been several reports of people experiencing pregnancy complications necessitating abortion but being unable to access care. Many of these stories involved life-threatening infections and the psychological trauma of carrying a nonviable pregnancy. Adding "pregnancy-related condition" to the definition of sex discrimination will blunt the blow of Dobbs and help ensure women and other pregnant people are able to access life-saving care.

Alliance of Multicultural Physicians

This exhibit protect or should be present in at least two areas of the final regulation. First termination of a pregnancy should be explicitly named in the definition of sex discrimination at section 92.101[a][2]. This new definition could read: "discrimination on the basis of sex includes but is not limited to discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions [bold and italics: including termination of pregnancy], sexual orientation, and gender identity."

The Century Foundation

We suggest that the language in section 92.101(a)(2) be amended to explicitly include transgender status. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between the two concepts. [Footnote 1: See e.g. "Making Admission or Placement Determinations Based on Sex in Facilities Under Community Planning and Development Housing Programs" Proposed Rule 85 Fed Reg 44811 (July 24 2020).] It is therefore preferable to enumerate both in the regulatory text. It is also important to make clear in the final rule that "pregnancy or related conditions" includes the termination of pregnancy. We therefore suggest that this provision be revised as follows: "Discrimination on the basis of sex includes but is not limited to discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits, pregnancy or related conditions [bold underline: including termination of pregnancy], sexual orientation, [bold underline: transgender status]; and gender identity."

Colors+

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The Proposed Rule Clarifies Protections for Pregnancy or Related Conditions We support that the Department's proposed rule explicitly includes "pregnancy or related conditions" in its definition of discrimination on the basis of sex [Footnote 29: 87 Fed. Reg. at 47858 47916 [Proposed § 92.101)]. Congress intended Section 1557 to prohibit discrimination against patients because of their medical history or needs which includes 1 they had an abortion or miscarriage or other pregnancy-related care. We also support HHS's proposal to repeal 45 C.F.R. § 92.6 which incorporates the language of Title IX's abortion provision [Footnote 30: Id. at 47859 (Proposed § 92.206)]

termination of pregnancy [§ 92.101(a)(2)]] In response to the Department's request for comment [Footnote: See 87 Federal Register 47824 47879 (August 4 2022)] We strongly encourage OCR to specify in the final rule that sex based discrimination includes discrimination based on "pregnancy related conditions including childbirth false pregnancy termination of pregnancy and recovery therefrom." As drafted the proposed rule does not consistently define sex discrimination to include pregnancy related conditions. We noted that sex discrimination includes "pregnancy or related conditions" in § 92.101(a)(2) but only "pregnancy" under § 92.101 and § 92.10. In light of the Supreme Court's decision in [Italics: Dobbs v. Jackson Women's Health Organization] 142 S. Ct. 2228 [2022] it is critical that HHS ensure that termination of pregnancy and pregnancy related conditions are protected throughout the regulation. Before [Italics: Dobbs] Latinas already faced significant barriers to receiving reproductive health care including limitations on linguistic access [Footnote in. José Parra Avila Mary Sabo Ake and Janet Katz "No Comprendo: Practice Considerations When Caring for Latinos with Limited English Proficiency in the United States Health Care System" Hispanic Health Care International December 2011, 9[4]: 159–167. a lack of culturally competent care [Footnote Ivonne Ross DeCamp et al. "The Voices of Limited English Proficiency Latina Mothers on Pediatric Primary Care Lessons for the Medical Home" Maternal and Child Health Journal January 2013, 17(1): 95–109.] and much higher rates of uninsurance [Hyperlink: https://www.census.gov/content/dam/Census/library/publications/2022/demo/p60-278.pdf] compared to non Hispanic White women. [Footnote In 2019 17.5% of Latina women were uninsured compared to 5.5% of non-Hispanic White women 8.6% of non-Hispanic Black women 6.5% of Asian American and Pacific Islander women 17.5% of Native American women and 7.2% of other women. UnidosUS analysis of American Community Survey (ACS) data for 2019 accessed

It is also important to make clear in the final rule that "pregnancy or related conditions" includes the termination of pregnancy. We therefore suggest that the provision be revised as follows "Discrimination on the basis of sex includes but is not limited to discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions [underlined/bold: including termination of pregnancy,]; sexual orientation, [bold/underlined transgender status;] and gender identity."

We support the department's inclusion of pregnancy or related conditions in the definition of sex discrimination in the proposed rule. However especially in the wake of [Italics: Dobbs], it is critical that the final rule explicitly name discrimination on the basis of termination of pregnancy as part of sex discrimination. "Termination of pregnancy" must be enumerated under prohibited sex discrimination in Section 92.101(a)(2) and abortion care must be clearly and consistently articulated with "pregnancy or related conditions" throughout the final rule. Adding "pregnancy or related conditions including termination of pregnancy" to the definition of sex discrimination and throughout the proposed rule will help to ensure that pregnant people are able to access life saving care.

In response to the Supreme Court decision in Dobbs v. Jackson Women's Health Organization the proposed rule strengthens protections against discrimination on the basis of sex including discrimination on the basis of pregnancy or related conditions (including abortion) and discrimination on the basis of sexual orientation and gender identity. The Colorado Health Foundation supports these protections as essential safeguards for fundamental human rights.

In addition the provisions clarifying anti discrimination provisions for specific populations are necessary and welcome including provisions to: Affirm gender based and disability and accessibility anti discrimination policies; Clarify language access requirements; and Include sex characteristics or orientation in coverage and restores coverage for gender identity or stereotype and pregnancy in definition of "sex."

Additionally: Support for NPRM's Reinstatement of Provisions from the 2016 Final Rule. Given the existing state law framework and our shared values CalHHS strongly supports the NPRM's principal objective to restore nondiscrimination and equal access policies to those promulgated under the 2016 Final Rule. This includes: -Expanding forms of sex discrimination to include discrimination on the basis of sex stereotypes sex characteristics including intersex traits pregnancy and related conditions sexual orientation and gender identity. Clarifying that nondiscrimination policies extend to associational bases

The AAFP also requests that HHS specify that "pregnancy-related conditions" includes termination of a pregnancy.

this rationale for why they are changing the current rule as it relates to "pregnancy or related conditions." "The Department's tentative view is that the current regulations may be misconstrued as leaving gaps in coverage of discrimination based on "pregnancy" "related conditions" or "recovery therefrom" because the regulations do not clearly define those terms. The proposed changes would clarify a recipient's obligations under Title IX to students and employees who are pregnant or experiencing pregnancy-related conditions to ensure full implementation of Title IX's nondiscrimination requirement. For example the current regulations do not specify the status of medical conditions that are related to or caused by pregnancy childbirth termination of pregnancy loss of pregnancy or lactation but that are not necessarily related to "recovery" from pregnancy. As it stands now the department's reasoning process appears to be arbitrary. The agency has not given adequate reasons for its choices. First the department fails to provide key examples analyses or demonstrable support for the claim that the current rule "may be misconstrued as leaving gaps in coverage". To effectively justify this change the department must show how the current rule misconstrues or leaves gaps in its protection of students. Second the clarifier "tentative" reveals the department's own weak stance: this is the product of a hunch or a concern on their part with no solid examples or studies to support the conclusion. While the department claims the proposed changes would clarify and ensure full implementation of Title IX the changes are substantial enough to call this claim into question. Instead the department should demonstrate the need for this change and then clarify the scope and practical meaning of this change. The lack of sufficient evidence to support their claim or justify such a change in the definition and language suggests that the department should wait until it has gathered sufficient data before suggesting these changes. If and the proposed rule changes the language from "pregnancy and..." to

It is also important to make clear in the final rule that "pregnancy or related conditions" includes the termination of pregnancy. We therefore suggest that the provision be revised as follows "Discrimination on the basis of sex includes but is not limited to discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions [Bold: including termination of pregnancy], sexual orientation, [Bold: transgender status]; and gender identity."

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Senate Democrats

UnidosUS

Eating Disorders Coalition for Research, Policy & Action

The Leadership Conference on Civil and Human Rights

The Colorado Health Foundation

(b)(5)

National Health Council

California Department of Health Care Services

American Academy of Family Physicians

The Heritage Foundation

SIECUS: Sex Ed for Social Change

explaining the need for redefinition or its reasoning the department has not explained the impact of this significant change The proposed language not does abortion as part of the definition of pregnancy yet The Department fails to explain the scope or reach this ruling would have upon differing views about life pregnancy and abortion First the proposed rule is silent on exactly how abortion is to be prosecuted under the regulation's prohibition against discrimination on the basis of "termination of pregnancy " The proposed rule would require educational institutions to make "reasonable modifications" to policies practices or procedures for students due to "pregnancy or related conditions " What does this look like in practice?Second the proposed rule will shape how reproductive capabilities are taught and discussed even in K 12 schools Title X will shape the expectations and values of young athletes and scholars to believe that abortion is necessary to follow their dreams This would impose a heavy burden on women, exactly the kind that Title IX previously sought to eliminate when it was enacted in 1972. Title IX is meant to alleviate undue burdens by considering of the demands and responsibilities of one's sex.Third does the department's version of Title IX implementation implicitly encourage young women to seek abortion? Our concern that the rule will do so stems both from the current political climate following the Dobbs decision and redefinition of pregnancy to include abortion. If abortion is included as part of Title IX's definition of pregnancy it could cause students to "read between the lines" and falsely equate the two Fourth it could lead an athlete to feel that she should choose an abortion even if it's not what she truly wants Accommodating nine months of pregnancy requires significantly more of a school than the much shorter timeframe of abortion/recovery Female students may internalize negative messages about pregnancy childbearing and their bodies given the highly competitive environment and their overwhelmingly motivated to success. Thus the proposed would hurt the very people it claims to protections against sex discrimination related to pregnancy or related conditions This approach is critically important in the wake of the Dobbs v Jackson Women's Health Organizations decision .Footnote 7 [https://www.supremecourt.gov/opinions/21pdf/19-1392_6j37.pdf. The 2020 rule removed prior regulations that prohibited covered entities from discrimination based on pregnancy false pregnancy termination of pregnancy and recovery from childbirth or related medical conditions thereby opening women of childbearing age to high-risk medical and emotional situations Thus we encourage HHS to strengthen its approach to defining sex discrimination related to pregnancy or related conditions at § 92 101(a)(2) and throughout the regulatory text.Reproductive justice framing abortion rights can be understood as a human rights issue connected to social structural and cultural inequalities relying on psychological science APA in 2022 again firmly denounced abortion restrictions and recommitted to advancing reproductive justice for childbearing individuals especially for those from socially and economically marginalized communities [Footnote 8 APA. (2022 February). APA Resolution Affirming and Building on APA's History of Support for Reproductive Rights. Washington D C [https://www.apa.org/about/policy/resolution-reproductive-rights.pdf] APA compiled and used decades of psychological research in policy statements amicus briefs and practice guidelines to demonstrate that people denied abortions are more likely to experience higher levels of anxiety lower life satisfaction and lower self-esteem compared with those who can obtain abortions [Footnote 9 [https://www.apa.org/topics/abortion/]. Further research suggests that the inability to obtain an abortion increases the risk for domestic abuse among those who are forced to stay in contact with violent partners putting them and their children at risk [Footnote 10 Roberts SCM Biggs MA Zolbner RS Gist AD H Rocca CH Foster DG. Risk of violence from the man involved in the pregnancy after

And Enforcement Of Vague Terms Such As "Termination Of Pregnancy" And Pregnancy Or Related Conditions.First we express concern that the proposed rule would alter Title IX's longstanding definition of "on the basis of sex" (incorporated by reference into Section 1557) to specifically include discrimination on the basis of "pregnancy or related conditions" which includes the "termination of pregnancy." The Department specifically seeks comment on this proposal in light of the Supreme Court's recent decision in Dobbs v Jackson Women's Health Organization and Executive Order 14076 (See E O 14076 entitled "Protecting Access to Reproductive Healthcare Services" available at https://www.federalregister.gov/documents/2022/07/13/2022-15358/protecting-access-to-reproductive-healthcare-services)We are concerned about this definition for multiple reasons Clarity Department clarify on the following 1) what the Department's intended interpretation application and enforcement of the NPRM's use of the phrase "termination of pregnancy" specifically entails; and2) whether the Department's intended interpretation application and enforcement of "termination of pregnancy" includes spontaneous termination of pregnancy (i.e. miscarriage) and the treatment of miscarriage once the unborn baby has already died; and3) whether the Department's intended interpretation application and enforcement of "termination of pregnancy" includes life saving treatment of women experiencing an ectopic pregnancy or placental abruption that might result in the death of the unborn child); and4) whether the Department intends to interpret apply and enforce the phrase "termination of pregnancy" as contemplated in the proposed language as to mean intentional termination of pregnancies with the goal of producing a dead baby (i.e. induced abortion) That the Department intends interpretation is supported by its reference to Dobbs and E O 14076, however including abortion in "pregnancy-related conditions" is very troublesome as

discrimination on the basis of pregnancy and pregnancy related conditions includes abortion care |The |Idaho| decision has unleashed chaos in our medical system In the post-|Roe| world discrimination against pregnant patients has become both more common and more dangerous with hospitals and providers turning away patients even in emergency situations |Footnote 23: See e.g. Sarah McCammon & Lauren Hodges Doctors' Worst Fears About the Texas Abortion Law are Coming True NPR (Mar 1 2022) [https://www.npr.org/2022/02/28/1083536901/texas-abortion-law-6-months, Kate Zernike Medical Impact of Roe Reverse Goes Well Beyond Abortion Clinics Doctors Say NEW YORK TIMES (Sept. 10 2022) https://www.nytimes.com/2022/09/10/us/abortion-bans-medical-care-women.html, Christine Vestal Some Abortion Bans Put Patients Doctors at Risk in Emergencies STATELINE AN NITIATIVE OF THE PEW CHARITABLE TRUSTS (Sept 7 2022) https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/09/01/some-abortion-bans-put-patients-doctors-at-risk-in-emergencies | It is important we that the final rule states clearly and explicitly that discrimination on the basis of pregnancy and pregnancy related conditions includes abortion care In order to ensure patients do not experience discrimination when accessing medically indicated care and preserve patients' trust in their providers The final rule should also specify that providers may not discriminate against patients for having accessed such care in the past Abortion is a type of pregnancy related care this discrimination based on abortion is a form of sex discrimination under Section 1557 The final rule should be clear that providers may not substitute their own bias for the provision of medically indicated care Such conduct not only denies medically necessary care to patients but also may erode the trust in the health care system and their health care providers For example when patients experience abortion stigma while accessing

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The Heritage Foundation

American Psychological Association

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Charlotte Lozier Institute

Center for Reproductive Rights

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Covered California

Center for Reproductive Rights

Health Care For All

Physicians for Reproductive Health

AARP

American Psychological Association

National Association of Health Underwriters

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These protections also apply to pregnancy-related conditions: for example a provider that offers prenatal care to cisgender women would not be permitted to deny that care to transgender men or nonbinary people. The same Center for American Progress research showed the need for these explicit protections as well.[Footnote 20: Ibid.] More than 20 percent of transgender or nonbinary respondents reported being denied reproductive health care due to their gender identity and that number was much higher for transgender and nonbinary patients of color.

[Bold: C. Proposed § 92.101 appropriately codifies the broad sweep of the ACA's sex discrimination prohibition.][Bold: 1. We strongly support proposed § 92.101's broad approach and encourage HHS to adopt further clarifications.] We strongly support the broad yet expressly not exhaustive description of covered grounds of discrimination including sex-based discrimination in proposed section 92.101. We suggest two clarifications to this language [and related language in other provisions]: • In section 92.101 (a) [1] add the phrase "or any combination thereof" after "disability." In section 92.101(a)(2): Add the phrase "including termination of pregnancy" after "related conditions." And the phrase "transgender status" after "sexual orientation."

[Bold: Abortion.][HHS's redefinition of "sex" is drawn from Title IX. The department uses Title IX's redefinition of pregnancy to include "or related conditions" which is defined as: "(1) Pregnancy, childbirth, termination of pregnancy or lactation, [2] Medical conditions related to pregnancy, childbirth, termination of pregnancy or lactation, or [3] Recovery from pregnancy, childbirth, termination of pregnancy, lactation or their related medical conditions." [Footnote 20: 87 FR 41390][This proposed redefinition of pregnancy was introduced a mere three weeks after the Supreme Court's decision in Dobbs v. Jackson Women's Health Organization on June 24 2022. This decision corrected the grave errors of [Italics: Roe v. Wade and Planned Parenthood v. Casey.] Nonetheless Title IX did not mention the Dobbs ruling nor its impact down the way pregnancy and abortion rulings will necessarily be interpreted in the United States. Not only does Section 1557 define sex discrimination to include "termination of pregnancy" the department goes so far as to question "what impact if any the Supreme Court decision in [Italics: Dobbs v. Jackson Women's Health Organization] has on the implementation of Section 1557 and these regulations." The department fails to explain why they are picking and choosing only certain parts of Title IX's definition of sex pregnancy and abortion to implement.[Footnote 21: HHS Announces Proposed Rule to Strengthen Nondiscrimination in Health Care July 25 2022 https://www.hhs.gov/about/news/2022/07/25/hhs-announces-proposed-rule-to-strengthen-nondiscrimination-in-health-care.html]

throughout pregnancy childbirth and the postpartum period is prohibited under Section 1557.][We urge the Department to clarify that Section 1557's prohibition of discrimination and mistreatment in the provision of pregnancy-related care includes the perinatal and postpartum period. Discrimination throughout pregnancy and the postpartum period is common especially for Black Indigenous Latinx Asian American and Pacific Islander (AAPI) and other people of color people with disabilities and others who live at the intersections of Section 1557's protected identities. Such discrimination includes mistreatment during labor and delivery.[Footnote 55: ABOLITION CARE NETWORK ET AL. SYSTEMIC RACISM AND REPRODUCTIVE INJUSTICE IN THE UNITED STATES: A REPORT FOR THE UN COMMITTEE ON THE ELIMINATION OF RACIAL DISCRIMINATION (2022) https://reproductiverights.org/wp-content/uploads/2022/08/2022-CERD-Report_Systemic-Racism-and-Reproductive-Injustice.pdf] A recent poll conducted by the AAMC Center for Health Justice of people in the United States who had given birth in the last five years reveals that more LGBTQ+ individuals (31%) reported having poor or worse birthing experience compared to cisgender heterosexual individuals (18%). [Footnote 56: AAMC CTR. FOR HEALTH JUSTICE POLLING SPOTLIGHT: UNDERSTANDING THE EXPERIENCES OF LGBTQ+ BIRTHING PEOPLE (2022) https://www.aamchealthjustice.org/news/2022/lgbtq-birth.] Individuals who identified as Black Hispanic LGBTQ+ had lower incomes and younger individuals were also more likely to report that they felt that their care was subject to bias or discrimination. [Footnote 57: AAMC CTR. FOR HEALTH JUSTICE FROM PREGNANCY TO POLICY (2022) https://www.aamchealthjustice.org/news/polling/pregnancy-policy.] The Department should affirm the rights of pregnant patients to receive high quality care free from discrimination. Experts advocates and storytellers from the Black Indigenous AAPI and Latinx populations have made especially clear the rule that the proposed rule recognizes various forms of sex discrimination that disproportionately impact BIPOC and Latinx communities. The Proposed Rule clarifies discrimination on the basis of sex as including but not limited to discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions; sexual orientation, and gender identity. As discussed further below prescribing discrimination on these bases will improve health care access for LGBTQ+ people of color in particular. However the Department must further clarify discrimination on the basis of pregnancy or related conditions in order to ensure access to vital health care services to pregnant people.

The Century Foundation

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InterACT: Advocates for Intersex Youth

The Heritage Foundation

Center for Reproductive Rights

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I support the proposed rule adding sexual orientation to Section 1557 of the Affordable Care Act. This will give LGBTQ+ and particularly LGBTQ+ leaders the ability to combat discrimination in healthcare settings. Without this protection LGBTQ+ people may delay care for fear of discrimination choose not to receive vital home and community based services like Meals on Wheels or have hours to find a doctor that will serve a transgender person struggle to have gender affirming care paid for by their insurance and much more.

I am an active voter and citizen who knows and loves many gay lesbian and transgender friends neighbors and family members. It is extremely important that sexual orientation and gender identity protections are added to Section 1557 of the ACA. This is an urgent issue that needs government intervention. As we have seen in recent years although it is not a new LGBTQ adults and children are being denied vital healthcare across the country. This not just cruel and immoral it is dangerous. Everyone deserves quality healthcare that supports and celebrates who they are and keeps them safe and thriving. We cannot allow bigotry to go unchecked in the healthcare system. The government must step in to protect these vulnerable groups. Please protect sexual orientation and gender identity in healthcare under the ACA. All Americans deserve care. All Americans deserve to be healthy.

Alliance of Multicultural Physicians

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We strongly support Proposed Rule Section 1557 of the Affordable Care Act. John Clarke increasingly serves residents of the LGBTQ community and want to ensure that supports are strengthened to provide health and living services in a safe welcoming environment. LGBTQ+ elders many of whom have experienced stigma and discrimination throughout their lives face unique and serious obstacles to healthy aging. At John Clarke Senior Living we wish to ensure that barriers to an open hospitable care environment are eliminated. Codifying protections against discrimination on the basis of sex including discrimination on the basis of sexual orientation and gender identity under the Proposed Rule Section 1557 will go a long way in supporting our efforts to provide that setting. Please ensure that all of our Elders are protected from discrimination.

John Clarke Senior Living

On behalf of Temple University Health System our patients and the vulnerable communities we serve thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services proposed rule on Section 1557 of the Patient Affordable Care Act. | We support this notice of proposed rulemaking that affirms Section 1557 regulations protect against discrimination based on gender identity sexual orientation or sex stereotypes.

Temple University Health System

I am writing on behalf of DignityUSA to express our strong support for the Proposed Rule on Section 1557 of the Affordable Care Act. DignityUSA represents the significant majority of Catholics in the U.S. who support justice equality and full inclusion of LGBTQIA people in our churches and society. We believe that the Proposed Rule is in full accord with these aims. The challenges currently faced by LGBTQIA people in accessing appropriate respectful health care is causing poor health outcomes and even costing lives. The Proposed Rule would help to end discrimination in health care and recognize that procedures that are optional or cosmetic for straight cisgender people can be medically necessary for LGBTQIA people especially for transgender and nonbinary individuals.

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Dignity, Inc. dba DignityUSA

|Bold: Nondiscrimination Provisions| |Italics: Discrimination Prohibited|Health centers have long been trusted health care settings for the LGBTQ community. In 2021 99% of health centers served 762000 patients that identify as bisexual gay lesbian or another sexual orientation. Furthermore 98% of health centers served patients who identified as transgender. Several health centers specialize in serving LGBTQ patients and provide services such as gender affirming surgeries mental health care needs resources for unstable housed LGTBQ youth and HIV treatment and prevention. Health centers are committed to providing patient-centered care and investing in workforce training to ensure staff understand best practices to provide informed and inclusive care. TPCA appreciates OCR's clarification in paragraph [all 2] of §92.101) that prohibits discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions, sexual orientation, and gender identity. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have just fixated on pressing distinctions between the two concepts. Therefore explicit language is needed to prevent this discrimination and consistency throughout the final rule is important.

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Tennessee Primary Care Association

|Bold: Nondiscrimination Provisions| |Italics: Discrimination Prohibited| Health centers have long been trusted health care settings for the LGBTQ community. In 2021 99% of health centers served 762000 patients that identify as bisexual gay lesbian or another sexual orientation. Furthermore 98% of health centers served patients who identified as transgender. Several health centers specialize in serving LGBTQ patients and provide services such as gender affirming surgeries mental health care needs resources for unstable housed LGTBQ youth and HIV treatment and prevention. Health centers are committed to providing patient centered care and investing in workforce training to ensure staff understand best practices to provide informed and inclusive care. MNACHC appreciates OCR's clarification in paragraph [all 2] of §92.101) that prohibits discrimination on the basis of sex stereotypes; sex characteristics including intersex traits; pregnancy or related conditions, sexual orientation; and gender identity. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have just fixated on pressing distinctions between the two concepts. Therefore explicit language is needed to prevent this discrimination and consistency throughout the final rule is important.

Minnesota Association of Community Health Centers

We strongly support the agency's clarification that Section 1557 unequivocally prohibits discrimination on the basis of sexual orientation or gender identity and sex characteristics including intersex traits. These forms of discrimination have long been part and unchecked in our medical system. This outright discrimination flies in the face of the very foundation of civil rights that our nation has proudly stood over the past decades. This rule will help to ensure that Section 1557 is properly interpreted and enforced to prohibit these forms of discrimination with a heathcare

38 Members of Congress

|Bold: B. Protecting LGBTQI Individuals from Unlawful Discrimination|The Proposed Rule expressly recognizes that discrimination "on the basis of sex" necessarily includes discrimination based on sex stereotypes sex characteristics sexual orientation and gender identity. 87 Fed. Reg. at 47838 [Footnote 13] It is settled law that federal civil rights statutes forbid discrimination on the basis of sex stereotypes and sex characteristics. Price Waterhouse v. Hopkins 490 U.S. 228 240 (1989) ("[G]ender must be irrelevant to employment decisions"). It is also settled law that "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex" because "homosexuality and transgender status [is] inextricably bound up with sex." Bostock 140 S. Ct. at 1471.] The States welcome this correction to the 2020 Rule and support HHS's return to proper statutory interpretation.

Attorneys General of California, New York, Massachusetts, and nineteen other States

Department recognizes in the preamble to the NPRM that people may experience discrimination in health care on more than one basis. It would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. We propose the following change to section 92.101(a)(1):"Except as provided in title I of the ACA an individual must not on the basis of race color national origin sex age or disability [both] or any combination thereof] be excluded from participation in be denied the benefits of or otherwise be subjected to discrimination under any health program or activity operated by a covered entity." This language should also be added to sections 92.207(a) [b](1) and [b](2). This addition is incredibly important as similar to the importance of understanding the intersectionality of race and sexuality with a comprehensive sex equal or factoring for intersectional discrimination within the various forms of discrimination that LGBTQAI+ youth can experience within the medical system is necessary. According to Rockefeller Institute of Government of SUNY [embedded hyperlink text (https://rockinst.org/blog/understanding-and-addressing-the-challenges-faced-by-lgbtq-people-of-color-in-accessing-mental-healthcare/)] LGTBQAI+ youth of color are vulnerable to risk of suicide and poor mental health due to mistrust of mental health providers and fear of discrimination. We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law including [italics: Price Waterhouse v Hopkins] and [Italics: Bostock v. Clayton County] makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation or and gender identity including transgender status. It is essential that this rule track those decisions to provide assurance to participants beneficiaries and enrollees and not to covered entities that these bases are unequivocally included. We also support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex-based.

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SIECUS: Sex Ed for Social Change

We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law including [Italics: Price Waterhouse v. Hopkins] and Bostock v. Clayton County] makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity including transgender status. It is essential that this rule track those decisions to provide assurance to participants beneficiaries and enrollees and not to covered entities that these bases are unequivocally included. We also support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex-based.

Eating Disorders Coalition for Research, Policy & Action

|Bold: II. The NPRM's proposal to restore protections for the LGBTQI+ community are essential and aligned with federal law and international human rights norms. A. The NPRM's proposed restoration of protections against discrimination for the LGBTQI+ community is essential. We support the Department's recognition in the proposed rule that sex discrimination includes discrimination on the basis of sex stereotypes sexual orientation gender identity and sex characteristics including intersex traits. LBGTQI+ people frequently experience discrimination in access to care. In a 2018 study one in five LGBTQ people including 51 percent of transgender people said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. [Footnote 67: Shallwani Ahmed Mirza & Carl. "A Recipe Discrimination Prevents LGBTQ People from Accessing Health Care (2016) CTR FOR AMER. PROGRESS https://www.americanprogress.org/issues/lgbt/news/2018/01/18/443148/discrimination-prevents-lgbtq-people-accessing-health-care.] That rate was substantially higher for LGBTQ people living in non-metropolitan areas with 41 percent reporting that it would be very difficult or impossible to find an alternative provider. [Footnote 68: Id.]

Center for Reproductive Rights

rons stent with federal law and internat ona human rights norms |The proposed rule's inclus on of sex stereotypes sexual orientat on gender identity and sex characte stics is consistent with settled federal law governing sex discrimination Supreme Court jurisprudence including the dec sions in [Italics: Price Waterhouse v Hopkins and Bostock v. Clayton County] makes clear that federal sex discrimination laws prohibit discrimination on the basis of sex stereotypes sexual orientat on and gender dent ty We also note that the proposed rule's consist interpretat on of sex discrim nation based on sex stereotypes sexual orientat on and gender identity is in keeping with international human rights norms. |Footnote 73: Convent on on the Elim nation of All Forms of Discrimination Against Women adopted Dec 18 1979 art 5(a) G A Res 34/180 U N GAOR 34th Sess Supp No 46 at 193 U N Doc A/34/46 (1980) U N T S 13 |entered into force Sept 3 1981| [hereinafter CEDAW]; CEDAW Committee General recommendat on No28 on the core ob gations of States parties under article 2 of the Convention on the Elimination of All Forms of D scrimination aga nst Women para 9 U N Doc CEDAW/C/GC/28 |2010| [hereinafter CEDAW Committee Gen Recommendation No 28]; CEDAW Committee Gene a Recommendation No 33 on women's access to justice para 7 U N Doc CEDAW/C/GC/33 |2015|; see also ESCR Committee General comment No 20 at para 27; Convention on the Rights of Persons with Disabilities adopted Dec 13 2006 art 8 para 1(b) G A Res A/RES/61/106 U N GAOR 61st Sess U N Doc A/61/611 |2006| [entered into force May 3 2008] | The UN High Commissioner for Human Rights has affirmed that all people including LGBT persons are entitled to enjoy the protect ons prov ded by the right to be free from discrimination. |Footnote 74: United Nations High Commissioner for Human Rights Discriminatory Laws and Practices and Acts of Violence Against Individuals Based on Their Sexual Orientat on and Gender Identity para 5 U N Doc A/HRC/19/41

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Pennie supports extending the nondiscrimination provisions to include the prohibition of d scrimination based on gender gender identity sexual orientation relationship status or and/or family status. These protections align with federal court rul ngs that consider the protect on against LGBTQI+ discrimination to be part of the sex based scrimination protect ons. Pennie concurs with HHS' assessment that members of the LGBTQI+ popul ation face barriers to appropriate health care and insurance access for needed coverage. Pennie believes that extending nondiscrim nation provis ons to expressly include sexual orientat on and gender identity is a necessary step to ensure all Pennsylvanians have equitable access to the health coverage and health care services they need.

In response to the Supreme Court decision in Dobbs v Jackson Women's Health Organization the proposed rule strengthens protections against d scrimination on the basis of sex including discrim nation on the basis of pregnancy or related condit ons including abortion and discrim nation on the basis of sexual orientat on and gender dent ty. The Colorado Health Foundation supports these protections as essential safeguards for fundamental human rights

In addition the provisions clarifying anti scrimi nat on provisions for specific popul at ons are necessary and welcome including provisions to: • Affirm gender-based and d sability and accessibility anti scrimi nat on policies, • Clarify language access requirements, and • Include sex characteristics or orientation in coverage and restore coverage for gender identity or stereotype and pregnancy in defini on of "sex."

|Bold/italics: Support for NPRM's Re statement of Provisions from the 2016 Final Rule| Given th s existing state law framework and our shared values CalHHS strongly supports the NPRM's principal objective to restore nondiscrim nation and equal access policies to those promulgated under the 2016 Final Rule. This includes: -Expanding terms of sex discrimination to include discr minat on on the bas s of sex stereotypes sex character stics, nc luding intersex traits pregnancy and related conditions sexual or entation and gender identity -Clarifying that nond scr minat on policies extend to associational bases.

The Proposed Rule Addresses Discr minatory Conduct that Disproportionately Impacts Communities of Co orFederal law has prohibited race discrim nation in health care since the passage of Title VI of the Civ Rights Act of 1964. However Title V does not apply to all hea th care related activities and programs nor does it apply to a forms of discrim nation n health care. Section 1557 therefore fills in a critical gap by extending antidiscrimination protect ons to patients at the intersection of multiple dent ties. The Proposed Rule prescribes many forms of discrimination that amplify the impacts of racism and subject people to dua discrimination. For example the Proposed Rule seeks to eliminate discrim nation against Limited English Proficient (LEP) individuals and people living with disabilities groups that are predominately comprised of people of color Likewise Sect on 1557 prescribes sex discr minat on in hea th care and the Proposed Rule clarifies that "sex d scrimination" includes d scr minat on on the bas s of sexual orientation and gender identity. Both cisgender women of co or and LGBTQI+ people of color face racism in health care that is amplified by their gender sexual orientat on or gender identity. As discussed further below the Proposed Rule restricts discriminatory conduct against these groups thus r educing health care access for people of color w h multiple system cally marginalized identities. Protect on of people's rights can only occur when we see and understand their diverse selves and the Proposed Rule recognizes this

Bold and Underline: Discrimination on the Basis of Sex Gender Identity and Sexual Orientation| "Bold: LGBTQ Children" The AAP strives to improve health care access and elim nate d sparities for ch ldren and adolescents who identify as lesbian gay bisexual transgender or quest on ng (LGBTQ) of their sexual orientat on or gender identity and strongly supports the proposed rule's prohibition of d scr minat on in the provision and coverage of gender affirm ng and transition related care. [Footnotes 11 and] Recommendations for Promoting the Health and Well-Being of Lesbian Gay Bisexual and Transgender Adolescents: A Posit on Paper of the Society for Ado escent Health and Medicine." Journal of Ado escent Health 52 no 4 (2013): 506–13. doi:10.1016/ jadohealth.2013.01.015. https://www.jahonline.org/article/S1054-139X%2813%2900057-8/fu text; Lafferty J. Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents Ped at cs 2018;142[4] (https://ped at cs.aappub l cations.org/cont ent/142/4/e20182162| Despite some advances in public awareness and legal protections youth who identify as LGBTQ contin ue to face disparities that stem from mu ltiple sources including inequitable laws and polic es societal discr minat on and a lack of access to quality evidence based health care including mental health care. Such challenges are often more intense for youth who do not conform to social expectat ons and norms regarding gender. We welcome the explic t recognition that section 1557's prohibition on sex discrimination includes discrim nation on the basis of sex stereotypes sexual orientat on or gender identity and sex characteristics including intersex traits We are pleased that the proposed rule ensures there are affirmative protections for LGBTQI+ individuals in health care. This includes clarifying that nond scr minat on requirements apply to health programs and activities provided through telehealth services and interpreting Medicare Part B as federally financed assistance for the purpose of coverage under the federal civil rights statutes the HHS Department enforces.

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Center for Reproductive Rights

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Pennsylvania Health Insurance Exchange Authority d/b/a Pennie

The Colorado Health Foundation

National Health Council

California Department of Health Care Services

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Alliance of Multicultural Physicians

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American Academy of Pediatrics

AAFP

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Protections against Discrimination on Basis of SexSex discrimination disproportionately impacts women of color LGBTQ+ people and individuals living at the intersections of multiple identities. This free identity results in access to less affordable health coverage and lower quality health care including more frequently receiving inaccurate diagnoses being provided less effective treatment and sometimes being denied care altogether. As the first broad prohibition against sex discrimination in health care § 1557 is crucial to ending gender-based discrimination by health care providers and health insurers.Gender Identity and Sexual Orientation.We applaud HHS for articulating a clear and expansive explanation of prohibition on the basis of sex. Supreme Court cases including Price Waterhouse v. Hopkins and Bostock v. Clayton County makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity including transgender status. It is essential that this rule track those decisions to provide assurance to participants beneficiaries and enrollees and notice to covered entities that these bases are unequivocally included. We also support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex based. We refer to the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have just cited to by dressing distinctions between the two concepts. Therefore explicit language is needed to prevent this discrimination and consistency throughout the final rule is important. We therefore recommend also including "transgender status" in § 92.206(b)(1) (b)(2) and (b)(4) and in §92.207(b)(3).

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Health Care For All

Ensuring that sexual orientation and gender identity are protected from discrimination.The proposed rule also looks to change the definition of sex discrimination to include discrimination based on sexual orientation and gender identity. Sexual orientation and gender identity were originally included in the 2016 regulations for section 1557 though not as explicitly as advocates argued was necessary [Footnote 16: Timothy Jost "HHS Issues Health Equity Final Rule" Health Affairs May 14 2016 https://www.healthaffairs.org/do/10.1377/forefront.20160514.054868/. The Trump administration eliminated both of these protections in its 2020 rule [Footnote 17: Musumeci et al. "Final Rule on Section 1557"].

The Century Foundation

• More Explicitly Prohibiting DiscriminationHHS focuses much of this rule on restoring nondiscrimination protections that were eliminated in the 2020 rule. HHS reiterates that Section 1557 provides a general prohibition of discrimination on the basis of race sex national origin age or disability under health programs and activities.Additionally HHS clarifies that the term "on the basis of sex" includes sex stereotypes sex characteristics including intersex traits pregnancy or related conditions sexual orientation and gender identity [Footnote 7: Consistent with legal conclusions reached in Price Waterhouse v. Hopkins 490 U.S. 228 (1989) (sex discrimination "includes discrimination based on sex stereotypes") and Bostock v. Clayton County 140 S.Ct. 1731 1742 (2020) (sex discrimination includes discrimination based on sexual orientation and gender identity)]. This broader definition will require covered entities to provide equal access to health programs and activities without the threat of discrimination on the basis of sex and will be prohibited from denying or limiting health services for gender-affirming care or the basis of an individual's sex assigned at birth gender identity or gender otherwise recorded. This clarification will also prohibit discrimination on the basis of sex race color national origin age and disability in the provision and administration of health insurance coverage.

Covered California

Additionally URAC urges CMS to move forward with its propuse to amend previous language so it will again identify and recognize discrimination on the basis of sexual orientation and gender identity as prohibited forms of discrimination based on sex. As proposed CMS should also amend its own regulations in order to apply the protections to Medicaid fee-for-service programs and managed care programs. This will promote consistency across HHS programs of policies and requirements that prohibit discrimination based on sexual orientation or gender identity.

URAC

[Bold: Include Sexual Orientation and Gender Identity as Forms of Discrimination "Based on Sex". The TTAG urges CMS to move forward with its proposal to amend previous language so it will again identify and recognize discrimination on the basis of sexual orientation and gender identity as prohibited forms of discrimination based on sex consistent with the U.S. Supreme Court's holding in Bostock v. Clayton County [Footnote 5: 140 S. Ct. 1731 (2020).]

Tribal Technical Advisory Group to CMS (TTAG)

We support the Proposed Rule as a way of increasing equity and removing many of the barriers faced by LGBTQIA people in the current health care system across the U.S. We urge full implementation of the Rule as proposed including those that protect transgender and non-binary individuals' access care that addresses gender dysphoria.

Dignity Health Dignity USA

Additionally we support the proposed rule's explicit language around discrimination "on the basis of sex" that clarifies application to sex stereotypes sex characteristics [including intersex traits] pregnancy or related conditions sexual orientation and gender identity.

AARP

On June 15 2020 the Supreme Court ruled in Bostock v. Clayton County that existing laws prohibiting sex discrimination protect against both sexual orientation discrimination and gender identity discrimination [Footnote 18: Bostock v. Clayton County 590 U.S. _ (2020)]. This proposed rule would align the protections under section 1557 with the Bostock ruling ensuring that LGBTQ patients receive the protections they deserve. Recent research by the Center for American Progress highlights the need for these protections: Nearly one in five LGBQ patients surveyed reported concerns over being denied good care if they disclosed their sexual orientation and half of transgender or nonbinary patients surveyed reported similar concerns if they disclosed the gender identity [Footnote 19: Caroline Medina and Lindsay Mahowald "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities" Center for American Progress September 8 2022 https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/].

(b)(5)

The Century Foundation

[Italic: Explicit prohibition of discrimination on the basis of sexual orientation gender identity and sex characteristics. We also strongly urge to clearly state that gender identity includes trans status.]We applaud expansive explanation of discrimination on the basis of sex. Supreme Court case law including Price Waterhouse v. Hopkins and Bostock v. Clayton County makes clear that federal sex discrimination law includes sex stereotypes sexual orientation and gender identity including transgender status. The explicit inclusion of sexual orientation is a welcome addition to the Obama Section 1557 rule. We also support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex based. Health disparities among intersex populations are primarily driven by stigma and discrimination especially with the lack of data around the experiences and needs of intersex people [Footnote 10: Medina Caroline Mahowald Lindsay. "Key Issues Facing People with Intersex Traits." Center for American Progress 22 Aug. 2022 www.americanprogress.org/article/key-issues-facing-people-intersex-traits/]. A 2018 survey of intersex individuals found that 43% of adult intersex individuals reported their physical health was fair or poor while 53% reported their mental health was fair or poor. [Footnote 11: Ibid].

Howard Brown Health

DETAILED COMMENTS ON "NONDISCRIMINATION IN HEALTH PROGRAMS AND ACTIVITIES"General Provisions1. Scope – Prohibited Discrimination: The Proposed Rule prohibits discrimination on the basis of race color national origin sex age or disability in the provision or administration of health insurance coverage and other health-related coverage. The 2020 rule amended 10 provisions in CMS regulations – of which cover at least some entities that are also subject to Section 1557 to delete language that prohibited discrimination on the basis of sexual orientation and gender identity. HHS proposes amending these regulations so that they again identify and recognize discrimination on the basis of sexual orientation and gender identity as prohibited forms of discrimination based on sex. Recommendation:BCBSA strongly supports reinstating the prohibition of discrimination on the basis of sexual orientation and gender identity.Rationale:BCBSA supports providing high quality services to all members regardless of their race color national origin sex gender identity sexual orientation age or disability. We believe everyone should have access to healthcare without experiencing discrimination no matter who they are where they live or what their health conditions may be.

Blue Cross Blue Shield Association

The Proposed Rule recognizes various forms of sex discrimination that disproportionately impact LBTQ and Latinx communities. The Proposed Rule clarifies discrimination on the basis of sex as including but not limited to discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions, sexual orientation, and gender identity. As discussed further below, proscribing discrimination on these bases will improve health care access for LGBTQ+ people of color in particular. However the Department must further clarify discrimination on the basis of pregnancy or related conditions in order to ensure access to vital health care services to pregnant people.

(b)(5)

The Proposed Rule Strengthens Protections for LGBTQIA+ IndividualsWe applaud HHS's proposed rule for making explicit that Section 1557's protections against discrimination on the basis of sex includes gender identity which is consistent with the interpretation of the Supreme Court decision in Bostock and federal anti-discrimination laws. We support the proposed rule for clarifying that discrimination on the basis of sex in health care programs and activities includes sex stereotypes, sexual orientation, gender orientation, gender identity and sex characteristics including intersex trait and marital parental or family status. Footnote 22 Id. at 47916 (Proposed § 92.101)(Sex stereotypes such as expectations about how people should present or communicate have historically created barriers to equitable health care access and services. We also support the restoration of enforcement of protections against discrimination on the basis of association which should protect LGBTQ+ couples who may be turned away from care. Footnote 23 Id. at 47918 (Proposed § 92.209).

(b)(5)

Alliance of Multicultural Physicians

Senate Democrats

LGBTQI+ peopleTransgender people of color face significant barriers to health care access. 65 percent of transgender people of color report experiencing some form of discrimination and 46 percent of transgender people report having their health insurance deny gender affirming care. Furthermore some transgender people report experiencing such hostile discrimination that doctors have refused to treat conditions such as asthma or diabetes. Proposed Section 92.206 requires equal program access on the basis of sex and addresses the conditions that lead to health disparities among transgender people more broadly. Under this section health care providers may not deny or limit health services based on their sex. This allows or ensures access to necessary health care services especially reproductive and gender affirming care. For example transgender men face barriers to pap smears necessary for cervical cancer screenings as well as breast cancer screenings. Cisgender gay and lesbian people also face egregious denials of care such as refusal to provide infertility treatments.

Alliance of Multicultural Physicians

I am an active voter and citizen who knows and loves many gay lesbian and transgender friends neighbors and family members. It is vitally important that sexual orientation and gender identity protections are added to Section 1557 of the ACA. This is an urgent issue that needs government intervention.As we have seen in recent years although it is nothing new LGBTQ adults and children are being denied vital healthcare across the country. This not just cruel and immoral is dangerous. Everyone deserves quality healthcare that supports and confirms who they are and keeps them safe and thriving. We cannot allow bigotry to go unchecked in the healthcare system. The government must step in to protect these vulnerable groups.Please protect sexual orientation and gender identity in healthcare under the ACA. All Americans deserve care. All Americans deserve to be healthy.

The proposed rule [RIN 0945-AA17] is a violation of the conscience rights of health care professionals and entities that seek to Do No Harm and to offer practical and life-giving care to the people they serve. Health care providers and insurers should not be coerced to perform or cover abortions or transgender procedures. It is improper and illogical to conflate sex discrimination with the issues of abortion and transgenderism. Provisions of the proposed rule that can be construed to require the providing for or coverage of such procedures violate rights of conscience and religious freedom as reflected in current federal conscience laws including the Weldon Amendment. For these reasons I oppose the abortion and gender identity provisions of the proposed rule.

(b)(5)

We strongly support Proposed Rule Section 1557 of the Affordable Care Act.John Clarke increasingly cares for residents of the LGBTQ community and want to ensure that supports are strengthened to provide health and living services in a safe welcoming environment.LGBTQ+ elders many of whom have experienced stigma and discrimination throughout their lives face chronic and serious obstacles to healthy aging. At John Clarke Senior Living we wish to ensure that barriers to an open hospitable care environment are eliminated. Codifying protections against discrimination on the basis of sex as including discrimination on the basis of sexual orientation and gender identity under the Proposed Rule Section 1557 will go a long way in supporting our efforts to provide that setting.Please ensure that all of our elders are protected from discrimination.

John Clarke Senior Living

On behalf of Temple University Health System our patients and the vulnerable communities we serve thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services proposed rule on Section 1557 of the Patient Affordable Care Act. | We support the intent of proposed rulemaking that affirms Section 1557 regulations protect against discrimination based on gender identity sexual orientation or sex stereotypes.

Temple University Health System

I am writing on behalf of DignityUSA to express our strong support for the Proposed Rule on Section 1557 of the Affordable Care Act. DignityUSA represents the significant majority of Catholics in the U.S. who support justice equality and full inclusion of LGBTQIA people in our church and society. We believe that the proposed rule is in full accord with these aims. The challenges currently faced by LGBTQIA people in accessing appropriate respectful health care is causing poor health outcomes and even costing lives. The Proposed Rule would help to end discrimination in health care and recognize that procedures that are optional or cosmetic for straight cisgender people can be medically necessary for LGBTQIA people especially for transgender and nonbinary individuals.

Dignity, Inc dba DignityUSA

Broad Nondiscrimination Provisions | Enhances Discrimination Prohibited|Health centers have long been trusted health care settings for the LGBTQ community. In 2021 99% of health centers served 762000 patients that identify as bisexual gay lesbian or another sexual orientation. Furthermore 96% of health centers served patients who identified as transgender. Several health centers specialize in serving LGBTQ patients and provide services such as gender affirming surgeries. Mental health care needs resources for unstable housed LGTBQ youth and HIV treatment and prevention. Health centers are committed to providing patient-centered care and investing in workforce training to ensure staff understand best practices to provide informed and inclusive care. TPCA appreciates OCR's clarification in paragraph [all]7 of [§92.101] that prohibits discrimination on the basis of sex stereotypes: Sex characteristics including intersex traits, pregnancy or related conditions, sexual orientation, and gender identity. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between the two concepts. Therefore explicit language is needed to prevent this discrimination and consistency throughout the final rule is important.

Tennessee Primary Care Association

(b)(5)

|Bold: Nondiscrimination Provisions] – |Italics: Discrimination Prohibited] Health centers have long been trusted health care settings for the LGBTQ community. In 2021 39% of health centers served 762000 patients that identify as bisexual gay lesbian or another sexual orientation. Furthermore 26% of health centers served patients who identified as transgender. Several health centers specialize in serving LGBTQ patients and provide services such as gender affirming surgeries mental health care needs resources for unstable housed LGTBQ youth and HIV treatment and prevention. Health centers are committed to providing patient centered care and investing in workforce training to ensure staff understand best practices to provide informed and inclusive care. MNACHC appreciates OCR's clarification in paragraph (a)(2) of §92.101) that prohibits discrimination on the basis of sex stereotypes; sex characteristics including intersex traits; pregnancy or related conditions; sexual orientation, and gender identity. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between the two concepts. Therefore explicit language is needed to prevent this discrimination and consistency throughout the final rule is important.

We strongly support the explicit clarification that Section 1557 unequivocally prohibits discrimination on the basis of sexual orientation or gender identity and sex characteristics including intersex traits. These forms of discrimination have run rampant and unchecked in our medical system. The outright discrimination we see in the face of the very foundation of civil rights that our nation has proudly stood over the past decades. This rule will help to ensure that Section 1557 is properly interpreted and enforced to prohibit these forms of discrimination within healthcare.

|Bold: B. Protecting LGBTQ Individuals from Discrimination|The Proposed Rule expressly recognizes that discrimination "on the basis of sex" necessarily includes discrimination based on sex stereotypes sex characteristics sexual orientation and gender identity. 87 Fed. Reg. at 47858 |footnote 13| It is settled law that federal civil rights statutes forbid discrimination on the basis of sex stereotypes and sex characteristics. Price Waterhouse v. Hopkins 490 U.S. 228 240 (1989) ("[G]ender must be irrelevant to employment decisions."). It is also settled law that "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based in sex" because "homosexuality and transgender status [is] inextricably bound up with sex." Bostock 140 S. Ct. at 1471. The States welcome this correction to the 2020 Rule and applaud HHS's return to proper statutory interpretation.

We suggest that the language in section 92.101(a)(2) be amended to explicitly include transgender status. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between the two concepts [Hard note 1: See e.g. "Making Admissions or Placements Determinations Based on Sex in Facilities Under Community Planning and Development Housing Programs." Proposed Rule 85 Fed. Reg 40811 (July 24 2020)]. It is therefore preferable to enumerate both in the regulatory text. It is also important to make clear in the final rule that "pregnancy or related conditions" includes the termination of pregnancy. We therefore suggest that this provision be revised as follows: "Discrimination on the basis of sex includes but is not limited to discrimination on the basis of sex stereotypes; sex characteristics including intersex traits; pregnancy or related conditions |bold underline: including termination of pregnancy|; sexual orientation; |bold underline: transgender status|; and gender identity."

Considering the onslaught of discriminatory attacks on transgender and nonbinary people we recommend the proposed rule adds explicit inclusion of "transgender status" to the relevant provisions of the regulatory text. We further urge the Department to provide more explicit examples of prohibited discrimination in coverage and services such as clarification on whether Section 1557 nondiscrimination protection includes coverage of and treatment for infertility. Many insurers refuse to cover fertility treatment or limit coverage of in vitro fertilization to cisgender heterosexual couples and exclude LGBTQIA+ couples [Footnote 28: See "As States 'LGBTQ Couples' IVF Hopes Hinge on New Infertility Definition" BLOOMBERG LAW [May 17 2022] https://news.bloomberglaw.com/health-law-and-business/lgbtq-couples-ivf-hopes-hinge-on-new-infertility-definition].

(b)(5)

Minnesota Association of Community Health Centers

(b)(5)

88 Members of Congress

(b)(5)

Attorneys General of California, New York, Massachusetts, and nineteen other States

(b)(5)

Colors+

(b)(5)

The Proposed Rule is a necessary return to proper legal interpretations of the protections offered by Section 1557. Discrimination against transgender people violates Title IX [Italics: See Grimm v. Gloucester City Sch. Bd. | 972 F.3d 586 619 (4th Cir. 2020) reh'g en banc denied 976 F.3d 399 (4th Cir. 2020) cert. denied 141 S. Ct. 2878 (2021). Even before the U.S. Supreme Court held that sex discrimination encompassed gender identity courts interpreted Title IX's sex discrimination prohibition to bar discrimination against transgender students [Italics: See e.g. Whitaker Kenosha Unified Sch. Dist. No. 1 Bd. of Educ. | 858 F.3d 1034 1049-50 (7th Cir. 2017). Federal appellate courts have also held that state restrictions on access to healthcare for transgender youth violate the Equal Protection Clause [Italics: Brandt v. Rutledge] 47 F.4th 661 [8th Cir. 2022]].

(b)(5)

Senate Democrats

(b)(5)

We suggest that the language in Section 92.101(a)(2) be amended to explicitly include transgender status. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which discrimination against transgender people has been attempted to be justified by raising distinctions between the two concepts and we therefore recommend enumerating both in the regulatory text for clarity.

Attorneys General of California, New York, Massachusetts, and nineteen other States

(b)(5)

The Department recognizes in the preamble to the NPRM that people may experience discrimination in health care on more than one basis. It would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. We propose the following change to section 92.101(a)(1): "Except as provided in Title I of the ACA an individual must not on the basis of race color national origin sex age or disability |Bold or any combination thereof| be excluded from participation in be denied the benefits of or otherwise be subjected to discrimination under any health program or activity operated by a covered entity." This language would also be added to sections 92.207(a) |b)(1)| and |b)(2)|. This addition is incredibly important as similar to the importance of understanding the intersectionality of race and sexuality with a comprehensive sex education or factoring for intersectional discrimination within the various forms of discrimination that LGBTQIA+ youth can experience within the medical system is necessary. According to Rockefeller Institute of Government of SUNY |embedded hyperlink text (https://rockinst.org/blog/understanding-and-addressing-the-challenges-faced-by-lgbtq-people-of-color-in-accessing-mental-health-care/)| LGTBQIA+ youth of color are vulnerable to risk of suicide and poor mental health due to mistrust of mental health providers and fear of discrimination. We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law including [Italics: Price Waterhouse v. Hopkins] and [Italics: Bostock v. Clayton County] makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity including transgender status. It is essential that this rule tracks these sections to provide assurance to participants beneficiaries and enrollees and not be covered entities that these bases are unequivocally included. We also support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex-based.

SIECUS: Sex Ed for Social Change

We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law including [Italics: Price Waterhouse v. Hopkins and Bostock v. Clayton County] makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity including transgender status. It is essential that this rule tracks these sections to provide assurance to participants beneficiaries and enrollees and not be covered entities that these bases are unequivocally included. We also support the explicit inclusion of a prohibition based on sex characteristics including intersex traits as such discrimination is inherently sex-based.

Eating Disorders Coalition for Research, Policy & Action

(b)(5)

We suggest that the language in section 92.101(a)(2) be amended to explicitly include transgender status. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between the two concepts. [Footnote 1: See e.g. "Making Admissions or Placement Determinations Based on Sex in Facilities Under Community Planning and Development Housing Programs" Proposed Rule 85 Fed Reg 44811 (July 24 2020).] It is therefore preferable to enumerate both in the regulatory text.

(b)(5)

Medical Society for Social Change

(b)(5)

Center for Reproductive Rights

(b)(5)

Eating Disorders Coalition for Research, Policy & Action

(b)(5)

Center for Elder Law & Justice

(b)(5)

Center for Reproductive Rights

(b)(5)

Ethics & Public Policy Center

(b)(5)

Pennsylvania Health Insurance Exchange Authority d/b/a Pennie

(b)(5)

The Colorado Health Foundation

(b)(5)

National Health Council

(b)(5)

Sam & Deborah Foundation for Transgender Youth

(b)(5)

California Department of Health Care Services

The Proposed Rule Addresses Discriminatory Conduct that Disproportionately Impacts Communities of Color Federal law has prohibited race discrimination in health care since the passage of Title VI of the Civil Rights Act of 1964. However Title VI does not apply to all health care-related activities and programs nor does it apply to all forms of discrimination. Section 1557 therefore fills in a critical gap by extending antidiscrimination protections to patients at the intersection of multiple identities. The Proposed Rule prescribes many forms of discrimination that amplify the impacts of racism and subject people to data discrimination. For example the Proposed Rule seeks to eliminate discrimination against Limited English Proficient (LEP) individuals and people living with disabilities — groups that are predominately comprised of people of color. Likewise Section 1557 prescribes sex discrimination in health care and the Proposed Rule clarifies that "sex discrimination" includes discrimination on the basis of sexual orientation and gender identity. Both cisgender women of color and LGBTQI+ people of color face racism in health care that is amplified by their gender sexual orientation or gender identity. As discussed further below the Proposed Rule restricts discriminatory conduct against these groups thus improving health care access for people of color with multiple systemically marginalized identities. Protection of people's rights can only occur when we see and understand their diverse selves and the Proposed Rule recognizes this.

(b)(5)

dysphoria rests on the notion that transgender identity is innate — that a person can simply be born as "a man trapped in a woman's body" or vice versa. Therefore assisting that person's hormone balance and restructuring the anatomy to align the body with the inner sense of identity should make things right. But does HHS have any biological basis to believe that a man trapped in the bodily form of a female lives life to those who "assign" a sex at birth? Can HHS be confident that hormones and surgery can "reassign" sex? To answer these questions we must start by examining what science tells us about the biological genesis of sex. The basis of sex determination are relatively clear. Sex in terms of male or female is identified by the organization of the organism for sexual reproduction. [Italics Langman's Medical Embryology.] Concisely explains how the sex of a new organism is determined at fertilization "An X-carrying sperm produces a female (XX) embryo and a Y-carrying sperm produces a male (XY) embryo. Hence the chromosomal sex of the embryo is determined at fertilization." A new human organism of a particular sex is created at that moment. Scientists now know that "the [Italics] presence] of a Y chromosome determines maleness and its absence determines femaleness." This is because the Y chromosome ordinarily carries the SRY ["sex determining region on Y"] gene. The SRY gene contains a transcription factor known as the testis determining factor (TDF) which directs the formation of the male gonads. Sex as a status—male or female—is a recognition of the organization of a body designed for dimorphic sexual reproduction. More than simply being [Italics identified] on the basis of such organization sex is a [Italics coherent concept] or by the basis of that organization. The fundamental conceptual distinction between a male and a female is the organism's organization for sexual reproduction. The conceptual distinction between male and female based on reproductive organization provides the only coherent way to classify the two sexes.

(b)(5)

Alliance of Multicultural Physicians

Ethics & Public Policy Center

[Bold and Underline: Discrimination on the Basis of Sex Gender Identity and Sexual Orientation] [Bold: LGBTQ Children] The AAP strives to improve health care access and eliminate disparities for children and adolescents who identify as lesbian gay bisexual transgender or questioning (LGBTQ) of their sexual orientation or gender identity and strongly supports the proposed rule's prohibition of discrimination in the provision and coverage of gender-affirming and transition-related care. [Footnotes omitted] Recommendations for Promoting the Health and Well-Being of Lesbian Gay Bisexual and Transgender Adolescents: A Position Paper of the Society for Adolescent Health and Medicine." Journal of Adolescent Health 52 no. 4 (2013): 506–13. doi: 10.1016/j.jadohealth.2013.01.019. https://www.jahonline.org/article/S1054-139X%2813%2900057-8/fulltext. Rafferty J. Ensuring Comprehensive Care and Support for Transgender and Gender Diverse Children and Adolescents. Pediatrics. 2018;142(4). https://pediatrics.aappublications.org/content/142/4/e20181162. Despite some advances in public awareness and legal protections youth who identify as LGBTQ continue to face disparities that stem from multiple sources including insidiously laws and policies societal discrimination and a lack of access to quality evidence-based health care including mental health care. Such challenges are often more intense for youth who do not conform to social expectations and norms regarding gender. We welcome the explicit recognition that section 1557's prohibition on sex discrimination includes discrimination on the basis of sex stereotypes sexual orientation or gender identity and sex characteristics including intersex traits.

American Academy of Pediatrics

Further the Rule will predictably result in the infliction of devastating permanent physical and psychological harm to children who doctors will reasonably feel bound to place on puberty blockers and cross-sex hormones and to sterilize through the removal of healthy reproductive organs for fear of being sued for "gender identity discrimination" under the Proposed Rule. The risks of inflicting severe physical and psychological trauma to families by not only encouraging but mandating medical "transition" and social conversion of children ostensibly to another sex cannot be understated and includes an elevated risk of suicide [Footnote 5 "See Protecting Our Children How Radical Gender Ideology is Taking Over Public Schools & Harming Kids HERITAGE FOUNDATION (Mar. 7 2022) https://www.heritage.org/gender/event/protecting-our-children-how-radical-gender-ideology-taking-over-public-schools-harming (testimony of mother whose daughter took her own life after and because of medical gender "transition"). See also Jay P. Greene Puberty Blockers Cross-Sex Hormones and Youth Suicide HERITAGE FOUNDATION (June 13 2022) https://www.heritage.org/sites/default/files/2022-06/BG3712_0.pdf (demonstrating invalidity of leading studies purporting to find that "gender affirming" interventions prevent suicide contra findings using superior research designs that show that easing access to puberty blockers and cross-sex hormones by minors without parental consent increases suicide rate.)] It will be the height of arbitrariness and capriciousness to finalize such a dangerous rule in the face of these and the many other grave harms identified in this comment when they are not only not mandated by Congress but go against the very statute the Proposed Rule purports to enforce.

(b)(5)

Ethics & Public Policy Center

The Health Connector fully supports the proposal to restore and strengthen the prohibition on sex discrimination and standards for gender identity nondiscrimination. Letting individuals know they will not be discriminated against when obtaining coverage or health care is a critical part of expanding coverage and reducing health disparities consistent with the Health Connector's mission. This proposal is especially important to ensure that transgender nonbinary and gender diverse individuals are able to access and use coverage and access health care services in a nondiscriminatory way allowing individuals to reach the fullest potential of their health and well-being.

Massachusetts Health Connector

Moreover we urge HHS to specifically include the term "transgender status" in the rule's relevant provisions to make it unequivocally clear that gender identity discrimination is intended to encompass transgender individuals. [Footnote 5 "See e.g. Williams v. Kincaid No. 21-2030 (4th Cir. Aug. 16 2022) (first-of-its-kind decision the Fourth Circuit found that the Americans with Disabilities Act and the Rehabilitation Act protects individuals with gender dysphoria and recognized that a transgender person's medical needs are just as deserving of treatment and protection as anyone else's.")]

U.S. House Committees on Energy and Commerce Ways and Means and Education and Labor

Protections against Discrimination on Basis of SexSex discrimination disproportionately impacts women of color LGBTQ+ people and individuals living at the intersections of multiple identities. This free identity results in access to less affordable health coverage and lower quality health care, including more frequently receiving inappropriate diagnoses being provided less effective treatment and sometimes being denied care altogether. As the first broad prohibition against sex discrimination in health care § 1557 is crucial to ending gender-based discrimination by health care providers and in health insurers. Gender identity and sexual orientationWe applaud HHS for articulating a clear and expansive explanation of prohibited discrimination on the basis of sex. Supreme Court cases, including Price Waterhouse v. Hopkins and Bostock v. Clayton County, makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation or gender identity, including transgender status. It is essential that this rule track those decisions to provide assurance to participating beneficiaries and enrollees and notice to covered entities that these bases are unequivocally included. We also support the explicit inclusion of discrimination based on sex characteristics, including intersex traits as such discrimination is inherently sex based. While the terms "gender identity" and "transgender status" are often used interchangeably, there have been instances in which those seeking to permit discrimination against transgender people have just cited to by pressing distinctions between the two concepts. Therefore, explicit language is needed to prevent this discrimination and consistency throughout the final rule is important. We therefore recommend also including "transgender status" in § 92.206(b)(1) (ii)(2) and (b)(4) and in § 92.207(b)(3).

(b)(5)

Health Care For All

Ethics & Public Policy Center

Ethics & Public Policy Center

Ethics & Public Policy Center

Ethics & Public Policy Center

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[Bold: F. Incorporating "gender identity" into Section 1557 anti-discrimination laws governing healthcare is harmful, unsustainable, and unconstitutional.]Logic, language and medical history show that "gender identity" is not "sex." HHS's National Institutes of Health (NIH) matter-of-factly states that "every cell has a sex." NIH requires all 80000 research grant applicants to account for sex as a biological variable in all animal and human studies. That's because it knows that a person's immutable sexual biology explains in significant part why men and women respond differently to medication, vary in the experience and manifestation of pain, and have disparate susceptibility to illnesses from heart disease and cancer to psychological conditions such as depression and anxiety. But sex in medicine and research is to be regulated by subjective "gender identity" male and female by a never-ending spectrum biology by placeholders assigned at birth and mothers by "birthing persons." Indeed, in a document just issued by the HHS Office of Population Affairs, I defined "gender identity" as "one's internal sense of self as man, woman, both or neither." [Footnote 89: Office of Population Affairs, U.S. Dep't. Health & Hum. Servs., Gender-Affirming Care and Young People (Mar. 2022), https://opa.hhs.gov/sites/default/files/2022-03/gender-affirming-care-young-people-march-2022.pdf.]

in Sex and Gender (1968) to express a person's psychological self-categorized or distinct from one's sex (male or female). [Footnote 90: R. Green, Robert Stoller's Sex and Gender: 40 Years On, 38 Arch. Sex. Behav. 1452 (2010), https://doi.org/10.1007/s10508-010-9665-5.] [D. John Money previously used the term "gender role." ("The term was instrumental in describing the psychological experience of a person who felt alienated from the sexed body (male or female)." "Gender identity disorder" a mental health diagnosis describing the mismatch between a person's perceived identity and biological sex did not ever appear in the APA Diagnostic and Statistical Manual of Mental Health Disorders (DSM) until 1980. [Footnote 91: Am. Psychiatric Ass'n, Diagnostic And Statistical Manual Of Mental Disorders 261 (3d ed. 1980).] Subsequent versions of the DSM retained the conceptual distinction between a person's natal sex and psychological self-perception. DSM IV described "gender dysphoria" as distress arising out of perceived conflict between a "biological sex" and "gender identity." [Footnote 92: Am. Psychiatric Ass'n, Diagnostic And Statistical Manual Of Mental Disorders 582–84 (4th Ed. 1994).] In 2013 the DSM was revised to replace the diagnosis of "gender identity disorder" with "gender dysphoria" based on clinical distress arising from the experience of gender incongruence (a perceived discordance or lack of harmony between the fact of a person's biological sex and the individual's self-perceived identity). [Footnote 93: Am. Psychiatric Ass'n, Diagnostic And Statistical Manual Of Mental Disorders 452 [5th Ed. 2013].] The American Psychological Association's current guidance on "Gender and sexual orientation diversity in children and adolescents in schools" (which promotes a gender-affirming approach to transgender identification) delineates the difference between "sex" and "gender identity." It defines "sex" as "a person's biological status, typically categorized as male, female or intersex. There are a number of indicators of biological sex, including sex chromosomes, gonads, internal

The Human Rights Campaign Foundation publication entitled [Coming Out: Living Authentically as Transgender or Non-binary] defines "gender identity" as a person's subjective sense of perception and a "transgender" gender identity as one that is "different from their sex assigned at birth." [Footnote 96: "Gender identity is one's innermost concept of self as man, woman, a blend of both or neither – how individuals perceive themselves and what they call themselves. One's gender identity can be the same or different from the sex assigned at birth." Coming Out: Living Authentically as Transgender or Non-binary, Human Rights Campaign Foundation, https://www.hrc.org/resources/coming-out-living-authentically-as-a-transgender-or-non-binary.] Expressing a transgender "gender identity" [italics: contradicts] but cannot [Italics: change] a person's immutable biological sex. Simply put, "gender identity" is not the same as "biological sex." In fact a declaration that one's "gender identity" is "transgender" signals a [italics: rejection] of one's biological sex or sex-based identity. In educational materials designed to explain the concept of "gender identity" in classroom settings, the Coming Schools Are Human Rights Campaign Foundation's educational arm recently described "gender identity" as simply "how you feel." [Footnote 97: Defining LGBTQ+ Words for Elementary School Students, Welcoming Schools, Human Rights Campaign Foundation, https://welcomingschools.org/resources/definitions-lgbtq-elementary-school.] If "gender identity" can be reduced to "feelings" then what does "discrimination on the basis of "gender identity" actually mean? [Italics: Hurtful feelings? [Italics: Unwelcome feelings/ [Italics: Unpleasant feelings?

investigation. The determination of "sex" as explained above is based on objective, empirically demonstrable facts. Classification of "sex" is necessary to the ethical, safe and effective practice of medicine. The benefit of a particular treatment is determined primarily by evaluating measurable physiological results that is evidenced not on the basis of the patient's subjective positive or negative feelings about the treatment. [Footnote 98: Michael Egnor, Operating on Healthy Bodies Defies Surgical Ethics and Trans People are no Exception, The Federalist, September 23, 2022, https://thefederalist.com/2022/09/23/operating-on-healthy-bodies-defies-surgical-ethics-and-trans-people-are-no-exception/.] The subjective, psychological and arbitrary nature of "gender identity" renders it an unstable basis for medical determinations or treatment decisions that by nature must consider objective facts about the person's whole body (including sex). Even the fluid feeling based premise of "gender identity" it is especially unsuitable for determining whether a person has experienced "sex" discrimination in any aspect of healthcare by re-defining "sex" to include "gender identity" in the healthcare arena and consequently privileging "gender identity" over sex-based determinations. HHS undermines the coherent and effective practice of medicine in ways that cannot be overstated. HHS embeds "gender identity" in its regulations as a tool for social engineering not the better care of patients. "Gender identity" is based on feelings which are indeterminable by others unless declared. And yet HHS uses "gender identity" as a vehicle to alter the science based sex based language and practice of medicine even though medicine necessitates recognizing sexual difference and the immutable reality of the sexed body for the provision of medically appropriate care. HHS's redefinition of sex to include "gender identity" will wreak havoc in the healthcare field. Under the proposed rule nearly all aspects of medical practice will become subject to scrutiny and necessary medical protocols will suddenly become susceptible to be treated a

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Physicians for Reproductive Health

Endocrine Society

The Century Foundation

Covered California

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The Heritage Foundation

Tribal Technical Advisory Group to CMS (TTAG)

Dignity, Inc dba DignityUSA

The Century Foundation

American Academy of Pediatrics

AARP

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I [Bold: In the wake of Dobbs v. Jackson Women's Health Organization, HHS must clarify the scope of Section 1557's protections against discrimination related to pregnancy and for LGBTQI+ people.] a. [Bold: LGBTQI+ Discrimination] PRH welcomes the explicit recognition that Section 1557's prohibition on sex discrimination includes discrimination on the basis of sex stereotypes, sexual orientation, or gender identity, and sex characteristics, including intersex traits. This follows settled federal law, and it is critical that the final rule consistently includes these bases. While the terms "gender identity" and "transgender status" are often used interchangeably, there have been instances in which those seeking to permit discrimination against transgender people have just fied it by pressing distinctions between the two concepts. Therefore, explicit language is needed to prevent this distinction and consistency throughout the final rule is important. We recommend also including "transgender status" in § 92.206(b)(1)(b)(7) and (b)(4) and § 92.207(b)(1).B.RECOMMENDATION. Include 'transgender status" after "sexual orientation" in § 92.101(a)(2) as follows: Discrimination on the basis of sex includes but is not limited to discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy; [Build: or related conditions including termination of pregnancy]; sexual orientation; [Bold/Italics: transgender status;] and gender identity.

We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex; however, we suggest that the language throughout the rule be amended to explicitly include transgender status. While the terms "gender identity" and "transgender status" are often used interchangeably, there have been instances in which those seeking to permit discrimination against transgender people have just fied it by pressing distinctions between the two concepts. [Footnote 1: "Making Admission or Placement Determinations Based on Sex in Facilities Under Community Planning and Development Housing Programs" Proposed Rule, 85 Fed Reg 44811 (July 24 2020)]. It is therefore preferable to specify both in the regulatory text. We believe that clarifying and clarifying protections for transgender individuals will make it easier for them to access the appropriate treatment and care needed to ensure their health and well being.

Ensuring that sexual orientation and gender identity are protected from discrimination. The proposed rule also looks to change the definition of sex discrimination to include discrimination based on sexual orientation and gender identity. Sexual orientation and gender identity were originally included in the 2016 regulations for section 1557 though not as explicitly as advocates argued was necessary. [Footnote 16: Timothy Jost, "HHS Issues Health Equity Final Rule," Health Affairs, May 14 2016 https://www.healthaffairs.org/do/10.1377/forefront.20160514.054868/. The Trump administration eliminated both of these protections in its 2020 rule. [Footnote 17: Musumeci et al. "Final Rule on Section 1557":

- More Explicitly Prohibiting Discrimination] HHS focuses much of this rule on restoring nondiscrimination protections that were eliminated in the 2020 rule. HHS reiterates that Section 1557 provides a general prohibition of discrimination on the basis of race, color, national origin, age, or disability under health programs or activities. Additionally, HHS clarifies that the term "on the basis of sex" includes sex stereotypes, sex characteristics, including intersex traits, pregnancy or related conditions, sexual orientation, and gender identity. [Footnote 7: Consistent with legal conclusions reached in Price Waterhouse v. Hopkins, 490 U.S. 228 (1989); [Sex discrimination] includes discrimination based on sex stereotypes]; and Bostock v. Clayton County, 140 S. Ct. 1731, 1742 (2020) (sex discrimination includes discrimination based on sexual orientation and gender identity)]. This broader definition will require covered entities to provide equal access to health programs and activities without the threat of discrimination on the basis of sex and will be prohibited from denying or limiting health services for gender-affirming care or the basis of an individual's sex assigned at birth, gender identity, or gender otherwise recorded. This clarification will also prohibit discrimination on the basis of sex, race, color, national origin, age, and disability in the provision and administration of health insurance coverage.

The Department nevertheless argues that Section 1557's uncontroversial bar on "sex discrimination" should be redefined controversially to cover gender identity and sexual orientation. [Footnote 11: See 85 FR 54178, 54177] But different treatment based on actions related to gender identity or sexual orientation does not constitute "sex" discrimination under a plain reading of Section 1557. Indeed, there is no evidence that Congress departed from the common objective definition of sex when drafting Section 1557. Absent clear congressional authorization, then the Department would not be justified in replacing the commonsense understanding of sex as a permanent reality grounded in biology with its view that sex is something merely "assigned at birth" and that a person's gender may be "neither both or a combination of male and female" regardless of biology and based solely on one's subjective "internal sense of gender." [Footnote 12: Ibid. 54174 and 51477] Under such a radical redefinition of "sex," a person or covered entity that in conscience and good faith declines to participate in "gender transition" treatments could face drawn-out litigation and liability. [Footnote 13: Ibid. 54220] Because decisions about medical procedures, treatments and insurance coverage made in line with reasonable medical moral and religious beliefs about biology and the best interests of the patient are nothing like invidious sex discrimination they should not be treated by the federal government as such.

Should Include Sexual Orientation and Gender Identity as Forms of Discrimination Based on Sex". The TTAG urges CMS to move forward with its proposal to amend previous language so it will again identify and recognize discrimination on the basis of sexual orientation and gender identity as prohibited forms of discrimination based on sex consistent with the U.S. Supreme Court's holding in Bostock v. Clayton County. [Footnote 5: 140 S. Ct. 1731 (2020).]

We support the Proposed Rule as a way of increasing equity and removing many of the barriers faced by LGBTQ+ people in the current health care system across the U.S. We urge full implementation of the Rule as proposed including those that protect transgender and nonbinary individuals' access care that addresses gender dysphoria.

On June 15 2020 the Supreme Court ruled in Bostock v. Clayton County that existing laws prohibiting sex discrimination protect against both sexual orientation discrimination and gender identity discrimination. [Footnote 18: Bostock v. Clayton County, 590 US _ (2020)]. This proposed rule would align the protections under section 1557 with the Bostock ruling ensuring that LGBTQ patients receive the protections they deserve. Recent research by the Center for American Progress highlight the need for these protections: Nearly one in five LGBQ patients surveyed reported concerns over being denied good care if they disclose their sexual orientation and half of transgender or nonbinary patients surveyed reported similar concerns. They discussed the "gender identity [Footnote 19: Caroline Medina and Lindsay Mahowald "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities" Center for American Progress September 8 2022 https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/].

Protections in the proposed rule against discrimination based on sexual orientation and gender identity align with the AAP policy to provide youth with access to comprehensive gender-affirming and developmentally appropriate health care. Gender affirming care is developmentally appropriate care that seeks to understand and appreciate a child's or adolescent's gender identity and experience through a safe and nonjudgmental partnership that includes general pediatricians, pediatric specialists, mental health providers, children and adolescents and their families. [Footnote viii: Rafferty] While gender-affirming care is irrefutably the standard of care, transgender and gender diverse individuals commonly face insurance related obstacles to obtaining developmentally appropriate care. These include coverage exclusions, waiting periods, high cost sharing, lack of access to providers and determinations that gender affirming care is cosmetic or not medically necessary.

We recommend that CMS use this opportunity of clarification to explicitly include transgender status, in addition to gender identity, in the final regulatory text. Transgender Americans should be treated consistently with their gender identity and not denied medically necessary sex-specific health care and services because those services are interpreted using outdated definitions of gender identity.

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These protections also apply to pregnancy-related conditions: for example a provider that offers prenatal care to cisgender women would not be permitted to deny that care to transgender men or nonbinary people. The same Center for American Progress research showed the need for these explicit protections as well [Footnote 20: Ibid.]. More than 30 percent of transgender or nonbinary respondents reported being denied reproductive health care due to their gender identity and that number was much higher for transgender and nonbinary patients of color.

[Italic: Explicit prohibition of discrimination on the basis of sexual orientation, gender identity, and sex characteristics. We also strongly urge to clearly state that gender identity includes trans status.]We applaud extensive explanation of discrimination on the basis of sex. Supreme Court case law including Price Waterhouse v. Hopkins and Bostock v. Clayton County makes clear that federal sex discrimination law includes sex stereotypes, sexual orientation, and gender identity including transgender status. The explicit inclusion of sexual orientation is a welcome addition to the Obama Section 1557 rule. We also support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex-based. Health disparities among intersex populations are primarily driven by stigma and discrimination especially with the lack of data around the experiences and needs of intersex people [Footnote 19: Medina Caroline Mahowald Lindsay. "Key Issues Facing People with Intersex Traits." Center for American Progress 22 Aug. 2022 www.americanprogress.org/article/key-issues-facing-people-intersex-traits/]. A 2018 survey of intersex individuals found that 43% of adult intersex individuals reported their physical health was fair or poor while 34% reported their mental health was fair or poor. [Footnote 11: Ibid].

[Bold: C. Proposed § 92.101 appropriately codifies the broad sweep of the ACA's sex discrimination prohibition.] [Bold: 1. We strongly support proposed § 92.101's broad approach and encourage HHS to add further clarifications."We strongly support the broad yet expressly not exhaustive description of covered grounds of discrimination including sex-based discrimination. In proposed section 92.101, We suggest two clarifications to this language [and related language in other provisions]:- In section 92.101 (a) (1) add the phrase "or any combination thereof" after "disability."- In section 92.101(a)(2):-- Add the phrase "including termination of pregnancy" after "related conditions."-- And the phrase "transgender status" after "sexual orientation."

individuals from discriminatory benefit designs and other practices by insurers which are contrary to well established evidence-based standards of care. We support the proposed rule which realigns regulatory protections with the evidence-based medical standards of care endorsed and recommended by the American Academy of Pediatrics, [Footnote ii: Rafferty J. Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents. Committee on Psychosocial Aspects of Child and Family Health Committee on Adolescence and Section on Gay, Lesbian, Bisexual and Transgender Health and Wellness. Pediatrics. Oct 2018, 142 (4) e20182162; the American Medical Association: [Footnote x: American Medical Association. Health insurance coverage for gender affirming care of transgender patients. 2019. Accessed on June 23 2022. https://www.ama-assn.org/system/files/2019-33/transgender-coverage-issue-brief.pdf; the American College of Obstetricians and Gynecologists. [Footnote x: American College of Obstetricians and Gynecologists. Health care for transgender and gender diverse individuals. ACOG Committee Opinion No. 823. 2021. Accessed on June 23 2022. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/09/health-care-for-transgender-and-gender-diverse-individuals] the American College of Physicians. [Footnote iii: Safer J Tangpricha V. Care of the Transgender Patient. Annals of Internal Medicine. 2019 Jul 2;171(1):ITC1-ITC16.] the American Psychiatric Association: [Footnote x: American Psychiatric Association. Position Statement on Treatment of Transgender (Trans) and Gender Diverse Youth. 2020. Accessed on June 23 2022 https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Policies/Position-Transgender-Gender-Diverse-Youth.pdf] the American Psychological Association; [Footnote xiv: American Psychological Association Guidelines for Psychological Practice with Transgender and Gender

DETAILED COMMENTS ON "NONDISCRIMINATION IN HEALTH PROGRAMS AND ACTIVITIES"General Provisions. 1. Scope – Prohibited Discrimination: The Proposed Rule prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in the provision or administration of health insurance coverage and other health-related coverage. The 2020 rule amended 10 provisions in CMS regulations, all of which cover at least some entities that are also subject to Section 1557, to delete language that prohibited discrimination on the basis of sexual orientation and gender identity. HHS proposes amending these regulations so that they again identify and recognize discrimination on the basis of sexual orientation and gender identity as prohibited forms of discrimination based on sex. Recommendation:BCBSA strongly supports reinstating the prohibition of discrimination on the basis of sexual orientation and gender identity. Rationale: BCBSA supports providing high-quality services to all members, regardless of the race, color, national origin, sex, gender identity, sexual orientation, age or disability. We believe everyone should have access to healthcare without experiencing discrimination, no matter who they are, where they live or what their health conditions may be.

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The Century Foundation

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Howard Brown Health

InterACT: Advocates for Intersex Youth

American Academy of Pediatrics

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Blue Cross Blue Shield Association

The Proposed Rule recognizes various forms of sex discrimination that disproportionately impact BIPOC and Latinx communities. The Proposed Rule clarifies discrimination on the basis of sex as including, but not limited to, discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions, sexual orientation, and gender identity. As discussed further below, proscribing discrimination on these bases will improve health care access for LGBTQI+ people of color in particular. However, the Department must further clarify discrimination on the basis of pregnancy or related conditions in order to ensure access to vital health care services to pregnant people.

Alliance of Multicultural Physicians

For the following example from a pediatrician from Arizona illustrates the impact that these sorts of protections can have on children. After expressing a male gender identity at the age of 9 the physician's patient was referred by his former physician to a psychiatrist who offered conversion therapy. The experience worsened the child's mental health issues and depression until his mother believed him but she started to affirm his identity. When the physician refused to use the patient's preferred pronouns or call him by his new name the family had to find a new provider. Later when the patient needed medication to support his development through puberty the family was repeatedly denied by the provider. When the family took legal action the patient prevailed in the case thanks to the strong protections provided by the 2016 rule or Section 1557. We are encouraged that these protections are enhanced in the Biden Administration proposed rule.

American Academy of Pediatrics

The Proposed Rule Strengthens Protections for LGBTQIA+ Individuals.We applaud HHS's proposed rule for making explicit that Section 1557's protections against discrimination on the basis of sex includes gender identity which is consistent with the interpretation of the Supreme Court decision in Bostock and federal anti-discrimination laws. We support the proposed rule for clarifying that discrimination on the basis of sex in health care programs and activities includes sex stereotypes, sexual orientation, gender orientation, gender identity, and sex characteristics including intersex traits and "marital, parental or family status" [Footnote 23: Id. at 47916 (Proposed § 92.101)]. Sex stereotypes such as expectations about how people should present or communicate have historically created barriers to equitable health care access and services. We also support the reversal on the enforcement of protections against discrimination on the basis of sexual orientation which should protect LGBTQ+ couples who may be turned away from care [Footnote 23: Id. at 47918 (Proposed § 92.206)].

Senate Democrats

HHS's proposed definition of sex discrimination in § 92.101 states:
"Discrimination on the basis of sex includes but is not limited to discrimination on the basis of sex stereotypes, sex characteristics (including intersex traits), pregnancy or related conditions; sexual orientation, and gender identity."
[Footnote 36: 87 Fed. Reg. 47351.] Despite defining sex discrimination HHS does not define "sex." It is irrational for HHS to define what constitutes discrimination "on the basis of sex" while failing to define "sex." Without knowing what "sex" is one cannot know what sex discrimination is. As explained below, "sex" in Title IX and thus § 1557 by extension is clearly and historically meant to refer to "biological sex." Indeed, HHS's purpose to expand Section 1557 to include "gender identity" (among other bases) would rewrite the law and create a major question that raises serious constitutional problems concerning the separation of powers under [*Italics: West Virginia v. EPA*.] [Footnote 37: No. 20-1530 (U.S. June 30 2022).]

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[Bold: D]. The Proposed Rule arbitrarily ignores that a person's sex is defined by biology. Even the decision in [*Italics: Bostock v. Clayton County*] on which the Proposed Rule heavily relies explicitly assumes that "sex" refers "only to biological distinctions between male and female." [Footnote 80: *Bostock*, 140 S. Ct. at 1739 (2020).] It is arbitrary and capricious for the proposed rule to avoid specifying precisely what sex in medicine and science means and how it relates to medical necessity with respect to gender dysphoria treatments. The concept of gender dysphoria is meaningless without sex. Just as transgender transition as a proposed medical solution is meaningless. What would a person be transitioning to and from exactly? If the agency cannot answer such a basic question with any semblance of scientific and medical rigor it has no basis to mandate coverage of such "transition" treatments and procedures in any context and certainly not as an essential health benefit. Moreover not only [*Italics: must*] the agency answer the question of what sex is in medicine it must answer it correctly and in accordance with logic and science.

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organs and functions assigned by the chromosomal complement." [Footnote 81: Institute of Medicine 2001. Exploring the Biological Contributors to Human Health: Does Sex Matter? Washington DC: The National Academies Press at p. 1 https://doi.org/10.17226/10028.] Sex is imprinted in every cell of the person's body and cannot change. [Footnote 82: Institute of Medicine 2001. Exploring the Biological Contributors to Human Health: Does Sex Matter? Washington DC: The National Academies Press. https://doi.org/10.17226/10028.] Even HHS's National Institutes of Health (NIH) matter-of-factly states that "every cell has a sex." [Footnote 83: National Institutes of Health Sex as a Biological Variable (March 18 2021). https://www.youtube.com/watch?v=eshnZrAKkyY&feature=youtu.be.] and as of this writing still requires its 80000 research grant applicants to account for sex as a biological variable in all animal and human studies. [Footnote 84: Consideration of Sex as a Biological Variable in NIH-funded Research (NOT-OD-15-102; June 9 2015). https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html.] This is because NIH knows that a person's immutable sexual biology explains in significant part why men and women respond differently to medication vary in their experience and manifestation of pain and have disparate susceptibility to illnesses from heart disease and cancer to psychological conditions such as depression and anxiety. Sex in medicine and research cannot be replaced by subjective "gender identity." Male and female are not part of an ever-multiplying spectrum nor are they merely placeholders assigned at birth. Indeed, a document just issued by the HHS Office of Population Affairs it defined "gender identity" as "one's internal sense of self as man woman both or neither." [Footnote 85: Office of Population Affairs U.S. Dep't Health & Human Servs. Gender Affirming Care and Young People (Mar. 2022) https://opa.hhs.gov/sites/default/files/2022-03/gender-affirming-care-young-people-march-2022.pdf.]

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dysphoria rests on the notion that transgender identity is innate—that a person can simply be born as "a man trapped in a woman's body" or vice versa. The failure accepting that person's Procrustean balance and restructuring the anatomy to align the body with the inner sense of identity should make things right. But does HHS have any biological basis to believe that a man could be born in the bodily form of a female inside to those who "assign" a sex at birth? Can HHS be confident that hormones and surgery can "reassign" sex? To answer these questions we must start by examining what science tells us about the biological genesis of sex. The basics of sex determination are relatively clear. Sex in terms of male or female is identified by the organism on of the organism for sexually reproductive acts. [*Italics: Langman's Medical Embryology*] concisely explains how the sex of a new organism is determined at fertilization: "An X-carrying sperm produces a female [XX] embryo and a Y-carrying sperm produces a male [XY] embryo. Hence the chromosomal sex of the embryo is determined at fertilization." A new human organism of a particular sex is created at that moment. Scientists now know that "the [*Italics: presence*] of a Y chromosome determines maleness and its absence determines femaleness." This is because the Y chromosome ordinarily carries the SRY ["sex-determining region on Y"] gene. The SRY gene contains a transcription factor known as the testis-determining factor (TDF) which directs the formation of the male gonads. Sex as a status—male or female—is a recognition of the organization of a body designed for dimorphic sexual reproduction. More than simply being [*Italics: identified*] on the basis of such organization sex is a [*Italics: inherent*] concept, or by or on the basis of that organization. The fundamental conceptual distinction between a male and a female is the organism's organization for sexual reproduction. The conceptual distinction between male and female based on reproductive organization [illegible] does the only coherent way to classify the two sexes [illegible]. people reasonably believe that maleness and femaleness are objective biological realities that are integral to who we are as human beings. On the basis of religious teachings moral reasoning scientific evidence and medical experience they have strong grounds to hold that one's sex is an immutable characteristic that should be respected not rejected or treated as a disease. [Footnote 9: Ryan T. Anderson "Sexual Orientation and Gender Identity (SOGI) Laws Threaten Freedom" Heritage Foundation Backgrounder No. 3082 November 30 2015. http://www.heritage.org/research/reports/2015/11/sexual-orientation-and-gender-identity-sogi-laws-threaten-freedom; Ryan T. Anderson "Sexual Orientation and Gender Identity Are Not Like Race: Why ENDA is Bad Policy" The Witherspoon Institute Public Discourse March 18 2015. http://www.thepublicdiscourse.com/2015/03/14643/ (accessed October 27 2015). John Finnis "Law Morality and 'Sexual Orientation'" in Human Rights and Common Good.] Accordingly many involved in providing medical care and those enrolled in health insurance plans have serious objections to participating in or paying for sex reassignment surgeries or gender transitions. Yet the regulations would label these kinds of reasonable beliefs as "discrimination" and seek to forbid them from being followed in the coverage or provision of health care services. Gender identity and sexual orientation (or like race or sex) can vary as self-reported and entirely self-defined characteristics independent of the body. Government should not grant special privileges on such bases when legal recognition of a group as a "protected class" is with few exceptions reserved for groups which objectively identifiable immutable characteristics. [Footnote 10: Anderson "Sexual Orientation and Gender Identity (SOGI) Laws Threaten Freedom". Ryan T. Anderson "ENDA threatens Fundamental Civil Liberties" Heritage Foundation Backgrounder No. 2852 November 1 2013. http://www.heritage.org/research/reports/2013/11/enda-threatens-

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of the scientific literature on sexuality and gender identity. The theory has as its key premise and femaleness is the distinction between the reproductive roles of the sexes. In mammals such as humans the female gestates offspring and the male impregnates the female. This conceptual basis for sex roles is primary and stable and allows us to distinguish males from females on the grounds of their reproductive systems even when there are individuals exhibit behaviors that are not typical of males or females. Mayer is a scholar-in-residence in the Department of Psychiatry at Johns Hopkins University and a professor of statistics and biostatistics at Arizona State University. McHugh is a professor of psychiatry and behavioral sciences at the Johns Hopkins University School of Medicine and for twenty-five years was the psychiatrist-in-chief at the Johns Hopkins Hospital. The editor of The New Atlantis in the introductory note to their report called McHugh "arguably the most important American psychiatrist of the last half-century."After explaining the "primary and stable" conceptual basis for maleness and femaleness Mayer and McHugh note that a structural difference for the purposes of reproduction is the only "widely accepted" way of classifying the two sexes. In biology an organism is male or female if it is structured to perform one of the respective roles in reproduction. This definition does not require any arbitrary measurable or quantifiable physical characteristics or behaviors; it requires understanding the reproductive system and the reproduction process. Different animals have different reproductive systems but sexual reproduction occurs when the sex cells from the male and female of the species come together to form newly fertilized embryos. It is these reproductive roles that provide the conceptual basis for the differentiation of animals into the biological categories of male and female. There is no other widely accepted biological classification for the sexes.This fundamental difference in organization is what allows scientists to distinguish male from female. When Dr. Deanna Adkins called this "an extremely

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Here is now one scholarpublished in Frontiers: Best Practice and Research. Clinical Endocrinology and Metabolism: "Females enter puberty earlier and undergo a more rapid pubertal transition whereas boys have a substantially longer growth period. After adjusting for dimorphism in size (height) adult males have greater total lean mass and mineral mass and a lower fat mass than females. These whole body differences are complemented by major differences in muscle distribution. Adult males have greater arm muscle mass larger and stronger bones and reduced limb fat and a similar degree of central abdominal fat. Females have a more peripheral distribution of fat in early adulthood, however greater parity and the menopause both induce a more android fat distribution with increasing age. Sex differences in body composition are primarily attributable to the action of sex steroid hormones with the dimorphisms during pubertal development. Oestrogen is important not only in body fat distribution but also in the female pattern of bone development that predisposes to a greater female risk of osteoporosis in old age. The result is that male and female bodies differ not only in their sex chromosomes (XX and XY) and in their organization for reproduction but also on average in size, shape, bone length and density, fat distribution, musculature and various organs including the brain. These secondary sex differences are not what define us as male or female; organization for reproduction does that. But this organization leads to other bodily differences. There are organizational differences and organism-wide differences in organs and tissues as well as differences at the cellular and molecular levels.

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between men and women and they are consequential for our health. Recognizing differences between the sexes is increasingly regarded as vitally important for good medical practice because scientists have found that male and female bodies tend to be susceptible to certain diseases in different ways to differing degrees and they respond to treatments differently. For this reason the best research protocols now require that both males and females be represented in samples and that the sex of participants be tracked so that any sex specific results can be recorded. The Institute of Medicine at the National Academy of Sciences published a report in 2001 titled Exploring the Biological Contributions to Human Health: Does Sex Matter? The executive summary answered the question in the affirmative saying that the explosive growth of biological information "has made it increasingly apparent that many normal physiological functions and many pathological 'dysfunctions' are influenced either directly or indirectly by sex-based differences in biology." Because genetics and physiology are among the influences on an individual's health the "incidence and severity of diseases vary between the sexes." This difference between male and female is thus "an important basic human variable that should be considered when designing and analyzing studies in all areas and at all levels of biomedical and health-related research." The chapter titles of the report sum up basic truths about our bodily nature: "Every Cell Has a Sex." "Sex Begins in the Womb." "Sex Affects Behavior and Perception." "Sex Affects Health." Some of the biological differences between the sexes that bear on health derive from hormone exposure but others come more directly from our genetic material. There are "multiple ubiquitous differences in the basic cellular biochemistries of males and females that can affect an individual's health. Many of these differences do not necessarily arise as a result of differences in the hormonal regime to which males and females are exposed but are a direct result of the genetic differences between the two

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A literature review in the Journal of Cellular Physiology tells us that "men are able to synthesize serotonin the neurotransmitter commonly associated with pleasant moods at a greater rate than women" and therefore men have a lower incidence of major depression anxiety and multiple sclerosis but a higher incidence of attention deficit hyperactive disorder and coronary artery disease. There are also differences in susceptibility to Alzheimer's disease and dementia. While scientists don't know how much of these differences are due to environment and how much to biology they do know that "innate physiological differences between males and females may play a large role in sex differences in disease onset susceptibility prevalence and treatment responses." Men and women also tend to respond differently to pain which has important implications for the use of painkillers and other medicines. Men and women have variable responses to pharmacological agents and the initiation and manifestation of diseases such as obesity autoimmune disorders and coronary heart disease to name a few."

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Differences in the chemistry and structure of the brain influence our response to stressful events and how we remember them. The differences between men and women in memory formation surrounding "emotionally arousing incidents" have implications for the treatment for post traumatic stress disorder.

Ethics & Public Policy Center

Acknowledging sex-based differences is vital for women's health as Jill Goldstein and colleagues emphasize in a paper for Frontiers in Neuroscience. "We now know there are significant sex differences in many chronic diseases including brain disorders" they write so understanding the causes of these differences "is critical to understanding women's mental health and healthcare needs." They cite studies demonstrating for example that "the vulnerability for sex-dependent risk for MDD [major depressive disorder] begins in fetal development." Neuroscience must therefore "adopt a 'sex dependent' and/or 'sex specific' lens in investigations of the brain." Of course male and female bodies are alike in many ways but there are notable differences. "On average male and average female bodies beyond our different organizations for reproduction" in other words there is a fundamental essential difference and there are substantial average differences. There is also wide variation among males as among females and considerable overlap between them even in the areas just discussed. While environmental factors are likely to influence many of these differences there is no denying the role of biology. [Footnote 86: RYAN T. ANDERSON WHEN HARRY BECAME SALLY: RESPONDING TO THE TRANSGENDER MOMENT 77 88 (2018) (internal citations omitted).]

Ethics & Public Policy Center

"Gender identity" imposes a new form of discrimination on the basis of immutable male/female sex. It is a personally-defined subjective identity not an objective biological reality. "Sexual orientation" creates a class based on emotional attraction also not an objective biological trait. If subjective categories of identity are to be protected under federal nondiscrimination law why only limit it to sex and not apply it to age or race? Accepting self-declared identity versus immutable objective reality as the basis for civil rights law is indefensible

Concerned Women for America

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LGBTQIA+ peopleTransgender people of color face significant barriers to health care access. 65 percent of transgender people of color report experiencing some form of discrimination and 46 percent of transgender people report having their health insurance deny gender affirming care. Furthermore some transgender people report experiencing such hostile discrimination that doctors have refused to treat conditions such as asthma or diabetes. Proposed Section 92.206 requires equal program access on the basis of sex and addresses the conditions that lead to health disparities among transgender people more broadly. Under this section health care providers may not deny or limit health services based on their sex. This seeks to ensure access to necessary health care services especially reproductive and gender-affirming care. For example transgender men face barriers to pap smears necessary for cervical cancer screenings as well as breast cancer screenings. Cisgender gay and lesbian people also face egregious denials of care such as refusal to provide infertility treatments.

The Proposed Rule is a necessary return to proper legal interpretations of the protections offered by Section 1557. Discrimination against transgender people violates Title IX. [talics See Grimm v. Gloucester Cty. Sch. Bd. | 972 F.3d 586 619 4th Cir. 2020) rehearing en banc denied 976 F.3d 399 (4th Cir. 2020) cert. denied 141 S. Ct. 2878 (2021). Even before the U.S. Supreme Court held that sex discrimination encompassed gender identity courts interpreted Title IX's sex discrimination prohibition to bar discrimination against transgender students [italics. See e.g. Whitaker Kenosha Unified Sch. Dist. No. 1 Bd. of Educ., 858 F.3d 1034 1049-50 (7th Cir. 2017). Federal appellate courts have also held that state restrictions on access to healthcare for transgender youth violate the Equal Protection Clause [italics; Brandt v. Rutledge] 47 F.4th 661 [8th Cir. 2022].

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Alliance of Multicultural Physicians

Attorneys General of California, New York, Massachusetts, and nineteen other States

exclaiming the need for redefinition or its reasoning the department has not explained the impact of this significant change. The proposed language includes abortion as part of the definition of pregnancy yet the department fails to explain the scope or reach its ruling would have upon differing views about life pregnancy and abortion. First the proposed rule is silent on exactly how abortion is to be protected under the regulation's prohibition against discrimination on the basis of "termination of pregnancy." The proposed rule would require educational institutions to make "reasonable modifications" to policies practices or procedures for students due to "pregnancy or related conditions." What does this look like in practice? Second the proposed rule will shape how reproductive capabilities are taught and discussed even in K-12 schools. Title IX will shape the expectations and values of young athletes and students to believe that abortion is necessary to follow their dreams. This would impose a heavy burden on women, exactly the kind that Title IX previously sought to eliminate when it was enacted in 1972. Title IX is meant to alleviate undue burdens by considering of the demands and responsibilities of one's sex.Third does the department's version of Title IX implementation unlawfully encourage young women to seek abortion? [Just concern that the rule would also stems both from the current political climate following the Dobbs decision and redefinition of pregnancy to include abortion. If abortion is included as part of Title IX's definition of pregnancy it could cause students to "read between the lines" and falsely equate the two. Fourth it could lead an athlete to feel that she should choose an abortion even if it's not what she really wants. Accommodating nine months of pregnancy requires significantly more effort than the much shorter timeframe of abortion/recovery. Female students may internalize negative messages about pregnancy childbearing and their bodies given the highly competitive environment and their own commitment to success. Thus the proposal would hurt the very people it claims

The Heritage Foundation

[italics. Well intended but inadequate. Justification]The proposed rule recognizes that this misconception often exists and rightly seek to provide further clarification. It says "the proposed revision would make clear that upon return to school a student must be restored to the student's previous academic status as well as to as much as practicable any extracurricular status the student may have held prior to the student's leave." We applaud the department's efforts to clarify Title IX protections. Here we write to encourage the department to clearly delineate its rule to protect the life of students and preborn children. The best way to do this is to remove any pressure to make an "impossible decision" about whether to receive an abortion. Instead Title IX funding and language should go towards providing women with a full understanding of their rights under Title IX flexibility and accommodations lactation rooms and access to pregnancy care centers who will help address each of their needs

The Heritage Foundation

[italics. Inclusion of lactation rooms]We applaud the inclusion of lactation rooms in the proposed rule. This measure supports the intended goal of Title IX's non-discrimination and provides much needed support and accommodations for mothers in this vulnerable season of life. The department rightly notes the recognition of lactation and breastfeeding accommodations in the Pregnancy Discrimination Act. Title IX's proposed rule reads "Courts have considered the scope of the term 'related medical conditions' under the PDA part clearly in connection with the issue of lactation." In 2013 for example the U.S. Court of Appeals for the Fifth Circuit held that under the PDA lactation is a medical condition related to pregnancy explaining that "[i]t is undisputed that lactation is a physiological result of being pregnant and bearing a child" and the definition of "medical conditions' includes physiological conditions. Equal Emp. Opportunity Comm'n v. Houston Funding II Ltd. 717 F.3d 425 428 29 (5th Cir. 2013). In 2017 the U.S. Court of Appeals for the Eleventh Circuit followed suit holding that lactation is a related medical condition and therefore covered under the PDA. Hicks v. City of Tuscaloosa 870 F.3d 1253 1259 (11th Cir. 2017) "We're pleased that here the Department considers the demands and responsibilities of motherhood and empowers those mothers with this accommodation they need to pursue an

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The Heritage Foundation

[illegible]Given the Supreme Court's decision in Dobbs the American people through their elected representatives are empowered to pass abortion laws that reflect their values. While Roe v. Wade was in effect top down national guidelines dictated state abortion law. This made the interpretation of Title IX's regulations easier to apply. Now the abortion landscape is quickly shifting and states have enacted– or are in the process of enacting – new policies that protect women and unborn children from abortion. It is essential that the Department of Education clarify how Title IX rule will be applied across jurisdictions with varying abortion policies. Given Title IX's inclusion of "termination of pregnancy" in the definition of pregnancy as a protected status and the abortion neutrality clause which references legal abortion the department must provide greater clarification on how the rule will interact with state law. By neither requiring nor "prohibiting" abortion access in schools Title IX's language creates a "grey zone." The department fails to explain how Title IX's rule regarding abortion will interact with state laws particularly a state's that protect the lives of preborn babies. Does the department believe that the proposed rule would preempt state level pro life laws? It's not a theoretical question, the administration has already indicated as much in an unrelated interim final rule regarding provision of abortion services at VA facilities to move that beyond conflicts with state laws violates federal law as well). Would this rule give schools the legal and monetary opportunity to defy their states' law under the guise of compliance with a federal regulation? The proposed rule when paired with the Dobbs ruling effectively creates an abortion "grey zone." Does this "grey zone" protect a K-12 school or institution of higher education who wants to use Title IX funds to promote information access referrals or travel stipends for women seeking an abortion? How does the department plan to prevent schools from doing so with Title IX funds in defiance of their own states' laws? By giving schools the option in places

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[Italics] The department continues to receive calls for clarification on both sides of the aisle. [This confusion as to the extent and meaning of the department's proposed rule as it relates to abortion is not limited to one ideological viewpoint. On July 20 2022 a coalition of sixty Democrats wrote a letter to the Department of Education requesting that it clarify "specific protections for pregnancy students under Title IX." It appears that even pro-abortion Democrat elected leaders are unclear about key aspects of Title IX's ruling as it relates to abortion. In particular, the democrat coalition asks the department to clarify how the Dobbs decision interacts with privacy laws affecting students. They recognize that the new post-Roe abortion landscape in which elected leaders can better advance policies that value and protects both the lives of women and the lives of preborn children requires a careful and specific consideration from the department as they issue sensitive rulings related to abortion and academic institutions. Similarly, this commenter humbly requests similar explanations and definitions from the department related to abortion and Title IX.

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[Wade, Title IX [1972] and Roe v. Wade [1973] went into effect less than a year apart. Each are distinct in their origins branch of government made up enforcement and reach. Nonetheless many athletes and scholars have begun to conflate the two given their symbiotic relationship. Two recent examples demonstrate this point. [Italics. Professional athletes and coaches misuse Title IX to fight for abortion rights," in an Amicus Brief submitted by over 500 professional collegiate and high school athletes coaches and organizations in the Dobbs v. Jackson Women's Health Organization the brief explicitly equates the power of Title IX protections with the right to abortion affordable under Roe v. Wade. A few quotes from the Amicus Brief highlight the dangerous conflation presented by athletes about Title IX and abortion rights - "As swimming gold medalist Katie Ledecky has observed 'Title IX has had a huge impact on women participating in sports and the evidence of that is clear with the results of women at the Tokyo Olympics.' But Title IX does not exist in a vacuum. Less than a year after its enactment this Court recognized that constitutional liberty interests include the right to abortion." - "Roe and Casey strengthen the practical impact of legislative guarantees of gender equality like Title IX. Without Roe's constitutional protection of women's bodily integrity and decisional autonomy women would not have been able to take advantage of Title IX and achieve the tremendous level of athletic participation and success that they enjoy today." - "For example if track star Sanya Richards-Ross' experience women's track and field would look entirely different without that right: 'Most of the women I knew in my sport have had at least one abortion.' Without the constitutional guarantee of reproductive freedom many women athletes would be forced to sacrifice the athletic pursuits and progress made toward gender equality in sports would be reversed." - "The most minute physical variances can affect athletic performance and opportunity—including the grant or denial of a scholarship or endorsement—and

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[Italics] Legal scholars argue Title IX should "include a positive provision for abortion. [The Harvard Journal of Law and Gender published an academic article in 2020 entitled "Reproducing Inequality Under Title IX." The article begins by highlighting the insufficient attention given to "[Title IX's] intersection with pregnancy and reproduction" [172]. It goes on to frame pregnancy and maternity as "significant obstacles" to educational attainment [172]. The authors criticize Title IX for only addressing pregnancy and reproduction after it has occurred and threatened academic or athletic pursuits. Instead they argue for a proactive approach. At length the authors argue that the abortion neutrality arises on predominies Title IX's potential as it does not require universities to provide abortion services for students. In short they believe Title IX should shift from a negative abortion provision [protecting a women from discrimination should she receive an abortion] to a positive abortion provision. This positive provision could take the form of requiring "education institutions to provide any support for students seeking or having an abortion such as referrals to abortion providers education about abortion as an option or access to abortion care as part of a student health" [174].

The Heritage Foundation

[Italics] Twisting Title IX to advance pro abortion policy goals is the wrong approach. [For both the athletes represented in the Amicus Brief and the legal scholars following the Harvard Journal of Law and Gender Title IX's protection from discrimination on the basis of sex has been manipulated to require abortion access for the sake of "gender equality." This is not gender equality; it's a rejection of the female sex altogether. The underlying message is that sterility is the normal and in fact desired state of the female body. And it only further frames pregnancy or motherhood as an abnormality or weakness unfairly imposed upon women. This could not be further from the truth. More importantly it could not be further from Title IX's original goal of protecting women from this sort of sex-based discrimination. These two examples demonstrate a powerful shift for the worse in how our athletes and scholars conceive of discrimination and reproductive care. In this line of thinking women need the right to an abortion to be protected from discrimination or undue burdens. This is an erroneous view of sex discrimination. Instead it was precisely because of a person's male or female sex that Title IX protected them from athletic or academic discrimination. This is why women and men may freely embrace the demands of motherhood or fatherhood. This is in contrary to the suggestion by one athlete in the Amicus Brief women will not lose scholarships their places on an athletic team and they will receive proper accommodations for class doctors' appointments or lactation rooms to care for their children.

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changed significantly since 1972. Given the rules' ambiguity and the change in terminology "termination of pregnancy" it is worth considering one method in particular which did not exist at Title IX's inception: chemical abortion. [Italics] Abortion pills. [The new front.] [The use of chemical abortion pills as opposed to surgical abortion procedures has risen to 54% of all abortion procedures and counting. In the chemical abortion process a woman typically takes two pills: mifepristone and misoprostol. Mifepristone blocks the uterus from receiving a critical hormone progesterone which is required to sustain a pregnancy. As a result of the progesterone inhibition the lining of the uterus deteriorates and cannot transfer adequate nutrients to the developing unborn child causing its death. Twenty-four to 48 hours after taking mifepristone a woman takes the second part of the abortion pill regimen misoprostol which causes uterine contractions to complete the abortion process and empty the uterus. The FDA approved the use of chemical abortion pills until up to ten weeks of pregnancy. They also suspended their in-person dispensing requirement under the guise of Covid-19 safety protocols. The Biden administration made that change permanent in December 2021. The combination of widespread use paired with a greater risk for complications and adverse side effects makes chemical abortion pills an essential part of this abortion conversation. When Title IX was enacted in 1972 the "termination of pregnancy" clause reliably referred to surgical abortions. The widespread use of chemical abortion pills raises new concerns that were not present when Title IX was enacted. Nor were these concerns an issue when similar regulations like the Pregnancy Discrimination Act went into effect. Because of this it is important to ensure the proposed rule adequately considers chemical abortion pills under it's "termination of pregnancy" provision. Could a campus health center be accused of sex discrimination if it chooses to not dispense or refer for abortion pills? If a campus health clinic dispenses abortion

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No comments are associated with this issue.

We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law including Price Waterhouse v. Hopkins and Bostock v. Clayton County makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity including transgender status. It is essential that this rule track those decisions to provide assurance to participants beneficiaries and enrollees and not create loopholes that these bases are adequately included. We also support the explicit inclusion of a discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex-based.

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|Bo d. B Protecting LGBTQ Individuals from Discriminat on|The Proposed Rule expressly recognizes that discrimination on the basis of sex necessarily includes discrimination based on sex stereotypes sex characteristics sexual orientation and gender identity. 87 Fed. Reg. at 47858 |Footnote 13 It is settled law that federal civil rights statutes forbid discrimination on the basis of sex stereotypes and sex characteristics. Price Waterhouse v. Hopkins 490 U.S. 228 240 (1989) ("[G]ender must be irrelevant to employment decisions"). It is also settled law that "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex" because "homosexuality and transgender status [is] inextricably bound up with sex." Bostock 140 S. Ct. at 1471. The States welcome this correction to the 2020 Rule and applaud HHS's return to proper statutory interpretation

its radical departure from longstanding law on sex discrimination by citing the Supreme Court's finding in Bostock v. Clayton County (2020) that the sex discrimination prohibited in Title VII of the Civil Rights Act also includes employment protection based upon an individual's sexual orientation or gender identity. The application of the Court's ruling to Title IX of the Education Amendments of 1972 and its incorporation into Section 1557 is profoundly misguided because this action ignores the Court's careful construction that exclusively limits its interpretation of the word sex in Title VII to mean sexual orientation and gender identity discrimination only in employment law. The dissenting opinion Justice Samuel Alito stated that "the Court does not claim that Title VII prohibits discrimination because of [italics: everything] that is related to sex." [Footnote 1 Bostock v. Clayton County 590 US_ (2020) Alito dissenting opinion Justia accessed September 23 2022 13 https://supreme.justia.com/cases/federal/us/590/17-1618/case.pdf] Indeed the justices refused to apply the redefinition of [italics: sex] to any other area of federal law with Justice Neil Gorsuch writing in the majority opinion "the employers worry that our decision will sweep beyond Title VII to other federal or state laws that prohibit sex discrimination. And under Title VII itself they say sex-segregated bathrooms locker rooms and dress codes will prove unsustainable after our decision today. But none of these other laws are before us. Under Title VII too we do not purport to address bathrooms locker rooms or anything else of the kind." [Footnote 7 Bostock v. Clayton County 590 US_ (2020) Opinion of the Court Justia accessed September 23 2022 31 https://supreme.justia.com/cases/federal/us/590/17-1618/case.pdf] According to the Court's own ruling the expansion of sex discrimination was crafted to fit the context of employment law not intended to be applied across the board to areas that affect the fundamental conscience and religious liberty of Christian

No comments are associated with this issue

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have a subsection in Part C dedicated to discrimination based on race and color we do want to emphasize the importance of protecting individuals from this discrimination and the compounding impact race and color can have on intersectional discrimination. Discriminatory health care systems and policies play an outsized role in the ability of People of Color to access quality health care in the United States. As has been indicated previously it is important that § 1557 extend anti-discrimination protections to patients at the intersections of multiple identities. For example Black people are more likely to have a disability relative to white people in every age group and according to the National Disability Institute and Transgender People of Color more frequently experience denial of care and medical abuse than white transgender people |Footnote 12: Nannette Goodman et al. Financial Inequality: Disability Race and Poverty in America National Disability Institute (February 2019) https://www.nationaldisabilityinstitute.org/wp-content/uploads/2019/02/disability-race-poverty-in-america.pdf] |Footnote 13: Caroline Medina et al. Protecting and Advancing Health Care for Transgender Adult Communities American Progress (August 18 2021) https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/] Like in the rest of the country in Massachusetts the COVID-19 pandemic highlighted the devastating impact of racial disparities in the health care system with communities of color facing barriers to quality care for many years and as a result dying at higher rate from COVID 19. [Footnote 14 Jillian McKay Disparities in Mass. COVID Deaths Are Widest among Younger Adults Boston University School of Public Health (March 19 2022) https://www.bu.edu/sph/news/articles/2022/racial-disparities-in-mass-covid-deaths-are-widest-among-younger-adults/] Given the deep legacy of racism and other forms of discrimination health systems and health policy §

No comments are associated with this issue

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ation American Association of Christian Schools

rgan Health Care For All

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The Department's requirement for covered organizations entities to develop and implement Section 1557 Policies and Procedures for their health programs and activities makes medical and fiscal sense in addition helping diminish discrimination and disparities in health. Not only will covered entities be "better positioned to prevent discriminatory conduct and to better avoid the risk of an employee providing services in a discriminatory manner" but it will also be less costly in the use of resources for processing complaints that are largely avoidable

The proposed rule requires covered entities to take appropriate steps to ensure that communications with individuals with disabilities and their companions with disabilities are as effective as communications with individuals without disabilities in its health programs and activities. [Bold: We urge OCR to extend this requirement to companions of individuals with LEP.] Many individuals will be accompanied by their family members a child or another close friend who may help with decision-making for a patient. Requiring provision of meaningful access to the companion of an individual with LEP can help facilitate this and ensure effective communication for all involved.

UnidosUS

Section 1557 Policies and Procedures are a necessary step toward preventing racism and other discriminatory conduct in health care As the Proposed Rule notes for patients of color trust in their health care providers would increase if these patients could voice their concerns directly to their health care providers which would in turn improve these patients' overall healthcare experiences. However existing Section 1557 policies and procedure requirements are disjointed confusing and ineffective The Proposed Rule would streamline these requirements by requiring covered entities to adopt and implement nondiscrimination policies against all forms of discrimination including language and disability access procedures [collectively Section 1557 Policies and Procedures]. The revised Section 1557 Policies and Procedures aim to prevent discrimination from occurring in the first place by ensuring covered entities have greater knowledge of their obligations under Section 1557

Alliance of Multicultural Physicians

Meaningful Access for LEP Individuals[OCR supports the provisions relating to meaningful access

Genesee County Legal Aid Society dba Center for Civil Justice

OCR also recommends that a requirement be added to allow for a "companion" of an LEP individual who needs language services be provided meaningful access to qualified interpreters and translated materials similar to the requirements for communication with companions of individuals with disabilities

Genesee County Legal Aid Society dba Center for Civil Justice

The proposed rule reduces discriminatory barriers to healthcare for individuals with LEP.Discrimination against individuals with LEP has undermined their ability to access high quality accurate and timely care [Footnote 12 See e.g. Alexander R. Green and Christopher Langage-Based Inequity in Health Care: Who is the "Poor Historian" AMA Journal of Ethics (May 2017)] We are encouraged that the proposed rule creates robust communication standards for covered entities and requires them to notify patients of the accommodations available to them. We are also pleased that as telehealth and machine translation become more common HHS is committed to safeguarding against deficiencies in such services including by setting quality standards for video remote interpreting services and requiring human review for critical matters. We urge HHS to adopt these proposed provisions in the final rule.

U.S. House Committees on Energy and Commerce Ways and Means and Education and Labor

We support the 2022 proposed rule's restored provisions from the 2016 Final Regulations regarding definitions for language assistance services required terms to provide meaningful access for limited English proficient (LEP) individuals standards for video remote interpretation and provisions of notices to inform individuals of their rights. We do however see opportunities to clarify and strengthen these provisions

Farmworker Justice

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2) HHS must provide support and resources to covered entities to ensure consistency in fulfilling language assistance training provisions and notice requirements. HHS is proposing to require covered entities provide notices of nondiscrimination and availability of language assistance services and other services to patients especially those with limited English proficiency (LEP). The agency also is proposing that covered entities have in place policies and procedures that support compliance with Section 1557 and train staff accordingly. AMA supports these proposed requirements and the goal of creating consistent procedural requirements for covered entities. However AMA is concerned that not all covered entities have the resources and staff support to ensure compliance with these requirements. We urge HHS to provide guidance templates and other resources to ensure some level of uniformity in the policy procedure and notice requirements—in plain language. This allows fulfillment of the requirements across covered entities removing potential confusion for patients as they navigate between entities. Furthermany covered entities are experiencing workforce challenges that may limit their ability to devote the necessary staff time to come into compliance with the proposed requirements. To mitigate this we urge HHS to provide support to covered entities to appropriately communicate and implement the policies and procedures and the necessary staff training. By providing this HHS can ensure consistency and fulfillment of the compliance training and patient education requirements in the above-captioned proposed rule. [Bold As such AMA urges HHS to provide support and resources with notice training and other procedural requirements to guarantee consistency in compliance with Section 1557 across covered entities]

We further agree with the proposal to require covered entities to provide language assistance for those with limited English proficiency free of charge and to offer a qualified interpreter to these individuals when interpretation is necessary. As proposed these individuals should not be required to provide their own interpreter or rely on anyone other than a qualified interpreter.

[Bold Policies and procedures] We support the provision related to implementing designated policies and procedures to meet Section 1557 requirements. We suggest that the final rule specifically requires covered entities to develop a language access plan. HHS has long recognized the benefit of creating a language access plan. HHS' 2003 LEP Guidance included elements of an effective language access plan [Footnote 3 U.S. Department of Health and Human Services Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons published August 2003 available at https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-vi/index.html] yet a number of these aspects are not included in the 2022 proposed rule. Language access plans help entities determine how to best meet the needs of LEP patients especially in communities where there may be emerging language needs due to changing demographics. We recommend that the proposed rule provide clear: - How to respond to LEP callers. - How to respond to written communications from LEP persons. - How to respond to LEP individuals who have in person contact with recipient staff. - How to ensure competency of interpreters and translation services

Meaningful access to care also requires addressing and removing language barriers. AMCP supports the proposal to require covered entities to provide language assistance for limited English proficient individuals without charge and to offer a qualified interpreter when interpretation is necessary as these requirements further remove barriers to access. Similarly AMCP agrees with the proposal to require covered entities to send notices of nondiscrimination and notices of availability of language assistance services and auxiliary aids and services annually or on request as well as posting them on the covered entity's website and in physical locations. AMCP encourages HHS to be mindful of the potential administrative burden of these requirements and offer covered entities additional flexibility to find innovative ways of addressing language barriers. [illegible] to ensure that all the individuals who use the care and coverage that covered entities can avoid discrimination by acknowledging that some English proficient individuals may be accompanied by companions with LEP who require language services to ensure the English speaking individual receives adequate care. For example our community partners commonly encounter parents with LEP of an English-speaking minor. We concur with the National Health Law Program that the same standards that apply for encountered individuals with an LEP should apply to encountered English speaking individuals with a companion with LEP particularly if that person is involved or consulted in decision making about the primary individuals' medical decisions or is involved in providing care. OCR should clarify that meaningful access "also does not only apply to patients or customers encountered but also any companions involved in decision making. Doing so would be aligned with the shift of covered entities being required to provide meaningful access to people with LEP that are "directly affected rather than "encountered."

[Italics] Increasing the Availability of Translated Documents] We urge OCR to clarify when a covered entity must to provide written documents in a language to meet meaningful access requirements. While we appreciate the language regarding machine translation we understand that many people with LEP prefer information in the form of written language over notices of availability. Throughout the pandemic processes for determining when written materials are translated into different languages have been fragmented and disorganized. One report on the experience in Massachusetts found "though all the state and private resources described above are available to all households regardless of citizenship or immigration status information about key programs has not been widely available to immigrants especially in languages beyond English and Spanish. "It took a month for the state unemployment assistance applications to be made available in Spanish and several more weeks for Portuguese Haitian Creole Chinese and Vietnamese to follow. [Footnote 26 "The Impact of COVID-19 on Immigrants in Massachusetts: Insights from our Community Survey" Massachusetts Immigrant & Refugee Advocacy Coalition August 2020 https://www.miracoalition.org/wp-content/uploads/2020/08/MIRA-COVID-19-survey-report-Aug2020.pdf NILC engaged with the Centers for Disease Control during the pandemic providing specific recommendations on improving COVID-19 prevention and care. [Footnote 27 "Amended Recommendations to Improve and Expand Equitable Access to COVID-19 Vaccines Testing and Treatment for Immigrants and Low-Income Communities of Color" National Immigration Law Center October 15 2021. Available upon request.] For example Vaccines.gov the federal government's primary digital tool for connecting individuals to vaccines still remains available only in English and Spanish.

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American Nurses Association

JBAC

Farmworker Justice

Academy of Managed Care Pharmacy (AMCP)

National Immigration Law Center

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National Immigration Law Center
California Department of Health Care Services

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Proficiency)|It is especially critical that older adults have robust language access resources and protections from discrimination. These provisions are key to ensuring the more than 8.5 million seniors (over age 60) sixty thousand people in Erie County and four million people with Medicare who are limited English proficient (LEP) can access care and services receive important healthcare information in a language they understand and are informed of their rights and how to enforce them. Healthcare information can be complex and can only be communicated effectively when an individual's primary language and must people's healthcare needs increase and become more complicated as they age. Furthermore older adults may be less inclined to ask for language assistance even if the language assistance is necessary for them to truly understand their healthcare. This is for a variety of reasons including past discrimination and out of a fear of inconveniencing others. In addition LEP older adults may feel pressure to rely on family members as interpreters even if those family members are not qualified to interpret health information which can inhibit the older adult's understanding of their health status and instructions from their provider. For example in Erie County five to ten percent (50000 to 130000) of people are of limited English proficiency. |Footnote 2: Limited English Proficiency Access in Buffalo and Erie County Partnership for the Public Good https://www.lep.gov/sites/lep/files/resources/US_Erie_LEP_count.ACS_5yr.2015.pdf (2003)| Providing access for LEP individuals to comfortably receive information regarding their health will target their social determinants of health.We strongly support the regulatory provisions to restore and clarify the covered entity's duty under Sec. 1557 to take reasonable steps to provide meaningful access to | to each eligible individual with LEP eligible to be served or likely to be directly affected by its health programs or activities. The 2019 rulemaking's watering down of this requirement along with the elimination of the Meaningful Access for Limited English Proficient Individuals (§ 92.201)We strongly support the proposal to restore and clarify the covered entity's duty under Sec. 1557 to take reasonable steps to provide meaningful access to |Italics: each eligible individual with LEP eligible to be served or likely to be directly affected by its health programs or activities. The 2020 rulemaking's watering down of this requirement along with the elimination of the in language tagging and notices harmed access to quality care for the more than 8.5 million older adults with LEP.CMS's guidance to nursing facilities provides an example of what meaningful access means on an individual level: "In order to provide culturally competent care staff must understand the cultural preferences of the individual and how it impacts the delivery of care. A key component is identifying how to communicate with the resident in order to be able to identify physical concerns and issues and for developing a trusting relationship with staff. For example if the resident is non-English speaking or has limited understanding of English the facility should identify how communication will occur with the resident. The care plan should identify the language spoken and what tools are available to communicate whether it be with a communication board or other systems or through translators." |Footnote 42: CMS State Operations Manual Appendix PP - Guidance to Surveyors for Long Term Care Facilities |revised July 2022| https://www.cms.gov/files/document/appendix-pp-guidance-surveyors-long-term-care-facilities.pdf, see also Justice in Aging Understanding CMS's New Nursing Facility Guidance (Jul 2022) https://justiceinaging.org/wp-content/uploads/2022/07/Understanding-CMSs-New-NF-Guidance-Issue-Brief.pdf; 42 C.F.R. § 483.10(c)(1)(Resident Rights and §483.21(b)(3)(iii) Comprehensive Person-Centered Care Planning |

Center for Elder Law & Justice

Justice in Aging

|Italics: Companions Who Have LEP]|Bold: We recommend that HHS add a requirement that a "companion" of an individual with LEP who needs language services be provided meaningful access including qualified interpreters and translated materials.] |Footnote 44: We support the proposed definition of companion in § 92.4: "Companion means a family member friend or associate of an individual seeking access to a service program or activity of a covered entity who, along with such individual is an appropriate person with whom a covered entity should communicate."| People who have LEP, including older adults may be parents/guardians for minors may have legal decision-making authority or may be accompanying their friend neighbor spouse partner or other family member as a caregiver or support person. The companion's understanding of the information is often as critical as is the understanding of the person receiving health care services. Providing a clear right to language services for companions will also help to delete inappropriate reliance on family members and others as interpreters.

Justice in Aging

We recommend that HHS add a requirement that a "companion" of an LEP individual who needs language services be provided meaningful access including qualified interpreters and translated materials. People who are LEP including older adults may be parents/guardians for minors may have legal decision-making authority or may be accompanying their spouse or other family member as a caregiver or support person. The companion's understanding of the information is often as critical as the person receiving health care services. Providing a clear right to language services for companions will also help to delete inappropriate reliance on family members and others as interpreters.

Center for Elder Law & Justice

To facilitate timely access we recommend requiring covered entities to note in the record |including electronic health records client/patient files| for each individual they serve whether language access is required and if yes what language.

Center for Elder Law & Justice

We also recommend that HHS specifically require covered entities to develop a communication access plan that addresses both language access and access ability for individuals with disabilities including supporting disabled people who are LEP. It is important for covered entities to plan in advance of what types of language services and communication supports it may need to provide by gathering data about the LEP population in its service area for example. This information is necessary to develop effective "language access procedures" of how to schedule an interpreter how to identify whether an individual is LEP etc. that the proposed rule requires.

(b)(5)

Center for Elder Law & Justice

In addition to reinstating these definitions the proposed rule also establishes new training requirements for both language assistance for LEP patients and reasonable accommodations for disabled patients. While every set of regulations implementing section 1557 has required covered entities to establish policies and procedures for their organization to comply with the law this training requirement is new. Employees who interact with patients would be required to undergo this training ensuring that any employee with whom a patient might interact is prepared to provide the services they are entitled to under section 1557.

The Century Foundation

OCR's provision of technical assistance that addresses specifically and in plain language what is required under 28 CFR 35.160 to 35.164 in conjunction with what is required under § 92.201 of the proposed rule will also be helpful.

Tennessee Disability Coalition

|Bold: Meaningful Access for Limited English Proficient Individuals (§92.201)|We support the proposed changes to the meaningful access requirements for individuals with LEP including the new requirements related to video and audio remote interpreting services. We also support the proposed revision providing that the meaningful access requirements encompass people "likely to be directly affected" rather than only "encountered."

UnidosUS

We also recommend that OCR add a requirement that a "companion" of an LEP individual who needs language services must also be provided meaningful access including access to qualified interpreters and translated materials. The 2022 proposed Rule requires covered entities to take appropriate steps to ensure effective communication for companions of individuals with disabilities. We believe the same should be afforded to LEP individuals particularly LEP parents/guardians of English-speaking minors/ unaccompanied adults and also family members friends or associates of LEP individuals who are appropriate persons with whom a covered entity should communicate. This could include individuals who participate in decision making with the LEP individual or need to understand the information for caregiving and other related reasons.

National Asian Pacific American Women's Forum

[Bold: Meaningful Access for Limited English Proficient Individuals
[§92.201)] [Bold: TPCA supports the provisions related to meaningful access.] It has been long recognized that the denial of adequate language services to LEP individuals constitutes discrimination on the basis of national origin. Specifically there are clear intersections between LEP status and race and/or ethnicity. With many LEP individuals being racial/ethnic minorities lacking adequate language services perpetuates discrimination against people of color by health care providers. This discrimination felt by patients may deter them from seeking critical health care services leading to adverse health outcomes and decreased trust in the health care system. Therefore improving meaningful access for LEP individuals will be an important tool in enhancing health equity by allowing patients to access and understand health care services in a language they prefer. With over 14000 individuals across the US health centers serve a large patient population who speak a variety of languages. A large part of the health center program's is to have translation services to serve our patients and meet community needs. In 2021 almost one fourth of health center patients preferred a language other than English. According to 2021 UDS data 11% of Tennessee health center patients are best served in a language other than English. Health centers will continue to prioritize hiring more translators and interpreters to better serve LEP individuals to ensure patients understand the care and services they receive to meet the growing need for our patient population.

We also recommend that OCR add a requirement that a "companion" of an LEP individual who needs language services must also be provided meaningful access including access to qualified interpreters and translated materials. The 2022 Proposed Rule requires covered entities to take appropriate steps to ensure effective communication for companions of individuals with disabilities. We believe the same should be afforded to LEP individuals particularly LEP parents/guardians of English speaking minors/ unaccompanied adults and also family members friends or associates of LEP individuals who are appropriate persons with whom a covered entity should communicate. This could include individuals who participate in decision-making with the LEP individual or need to understand the information for caregiving and other related reasons.

(b)(5)

Tennessee Primary Care Association

Farmworker Justice

Hold: Meaningful Access for Limited English Proficient Individuals
§92.201) MNACHC supports the provisions related to meaningful access]. It has been long recognized that the denial of adequate language services to LEP individuals constitutes discrimination on the basis of national origin. Specifically there are clear intersections between LEP status and race and/or ethnicity. With many LEP individuals being racial/ethnic minorities lacking adequate language services perpetuates discrimination against people of color by health care providers. This discrimination felt by patients may deter them from seeking critical health care services leading to adverse health outcomes and decreased trust in the health care system. Therefore improvingmeaningful access for LEP individuals will be an important tool in enhancing health equity by allowing patients to access and understand health care services in a language they prefer. With over 14000 individuals across the US health centers serve a large patient population who speak a variety of languages. A large part of the health center program's is to have translation services to serve our patients and meet community needs. In 2021 almost one-fourth of health center patients preferred a language other than English. Health centers will continue to prioritize hiring more translators and interpreters to better serve LEP individuals to ensure patients understand the care and services they receive to meet the growing need for our patient population.

Minnesota Association of Community Health Centers

ain meaningful access for specific protections that address discrimination based on national origin and limited-English-proficiency. As the report documents language is one of many social determinants of health leading to disparities. Health disparities among LEP patients compared to their English proficient counterparts is well documented. In the report, evidence also demonstrates it has been so despite previous versions of anti-discriminatory provisions. Loopholes lack of specificity and vagueness of the language render the provisions weak difficult to enforce and less effective, they do not provide sufficient support for meaningful access. While it's desirable for health organizations to have some autonomy as to how they will comply with anti-discrimination provisions without specific validated requirements for protocols and instruments the provisions are not sufficiently effective or enforceable. The rules must be strengthened through clear specific language to close these loopholes. Two examples are 1) a lack of specific minimum basic standards and validated testing instruments for interpreter qualification and for providers practicing medicine in non-English languages

(b)(5)

Alliance of Multicultural Physicians

Wisconsin Primary Health Care Association

Wisconsin Primary Health Care Association

(b)(5)

[Bold Additional Recommendations] In addition to the above comments the NHC has two additional recommendations for CMS We ask CMS to include caregivers as a group that must have meaningful access under the language access requirements specifically. Caregivers are often an important part of the care team and we must assure that they have access to information about the individual's health care

(b)(5)

National Health Council

The Proposed Rule would restore robust protections for LEP individuals and help ensure that LEP individuals have meaningful access to health programs and activities in several key ways. 87 Fed. Reg. at 47828. First the Proposed Rule largely reinstates the requirement that covered entities take reasonable steps to provide meaningful access to each LEP individual eligible to receive services or likely to be directly affected by its health programs and activities. 87 Fed. Reg. at 47860-63. The Proposed Rule continues to require that language assistance services be provided free of charge be accurate and timely and protect the privacy and independent decision-making ability of a LEP individual. 87 Fed. Reg. at 47861 47915. Together these provisions will increase LEP individuals' access to accurate timely and high-quality language access services that are necessary to navigate health services and coverage

Attorneys General of California, New York Massachusetts, and nineteen other States

Meaningful access goes beyond simply having phone and communications systems in place generally to actually identifying for each resident the language and which tools are specifically available to effectively communicate with that individual. By restoring the intent of this provision to provide meaningful access to each individual the proposed rule extends the same principle to LTSS settings outside of the federally regulated nursing facility context. Importantly Sec. 1557 applies to assisted living facilities that receive Medicaid funding but are not otherwise federally regulated Health care information is complex and can only be communicated effectively in an individual's primary language and must people's health care needs increase and become more complicated as they age. Furthermore older adults may be less inclined to ask for language assistance out of a fear of inconveniencing others even if the language assistance is necessary for them to truly understand their health care. Older adults with LEP may feel pressure to rely on family members as interpreters even if those family members are not qualified to interpret health information which can inhibit the older adult's understanding of the health status and instructions from their provider. To facilitate timely access to qualified interpreters [Bold] we recommend requiring covered entities to note in the record (including electronic health records client/patient files) for each individual they serve whether language access is required and if yes what language.'

Justice in Aging

A Diabetes Educator in Virginia shared the story of her client an older man who had immigrated from Haiti. His medical charts indicated that he had refused interpreter services and he had previously been non-compliant with medication. The educator used a language line to secure a French interpreter as indicated in the patient's record. She found in communicating through the interpreter that the patient was attentive and eager to learn about managing his care. She also discovered that the patient had in fact not been offered interpreter services in any of his prior appointments and that he did not understand diabetes and had never received education about his condition. While he had been described in his medical chart as non-compliant with care recommendations he simply did not understand his condition nor did he have the tools or means to obtain the supplies and information he needed without access to an interpreter. Because the patient was unaware of his right to an interpreter he lost valuable time in the management and mitigation of his diabetes.Research shows how widespread such stories are. In one study looking at care transitions researchers reported that access to language services was limited and varied significantly by race ethnicity and language. More than half of patients in the study with LEP reported lacking access to medical interpreters and translated materials. With respect to disparities "Hispanic or Latino patients and patients with limited English proficiency were less likely to report access to a computer and less likely to access the Patient Gateway portal. Black or African American patients were also less likely to use the Patient Gateway portal. Asian patients were more likely to be worried about getting home health services." [Footnote 4:] Esteban A. Barreto et al. The Role of Race Ethnicity and Language in Care Transitions (July 21 2021) https://www.ajmc.com/view/the-role-of-race-ethnicity-and-language-in-care-transitions].

Justice in Aging

[illegible] services for individuals with limited English proficiency.[] FPL and effective communication and reasonable modifications to policies and procedures for people with disabilities Required content for inclusion in trainings must be specific. For example 1. Hea thcare providers are dependent on language services for the provision of equitable health care. Provider comprehension and communication are essential for a ccurate diagnosis treatment and provision of all care Patient comprehension is essential for participation and adherence. Providers and patients are equally dependent on language services 2. Language-based disparities in health care (i.e. lack of translation of discharge summaries) are common and may result in harm. [Footnote 8:] 1. Malevanchik CM Wheeler K Gagliano J Kanner and S Yoon "Disparities After Discharge The Association of Limited English Proficiency and Postdischarge Patient-Reported Issues" Jt Comm J Qual. Patient Saf. vol. 47 no. 12 pp. 775–781 Dec. 2021 doi:10.1016/j.jcjq.2021.08.013.][Footnote 9: The Joint Commission or "QuickSafety 13: Overcoming the challenges of providing care to limited English proficient patients" Oct. 2021 [Online]. Available: https://www.jointcommission.org/resources/news-and-multimedia/news-letters/newsletters/quick-safety/quick-safety-issue-13-overcoming-the-challenges-of-providing-care-to-lep-patients/overcoming-the-challenges-of-providing-care-to-patients-with-limited-english-proficiency.pdf?db=web&hash=[illegible]] Training must include specific evidence on health disparities documents in the report.3. Staff trainings on language access and LEP care must hold equal standing with other required institutional trainings (i.e. safety infection control workplace violence no-cy sexual harassment. Trainings in patient safety or infection control for example are incomplete if language access is not addressed in settings of threats to patient safety or of infection control where communication with patients is critical.4. When and how institutions may determine and document patient

(b)(5)

The Leadership Conference on Civil and Human Rights

The proposed rule also ensures "meaningful access" to health care services by providing clarity on the steps providers and other covered entities must take to effectuate this goal. For example the proposed rule requires covered entities to provide qualified interpreter and translator when providing language services and requires human translators to review materials generated by machine translation in most cases. [Footnote 5: Proposed Sec. 92.210.] Clarifying the definition of LEP and ensuring quality translation services will significantly reduce barriers to quality health care for these patients.

[illegible] new opt and implement written language access procedures to provide meaningful access to LEP individuals. At a minimum language access procedures must include contact information for the Section 1557 Coordinator (if applicable) how an employee identifies whether an individual is LEP how an employee obtains the services of qualified interpreters and translators names of any qualified bilingual or multilingual staff members and a list and the location of any oral and written translated materials the covered entity has the languages they are translated into and the publication date.Recommendation: BCBSA recommends HHS allow an issuer to identify the process and business rules they use to identify LEP individuals how they provide language access and how they create and store translation resources or translated materials.Rationale: The proposed requirement seems designed for smaller businesses where translation or interpretation is ad hoc rather than automated. A large insurer that translates all member facing materials into Spanish or even a smaller insurer that defaults to Spanish because of the population they serve would have an overwhelming amount of work cataloging every version of every communication. We recommend allowing the issuer the option of providing the business rules it uses to identify LEP individuals and ensure they receive appropriate interpretation or translation services vendors. For translated materials that would mean allowing a how and where those materials are stored in the normal course of business rather than creating a duplicative process.Most issuers use a vendor for the purpose of translation and interpretation. It is not reasonable to assume the issuer will be able to track the staff the vendor relies on or assume that the vendor uses a staff model given the range of languages the vendor may need to support and how much the demand for a given language might vary. One large insurer provided interpretation services for 76 unique languages for 43 months starting in 2019. Twenty eight percent of the languages requested were unique

(b)(5)

Blue Cross Blue Shield Association

(b)(5)

The proposed rule reduces discriminatory barriers to health care for individuals with LEP. Discrimination against individuals with LEP has undermined their ability to access high quality, accurate, and timely care. [Footnote 12: See e.g. Alexander R. Green and Christopher Pelaccia, Language-Based Inequity in Health Care: Who is the "Poor Historian?" AMA Journal of Ethics [Mar. 2021].] We are encouraged that the proposed rule creates robust communication standards for covered entities and requires them to notify patients of the accommodations available to them. We are also pleased that as telehealth and machine translation become more common, HHS is committed to safeguarding against deficiencies in such services including by setting quality standards for video remote interpreting service and requiring human review for critical matters. We urge HHS to adopt these proposed provisions in the final rule.

(b)(5)

U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

proposed rule and supports its goal of eliminating discrimination in health care. We have concerns about the unintended consequences that the rule may have if implementation carries a disproportionately high cost for physician practices, especially those that are small or medium sized. For example, while interpretation services are vital to ensuring quality care for immigrant families, the cost of interpretation is often borne by the physician practice. Many pediatricians and pediatric subspecialists, especially those practicing in small or medium sized groups, may experience hurdles such as financial or other resource constraints that limit implementation of the proposed standards. In many parts of the U.S. such as New York and Los Angeles, the number of preferred languages and dialects is so great that providing accessibility to language assistance services during all hours of operation—twenty four hours a day, seven days a week in the case of hospitals—imposes an enormous workload and financial burden on health care organizations. Moreover, for immigrant children and children in immigrant families, the inability of a practice to provide interpreter services could have the unintended consequences of providers being unwilling to accept these patients, worsening an already critical access problem for many vulnerable children. In addition to the costs associated with translation services used when seeing patients, the ability to provide communication to patients in multiple languages and modalities such as in written materials and online have large financial implications. Payment for interpreter services should become a mandatory rather than optional service. If this standard is to be realistically implemented by providers, private and public insurance payers should pay for qualified medical interpreter and translation services. Given the increased cost-effectiveness and quality of care provided with medical interpretation, payers should recognize and reimburse for the increased time needed during a medical encounter when using an interpreter. Pediatricians have also voiced concerns. Two main organizational leeway in deciding how to qualify interpreters and bilingual professionals has led to the use of subjective self-assessments or assessments by unqualified persons (e.g. monolingual evaluating provider fluency in two languages) resulting in unreliable, inaccurate language proficiency assessment and, ultimately, in compromised, substandard care.

American Academy of Pediatrics

[Italics, Emphasis Added] OCR should require covered entities to develop training that encourages the best approaches to meeting the needs of LEP patients. For example, the provision should require training on how to best work with interpreters, particularly the type of interpreters the covered entity uses. Training health care providers and administrators on best practices of translator services use is important to ensure LEP individuals feel comfortable navigating the health care system and accessing the care they need. Quality, timely, and seamless translation in clinics allows AAPI women to [Hyperlink: understand and make informed health care decisions; https://www.nih.gov/first-steps-nih/nih-office-director/office-communications-public-liaison/clear-communication/language-access clear communication] for themselves and their families and helps close health care disparities those with LEP often face.

National Asian Pacific American Women's Forum

We also recommend a requirement to develop policies and procedures to assess and retain the competency of bilingual and multilingual staff. During listening sessions co-facilitated by EJI and the Association of Asian Pacific Community Health Organizations (AAPCHO), participating health centers emphasized the important role of bilingual and bicultural staff that represents the community served to provide accurate and culturally comprehensible interpretation. [Footnote 4: Farmworker Justice, Issue Brief: The Impact of Language on Health Care Accessibility, published June 2022, available at https://www.farmworkerjustice.org/wp-content/uploads/2022/06/Language-Access-Issue-Brief_FINAL_June-2022.pdf.] Bilingual and multicultural staff must be provided training and compensation opportunities to support professional development and prevent staff turnover/burnout.

(b)(5)

Farmworker Justice

The Proposed Rule improves language access by emphasizing that the definition of "limited English proficient individual" includes those who may be competent in English for certain types of communication (e.g., speaking or understanding) but still be LEP for other purposes (e.g., reading or writing). This will ensure providers and other covered entities understand that people who have some English competency may still need translated written materials, for example. The Proposed Rule also ensures "meaningful access" to health care services by providing clarity on the steps providers and other covered entities must take to effectuate this goal. For example, the Proposed Rule requires covered entities to provide a qualified interpreter when providing interpretation services and requires human translators to review materials generated by machine translation in most cases. Clarifying the definition of LEP and ensuring quality translation services will have far-reaching consequences for patients who both seek and receive care, thus reducing barriers to quality health care for people of color. Again, this comes down to greater nuance in understanding of diverse individuals and communities, including a more nuanced understanding of what LEP consultation is in a care setting.

(b)(5)

Alliance of Multicultural Physicians

The proposed rule includes additional changes that specifically support the LEP community. It restores requirements to provide meaningful access for LEP individuals and includes a nuanced definition of LEP that recognizes that a person who is competent in some communications may still require assistance in other contexts. [Footnote 14: Id. at 47911, 17 (Proposed § 92.201).]. The rule also obligates entities to provide a qualified interpreter, which includes a limitation that relying on a minor child (except in limited circumstances) for interpretation can only be used as a temporary measure in an emergency until a qualified interpreter is found. [Footnote 14: Id.] Language access remains a barrier to care for the over 25 million households in the U.S. who are LEP. [Footnote 15: Question and Answers on the 2022 Proposed Rule Addressing Nondiscrimination Protections under the ACA's Section 1557, NATIONAL HEALTH LAW PROGRAM (Aug. 15, 2022) https://healthlaw.org/resource/questions-and-answers-on-the-2022-proposed-rule-addressing-nondiscrimination-protections-under-the-acas-section-1557/.; American Community Survey 2020, Table S1601, Language Spoken at Home, American Community Survey 5-Year Estimates, available at https://data.census.gov/cedsci/table?q=S1601&tid=ACSST5Y2020.S1601; Table S1602 Limited.] For example, recent studies suggest that LEP individuals—who are more likely to be Latino or Asian—have lower rates of COVID-19 vaccinations and have higher rates of COVID-19 infections, hospitalizations, and deaths. [Footnote 16: Ye Zong and Jeanne Batalova, "The Limited English Proficient Population in the United States," 2013 MIGRANT POLICY INSTITUTE https://www.migrationpolicy.org/article/limited-english-proficient-population-united-states-2013.].

Senate Democrats

proposing to require that covered entities take reasonable steps to ensure each individual with limited English proficiency (LEP) who is "eligible to be served or likely to be directly affected" has meaningful access to the entities' health programs and services. HHS has revised this language from the 2016 version of this rule to reference an LEP individual "directly affected" rather than "likely to be encountered" to provide additional clarity about the applicability of the rule and align the language with additional guidance and regulation. As consistent with previous iterations of this rule HHS requires that these services be free of charge accurate and timely.[Bold The AAFP supports HHS' efforts to ensure all individuals have meaningful access to health programs and services regardless of language barriers and this proposal is aligned with AAFP's position paper on providing culturally sensitive care [Hyperlink: https://www.aafp.org/about/policies/all/cultural-proficiency-position-paper.html'.]Bold: The AAFP also appreciates HHS' clarifying language around LEP individuals directly affected by a program or service as opposed to "likely to be encountered." While this change from the 2016 rule is necessary and will reduce some burden on small or solo practices who may have otherwise struggled to meet the previous definition it should be noted that providing translation services can be financially burdensome for primary care practices that already operate on thin margins]. With this in mind the AAFP encourages HHS to use its authority to ensure funding is made available for interpreter services in primary care practices .[Bold: Current data indicates LEP individuals are less likely to be insured and less likely to have a usual source of care than those with full English proficiency [Footnote 7: Feiles S Fuentes A. M. Robledo Cornejo M. L. N. L. Castaneda Avila M. A. T. al J & Lanane K L. (2020). The Role of Limited English Proficiency and Access to Health Insurance and Health Care in the Affordable Care Act Era. Health equity 4(1) 503–517. https://doi.org/10.1089/heq.2020.0053]

(b)(5)

American Academy of Family Physicians

Finally we strongly support the proposed language requiring that a covered entity which uses machine translation must also have the translation reviewed by a qualified human translator for any text critical to the rights benefits or meaningful access of an LEP individual when accuracy is essential or when the source documents or materials contain complex multilateral or technical language

UnidosUS

The proposed rule recognizes a stigma as barriers to health care for individuals with LEP.Discrimination against individuals with LEP has undermined their ability to access high quality accurate and timely care .[Footnote 12: See e.g. Alexander A Green and Charlotte Blaze Language-Based Inequity in Health Care: Who is the "Poor Historian" AMA Journal of Ethics [Mar. 2021].] We are encouraged that the proposed rule creates robust communication standards for covered entities and requires them to notify patients of the accommodations available to them. We are also pleased that as telehealth and machine translation become more common HHS is committed to safeguarding against deficiencies in such services including by setting quality standards for video remote interpreting service and requiring human review for critical matters .We urge HHS to adopt these proposed provisions in the final rule

U.S. House Committees on Energy and Commerce Ways and Means and Education and Labor

The Proposed Rule also addresses the use of machine translation and in particular proposes to require covered entities that utilize machine translation to have translated materials reviewed by a qualified interpreter when the underlying text is "critical to the rights benefits or meaningful access of a LEP individual." 87 Fed. Reg. at 47861 47916. The States have some experience with machine translation and found that it often produces inaccurate or misleading translations which in turn can cause needless confusion or even barriers for LEP individuals in navigating to care .[Footnote 58: Julie Zauzmer Weil D.C. Says Long Awaited Translator of Vaccine Website Is Coming This Weekend Wash. Post (Apr. 9 2021) https://www.washingtonpost.com/local/coronavirus-vaccine-translation-spanish/2021/04/03/43ed126a-9942-11eb-962f-78c1d8228613_story.]. Scholarly research has also likewise found that machine translation can produce high error rates and that it is currently "unacceptable" for use in healthcare settings. [Footnote 59: Kristin N. Dew et al. Development of Machine Translation Technology for Assisting Health Communication: A Systematic Review 85 J. of Biomedical Informatics 56 57 64 (2018) https://pubmed.ncbi.nlm.nih.gov/30031857/.] Given the well-documented issues with machine translation the States support—at a minimum—HHS's proposal to require that materials translated by machine translation be reviewed by a qualified interpreter where when the underlying text is "critical to the rights benefits or meaningful access of a LEP individual." 87 Fed. Reg. at 47916. The States would further suggest that HHS collect data on the use of machine translation by covered entities to evaluate the circumstances in which it is used by covered entities and the accuracy of its results.

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Attorneys General of California, New York, Massachusetts, and nineteen other States

Meaningful Access for Limited English Proficient Individuals (§ 92.201)[Italics: Machine translation] During the pandemic we consistently heard from community partners of problems with machine translated information for individuals with LEP. This is not a new problem as health entities have been using machine translation for years now to avoid their responsibilities to ensure people with LEP have equal access to health care. For example many websites including those of state agencies offer Google translate buttons instead of translating website content. This is not meaningful. Across considering the error rates with such tools We do not support the use of machine translation in emergent circumstances because covered entities should develop plans in place that would not require the use of it. For example if an agency is likely to encounter people in emergency scenarios that may require rapid response they should have plans for how to quickly find written interpretation in that scenario. An error in machine translation in a situation where a person is already under duress could lead to worse outcomes or reduced trust. We do support agencies using technology to store translations they have already vetted and maintain glossaries of commonly used terminology to ensure consistency and save costs of retranslations.
LCI strongly supports the inclusion of a definition of machine translation and recognition that machine translation of critical information must be reviewed by a qualified human translator

(b)(5)

National Immigration Law Center

Genesee County Legal Aid Society dba Center for Civil Justice

The Proposed Rule improves language access by emphasizing that the definition of "limited English proficient individual" includes those who may be competent in English for certain types of communication (e.g. speaking or understanding) but still be LEP for other purposes (e.g. reading or writing). This will ensure providers and other covered entities understand that people who have some English proficiency may still need translated written materials for example. The Proposed Rule also ensures "meaningful access" to health care services by providing clarity on the steps providers and other covered entities must take to effectuate this goal. For example the Proposed Rule requires covered entities to provide a qualified interpreter when providing interpretation services and requires human translations to review materials generated by machine translation in most cases. Clarifying the definition of LEP and ensuring quality translation services will have far-reaching consequences for patients who both seek and receive care thus reducing barriers to quality health care for people of color. Again this comes down to greater nuance in understanding of diverse individuals and communities resulting a more nuanced understanding of what LEP consistutes in a care setting

Alliance of Multicultural Physicians

[Italics: Meaningful access for LEP individuals]We support the provisions related to meaningful access including the requirements related to machine translation.

National Asian Pacific American Women's Forum

Regarding the proposed "evaluation of compliance" as mentioned above we urge OCR to require covered entities to develop a language access plan. While we appreciate that measuring compliance with the meaningful access requirements may take into consideration an entity's written language access procedures [Bold: we urge OCR to revise this section to reflect any new requirement for a language access plan.] The 2016 Final Rule acknowledged the importance of access plans as a tool for measuring compliance when it described this as another factor that can be taken into account by the OCR director

UnidosUS

(b)(5)

National Immigration Law Center

the framework for how OCR will evaluate compliance with this rule. We were concerned with the 2020 rule's combination of this test in particular its shift of focus from providing meaningful access to individual people with LEP to broadly people with LEP as a group. This shift misaligns Section 1557's standards with those of Title VI which specifies that "no person" shall be excluded from programs or activities funded by the government rather than groups of people. Returning to a standard where the nature and importance of the covered entity relative to the "limited English proficient individual" is a more appropriate landing point. However as described above do we not think it is sufficient for covered entities to only develop internal policies and procedures which is proposed to be the primary example of how compliance will be assessed. Instead we believe that the additional content including planning and evaluation are essential to ensuring a person with LEP has access to health services. In this way this new rule proposes a weaker standard for evaluating compliance. We urge OCR to fully reflect the 2016 final rule here and replace "procedures" with "plan" at §(c)(3) in this section.

Meaningful Access for Limited English Proficient Individuals:The AIDA recommends that the Department retain the four-factor test. Dental practices must have flexibility in achieving compliance with requirements for access by individuals with LEP because of their limited resources and patient populations.

American Dental Association

Regarding the section on "evaluation of compliance" we raise concerns around the lack of a requirement to develop a language access plan. We appreciate that OCR will evaluate the entity's written language access procedures but those procedures will only be as good as the information on which they are based. The proposed rule does not seem to require a covered entity to gather information about the needs of LEP individuals in its service area prior to developing policies and procedures.

National Asian Pacific American Women's Forum

proposing to require that covered entities take reasonable steps to ensure each individual with limited English proficiency (LEP) who is "eligible to be served or likely to be directly affected" has meaningful access to the entities' health programs and services. HHS has revised this language from the 2016 version of this rule to reference an LEP individual "directly affected" rather than "likely to be encountered" to provide additional clarity about the applicability of this rule and align the language with additional guidance and regulation. As consistent with previous iterations of this rule HHS requires that these services be free of charge accurate and timely.|Bold: The AAFP supports HHS' efforts to ensure all individuals have meaningful access to health programs and services regardless of language barriers and this proposal is aligned with AAFP's position paper on providing culturally sensitive care.|Hyperlink: https://www.aafp.org/about/policies/all/cultural-proficiency-position-paper.html".|Bold: The AAFP also appreciates HHS' clarifying language around LEP individuals directly affected by a program or service as opposed to "likely to be encountered." While this change from the 2016 rule is necessary and will reduce some burden on small or solo practices who may have otherwise struggled to meet the previous definition it should be noted that providing translation services can be financially burdensome for primary care practices that already operate on thin margins. With this in mind the AAFP encourages HHS to use its authority to ensure funding is made available for interpreter services in primary care practices.|Bold: Current data indicates LEP individuals are less likely to be insured and less likely to have a usual source of care than those with full English proficiency.|Hanlon A. L. Bailes S. Fuentes A. M. Robledo Cornejo M. L. N. L. Castaneda Avila M. A. T. a l. & Lanane K. L. (2020). The Role of Limited English Proficiency and Access to Health Insurance and Health Care in the Affordable Care Act Era. Health equity 4(1) 509–517. https://doi.org/10.1089/heq.2020.0051

American Academy of Family Physicians

As a children's hospital serving a diverse population of patients and families we are committed to ensuring our services are accessible to all who need us. This commitment is reflected in our institutional declaration on equity diversity and inclusivity. Language access is an important component of patient and family centered care and we particularly support the stipulations related to access for individuals with limited English proficiency (LEP) especially the situation that family members should not be required to translate for a patient.

Boston Children's Hospital

HCA also supports the clarification in the 2022 Proposed Rule related to the restricted use of certain persons to interpret or facilitate communication. The prior regulations recognized that an LEP individual cannot be required to provide their own interpreter and that a minor can only be used to interpret in an emergency and that an adult accompanying an adult should not act as an interpreter without the person's consent or in an emergency. The 2022 Proposed Rule adds an exception that in an emergency situation there is an accompanying adult or minor should be "a temporary measure." When health care facilities do not have interpreter services the burden can fall on the individual patient or their family especially children. This benefit will provide protections under these circumstances if there is an issue with the patient receiving proper care due to the language barrier.

Tennessee Primary Care Association

(b)(5)

[illegible] also supports the clarification in the 2022 Proposed Rule related to the restricted use of certain persons to interpret or facilitate communication. The prior regulations recognized that an LEP individual cannot be required to provide their own interpreter and that a minor can only be used to interpret in an emergency and that an adult accompanying an adult should not act as an interpreter without the person's consent or in an emergency. The 2022 Proposed Rule adds an exception that in an emergency situation there is an accompanying adult or minor should be "a temporary measure." When health care facilities do not have interpreter services the burden can fall on the individual patient or their family especially children. This benefit will provide protections under these circumstances if there is an issue with the patient receiving proper care due to the language barrier.

(b)(5)

Wisconsin Primary Health Care Association

We are pleased to see the proposed rule's language regarding restricted use of certain minors and adults to act as interpreters. Ordinarily relying on minor children or accompanying adults to interpret for an individual in the health care setting should only be a last resort in extreme circumstances and when the patient with LEP requests and agrees to this measure. We support the clarification as included in the proposed rule that this arrangement should only be a temporary measure in emergency situations.

UnidosUS

AHA/AHA also supports the clarification in the 2022 Proposed Rule related to the restricted use of certain persons to interpret or facilitate communication. The prior regulations recognized that an LEP individual cannot be required to provide their own interpreter and that a minor can only be used to interpret in an emergency and that an adult accompanying an adult should not act as an interpreter without the person's consent or in an emergency. The 2022 Proposed Rule adds an exception that in an emergency situation there is an accompanying adult or minor should be "a temporary measure." When health care facilities do not have interpreter services the burden can fall on the individual patient or their family especially children. This benefit will provide protections under these circumstances if there is an issue with the patient receiving proper care due to the language barrier.

Minnesota Association of Community Health Centers

CCJ strongly supports the clarification on relying to the restricted use of certain persons to interpret or facilitate communication. CCJ agrees that minor children and accompanying adults should not act as interpreters unless in an emergency situation and only as a "temporary measure."

Genesee County Legal Aid Society dba Center for Civil Justice

Third the Proposed Rule requires that covered entities train staff on the provision of language assistance services and restores the requirement that covered entities must provide a "qualified" interpreter which ensures that LEP individuals will have access to higher quality interpretation services than what is currently required under 2020 Rule.

Attorneys General of California, New York, Massachusetts, and nineteen other States

[Italics] Restricted use of certain persons to interpret or facilitate communications. We support the improvements clarifying who may interpret or facilitate communications. It is important for covered entities and people with LEP to understand that no person should be required to pay for their own interpreter or anything that was communicated in previous notices and taglines. This additional clarification strengthens the existing standard that no one should have to provide their own interpreter. We also support clarifications about the circumstances where an untrained interpreter would be an acceptable substitution for one provided for and paid by the covered entity. For example, the proposed rule clarifies that in an emergency an accompanying adult is acceptable only as a temporary measure while a qualified interpreter is located. This provision underlines our recommendation that covered entities be required to develop language access plans which would cover planning for scenarios such as finding an interpreter in an emergency. We also appreciate that when an accompanying individual is requested by the person with LEP to be the interpreter that request is documented. However, we believe OCR should clarify that this should not be a one time process over the course of multiple interactions with a covered entity. For example, we have heard of times when providers have assumed without checking that a family member who has served as an interpreter for an individual with LEP in the past would do so again. Covered entities should confirm a person's interpreter preference at each interaction. OCR could clarify this by amending [sic][,]in] to add "for a given interaction" after "requests that the accompanying adult interpreter or facilitate communication." In addition, OCR should not use the admonition in its Title VI LEP guidance that the covered entity may still need to provide its own interpreter if it is unclear whether the patient-preferred interpreter is competent to interpret, including whether there may be a conflict of interest.

(b)(5)

The proposed rule includes additional changes that specifically support the LEP community. It restores requirements to provide meaningful access for LEP individuals and includes a modified definition of LEP that recognizes that a person who is competent in some communications may still require assistance in other contexts [Footnote 13: Id. at 47916-17 (Proposed § 92.201).]. The rule also obligates entities to provide a qualified interpreter which includes a limitation that relying on a minor child family member or friend for interpretation can only be used as a temporary measure in an emergency until a qualified interpreter is found [Footnote 14: Id.]. Language access remains a barrier to care for the over 26 million households in the U.S. who are LEP. [Footnote 15: Question and Answers on the 2022 Proposed Rule Addressing Nondiscrimination Protections under the ACA's Section 1557 NAT'L DNAI HEALTH LAW PROGRAM (Aug. 15, 2022), https://healthlaw.org/resource/questions-and-answers-on-the-2022-proposed-rule-addressing-nondiscrimination-protections-under-the-aca-s-section-1557/, American Community Survey 2020; Table S1601 Language Spoken at Home, American Community Survey 5-Year Estimates, available at https://data.census.gov/cedsci/table?q=S1601&tid=ACSST5Y2020.S1601, Table S1602 [Limited]. For example, recent studies suggest that LEP individuals — who are more likely to be Latinx or Asian — have lower rates of COVID-19 vaccinations and have higher cases of COVID-19 infections, hospitalization and deaths. [Footnote 16: See Zong and Jeanne Batalova, "The Limited English Proficient Population in the United States," 2018 MIGRANT POLICY INSTITUTE, https://www.migrationpolicy.org/article/limited-english-proficient-population-united-states-2018].

Additionally, we are glad that the Department has proposed allowing a dental practice to use a non-qualified interpreter in emergency situations. However, we ask the Department to provide that same emergency exception for using bilingual staff as interpreters or for performance standards for video remote interpreting. Dental offices have small staffs but their staff is also often diverse and dental offices should be able to use their staffers' skills in different languages when needed in emergency situations. The NPRM also says that video remote interpreting has to be over a dedicated high speed wide bandwidth video connection or wireless connection. That standard may be difficult to meet for dental offices in rural areas. And it may be especially difficult to meet that standard in an emergency such as a natural disaster that disrupts access to the high-speed connection.

National Immigration Law Center

We also support the clarification in the 2022 Proposed Rule related to the restricted use of certain persons to interpret or facilitate communication. The prior regulations recognized that an LEP individual cannot be required to provide their own interpreter that a minor can only be used to interpret in an emergency and that an adult accompanying an adult should not act as an interpreter without the person's consent or in an emergency. The 2022 Proposed Rule adds an exception that in an emergency situation the reliance of an accompanying adult or minor should be a "temporary measure." We support this addition. Children and other family members of LEP immigrants are too often burdened with [Hyperlink: acting as a translator: https://news.medill.northwestern.edu/chicago/kids-serve-as-translators-for-parents-who-speak-little-english/] during interactions with English speaking service providers. For children especially this burden can be uncomfortable, laborious and traumatic, specifically when dealing with sensitive health information. For AAPI women who are [Hyperlink: often their families' chief caregivers; https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/fact-sheets/women-and-job-based-health-benefits.pdf], direct and professional interpretation of health care information is critical in making health care decisions for themselves and their families and reducing the burden from children who should not be placed in the difficult position of interpreting health care information for their LEP parents or other family members.

Senate Democrats

We support the 2022 proposed rule's restored provisions from the 2016 Final Regulations regarding definitions for language assistance services, required steps to provide meaningful access to limited English proficient (LEP) individuals, standards for video remote interpretation and provision of notices to inform individuals of their rights. We do however see opportunities to clarify and strengthen these provisions.

American Dental Association

(b)(5)

Instances where remote interpreting services have support the restoration of requirements ensuring the quality of video interpreting services which have become more essential in the COVID-19 pandemic but were deleted in the 2020 rule. We have heard from community partners that video interpreting can be effective in circumstances when visual cues and body language are important for all parties in an interaction. Telehealth can be an important tool for expanding access to interpretation for people who are LEP as well as people with disabilities and we encourage HHS to include [via a video remote interpreting service] to the definition of a qualified interpreter for a limited English proficient individual. We support the proposed requirements to ensure adequate and clear corrections and training.

National Asian Pacific American Women's Forum

[Bold: Meaningful access for LEP individuals]We appreciate the restoration of requirements related to video interpretation. The 2020 final rule removed requirements related to video interpretation for LEP individuals. Yet video interpretation is an important tool not only for deaf or hard-of-hearing patients but also LEP patients. In a health care setting face-to-face contact is often preferred over phone contact to build the trust between the patient and the provider as well as the interpreter. There are nonverbal clues that may be essential to understanding the patient's health needs. Absent the availability of in person interpreters ensuring access to quality video interpretation allows providers along with their patients to determine which technology (phone or video) is appropriate to ensure LEP patients receive the highest quality of care.

Farmworker Justice

No comments are associated with this issue

No comments are associated with this issue

(b)(5)

Justice in Aging endorses the Consortium for Constituents with Disabilities' (CCD) comments with respect to Effective communication for individuals with disabilities (§ 92.202) Accessibility for buildings and facilities (§ 92.203) Accessibility of information and communication or technology for individuals with disabilities (§92.204) and Requirement to make reasonable modifications (§ 92.205). Given that more than one-third of older adults have at least one disability these provisions are very important to ensuring that people can access quality health care and LTSS as they age. We urge HHS to ensure these provisions and the provisions with respect to language access work together to ensure that older adults and others with disabilities and LEP have meaningful access.

Farmworker Justice

National Immigration Law Center

Justice in Aging

(b)(5)

[Bold: Effective and Accessible Communication] DRM supports §§ 92.202 and 92.204 on effective communication and accessible information and communication technology (ICT) requirements for people with disabilities.

Effective Communication for individuals with Disabilities [§92.202] and Accessibility of Information and Communication Technology for Individuals with Disabilities [§92.204]WPHCA supports §§ 92.202 and 92.204 on effective communication and accessible information and communication technology (ICT) requirements for people with disabilities. Community Health Centers are the largest primary care network in the United States and 1 in 5 Medicaid beneficiaries is a Community Health Center patient. Medicaid is the primary insurer for people with disabilities making Community Health Centers a primary site for all populations to access those services. Primary care providers at Community Health Centers take the time to build a relationship with patients over time allowing them to be well positioned to provide whole person targeted care and address overall personal health needs. Community Health Centers always strive to meet patients where they are depending on their abilities and health needs and will continue to utilize communication services and make information easily available and accessible to patients with disabilities.WPHCA has engaged with various technical resources to improve digital health literacy for patients including patients of all abilities. These trainings help Community Health Centers meet the needs of their patients aided by effective use of tools such as remote monitoring telehealth patient portals and more.

Section 1557 Policies and Procedures are a necessary step toward preventing racism and other discriminatory conduct in healthcare.As the Proposed Rule notes for patients of color trust in their health care providers would increase if these patients could voice their concerns directly to their health care providers which would in turn improve these patients' overall health care experiences. However existing Section 1557 policies and procedure requirements are disjointed confusing and ineffective. The Proposed Rule would streamline these requirements by requiring covered entities to adopt and implement nondiscrimination policies against all forms of discrimination including language and disability access procedures (collectively Section 1557 Policies and Procedures). The revised Section 1557 Policies and Procedures aim to prevent discrimination from occurring in the first place by ensuring coverage entities have greater knowledge of their obligations under Section 1557

[Bold: Effective Communication for Individuals With Disabilities [§92.202] and Accessibility of Information and Communication Technology for Individuals With Disabilities [§92.204]: [Bold: TPCA supports §§ 92.202 and 92.204 on effective communication and accessible information and communication technology (ICT) requirements for people with disabilities. Health centers are the largest primary care network in the United States and 1 in 5 Medicaid beneficiaries is a health center patient. Medicaid is the primary insurer for people with disabilities making health centers a primary site for all populations to access those services. Primary care providers at health centers take the time to build a relationship with patients over time allowing them to be well-positioned to provide whole person targeted care and address overall personal health needs. Health centers always strive to meet patients where they are depending on their abilities and health needs and will continue to utilize communication services and make information easily available and accessible to patients with disabilities.

[Bold: Effective Communication for Individuals With Disabilities [§92.202] and Accessibility of Information and Communication Technology for Individuals With Disabilities [§92.204]: MNACHC supports §§ 92.202 and 92.204 on effective communication and accessible information and communication technology (ICT) requirements for people with disabilities. Health centers are the largest primary care network in the United States and 1 in 5 Medicaid beneficiaries is a health center patient. Medicaid is the primary insurer for people with disabilities making health centers a primary site for all populations to access those services. Primary care providers at health centers take the time to build a relationship with patients over time allowing them to be well-positioned to provide whole person targeted care and address overall personal health needs. Health centers always strive to meet patients where they are depending on their abilities and health needs and will continue to utilize communication services and make information easily available and accessible to patients with disabilities.

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Disability Rights Maine

WisLumbin Primary Health Care Association

Alliance of Multicultural Physicians

Tennessee Primary Care Association

(b)(5)

Additionally it is important to also recognize the language access needs of individuals who communicate primarily by American Sign Language (ASL). ASL interpretation and translation services and written communications should be available to these families.

individuals and the health care system without which individuals with Limited English Proficiency (LEP) may not enroll in programs for which they are eligible may not receive timely or comprehensive health care and may not know their rights to free timely and competent language services. The AAPI community is diverse and is made up of [Hyperlink: more than 50 ethnic groups, https://www.apiahf.org/resources/census-data-spotlights/] and speaks [Hyperlink: over 100 different languages: https://www.nationsonline.org/oneworld/asian_languages.htm]. Data from the Census found that nearly [Hyperlink: 50 percent of foreign born AAPI women have LEP, https://cdn.americanprogress.org/wp-content/uploads/2014/04/AAPILanguageAccess1.pdf] which causes [Hyperlink: interactions with medical providers difficult and exacerbates health disparities: https://www.aapcho.org/wp/wp-content/uploads/2014/08/NAPAHO-LEP-Fact-Sheet_2014_final.pdf]. Women – especially immigrant AAPI women – are often their household's [Hyperlink: primary caregivers, https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/fact-sheets/women-and-job-based-health.pdf] and make a majority of U health care decisions in their families. AAPI and immigrant women also face significant barriers to accessing health care coverage and reproductive care services due to [Hyperlink: systemic and language barriers, https://static1.squarespace.com/static/5ad6f1e52ee4eb7194e7fbd8/t/5b0c8c8bf07614913f2397a/1528457922587/AAPI+community+and+abortion+care.pdf] which have been exacerbated since the fall of Roe v. Wade. Access to culturally competent navigators qualified interpreters and translated resource materials allows AAPI women to connect themselves and their family members with necessary care. We support many provisions in the 2022 Proposed Rule, including those that mandate qualified interpreters, machine translation, civil rights training

We further support the prohibitions on discrimination on the basis of disability and the proposed rules related to access for individuals with disabilities

[Bold: III. Effective and Accessible Communication][Bold/Italics: Effective communication for individuals with disabilities [§ 92.202]Accessibility of information and communication technology for individuals with disabilities [§ 92.204]:The Tennessee Disability Coalition supports §§ 92.202 and 92.204 on effective communication and accessible information and communication technology (ICT) requirements for people with disabilities. So often people with disabilities are confronted by health care services that do not address the needs for effective communication. As a result the person's understanding and knowledge of what has been said/shared is significantly reduced

P&A believes covered entities should at minimum be required to provide notice about requirements to ensure effective communication for people with disabilities including their companions with disabilities. We believe notice should include not only the 1557 coordinator's name but also the easiest way to request these communication accommodations for the individual with disabilities and/or their companion. Effective communication in our view encompasses more than auxiliary aids and devices to include how things are worded, encouragement of plain language policies universally designed to meet the reading level and comprehension of everyone are essential to satisfy this standard of "effective communication". P&A would like to see Department guidance and best practices to this effect. Policies should be designed not to add a layer of complexity but to easily facilitate accommodations with as little burden on the person with a disability and/or their companion

(b)(5)

Minnesota Association of Community Health Centers

American Academy of Pediatrics

National Asian Pacific American Women's Forum

Boston Children's Hospital

Tennessee Disability Coalition

ND Protection & Advocacy Project

(b)(5)

applications and medical diagnostic equipment. Plain language, easy read and graphic language should always be used. Key aspects of [Hyperlink: plain language; https://www.plainlanguage.gov/about/definitions/] include: use of active voice, brief sentences and paragraphs, common words and design features [i.e., clear headings and tables]. [Hyperlink: Text in Easy Read: https://www.learningdisabilities.org.uk/learning-disabilities/a-to-z/e/easy-read] is accessible to people with learning and other disabilities. Prevalent Easy Read rules are the use of brief sentences, images representing each sentence, simplified language, large font, simple fonts and minimal design elements. Easy Read documents tend to be longer than non-Easy Read materials. Graphic illustrations can allow people with IDD to better understand concepts. [Bold: Steps HHS can take to help covered entities meet their language access and effective communication responsibilities.] HHS should not just focus on Limited English proficiency. HHS should use Plain Language and Easy Read. It should also ensure that people with IDD can communicate in the way they would like (Verbal, AAC device, etc.) preferred.

Effective Communication for individuals with Disabilities. The NPRM's sections on effective communication for individuals with disabilities, accessibility of information and communication technology for individuals with disabilities and requirement to make reasonable modifications require covered entities to comply with Americans with Disabilities Title II rules rather than Title III rules. To help reduce the burden, confusion and complexity of compliance, ADA urges OCR to require recipients of federal financial assistance to comply with the requirements of Title II, rather than Title II, of the Americans with Disabilities Act if the recipient is otherwise covered by Title II. Requiring small practices to comply with both Title II for Section 1557 purposes and Title III for Americans with Disabilities Act purposes is burdensome, confusing and unnecessarily complex. The burden on small practices of complying with both Title II and Title III would likely outweigh any benefit to individuals with disabilities.

Disability Protection Organizations strongly support the proposed rule's enhancements to protections for people with disabilities. MCFA's HelpLine often speaks with Massachusetts residents who are deaf and/or blind and need accessible information to access health coverage and care. Through our work with and advocacy alongside Massachusetts residents with disability, our organizations know the number of physical, financial and technological barriers that prevent patients with disabilities from receiving the care they needs. We support the provisions related to effective communication and accessible information and communication technology (ICT) requirements for people with disabilities. As technology used in health care develops and evolves, it must consider how to consider the user experience of individuals with disabilities. With regard to accessibility to buildings and facilities, we support these provisions that preserve prior existing requirements for structural accessibility and the provision of reasonable modifications. However, we strongly recommend incorporating within the proposed rule existing standards relating to accessible medical and diagnostic equipment that were developed by the U.S. Access Board and finalized in 2017. [Footnote 2: Medical Diagnostic Equipment Accessibility Standards https://www.access-board.gov/mde/.] For some people with disabilities, equipment accessibility is as necessary to equally effective health care as the accessibility of buildings and facilities. Equipment accessibility is also equally linked to requests for reasonable modifications in a covered entity's policies and procedures.

(b)(5)

[Bold: § 92.202 - Effective communication for individuals with disabilities.] We support the provisions in this section regarding effective communication for people with disabilities. Effective communication is critical to ensuring that people with disabilities have access to quality health care. We emphasize that protections are needed for individuals who require but all too frequently lack meaningful, effective access to the robust language-based Augmentative and Alternative Communication (AAC) they need to express themselves and be understood. We strongly urge HHS to incorporate the following HHS guidance directly into the final regulations as well as all its subsequent guidance, technical assistance and enforcement activities: Nun Discrimination in Standards of Care – March 28, 2020 [Hyperlink: https://www.hhs.gov/sites/default/files/ucr-bulletin-3-28-20.pdf]; and The Rights of Persons with Disabilities to Have Reasonable Access to Support Persons in Hospital Settings During COVID-19 – June 9, 2020.
No comments are associated with this issue.

The proposed rule facilitates access to health care services for people with disabilities. We are pleased that the proposed rule creates standards that seek to create equity in quality of care for all patients, including those with disabilities who often experience stigma, bias and discrimination in the health care system that adversely affects their ability to access needed care and can lead to missed, delayed or inaccurate diagnosis and treatment, sometimes with deadly consequences. [Footnote 13: See, e.g., National Council on Disability, Enforceable Accessible Medical Equipment Standards: A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities (May 20, 2021).] The proposed rule ensures that those with disabilities—including mobility impairments—are not excluded from competent care based on a facility's physical design, requires that people are informed of the accommodations available to them and requires that covered entities provide auxiliary aids for those with sensory, manual or auditory disabilities.
Recognizing that people with disabilities may face overlapping forms of discrimination, we appreciate that the proposed rule stipulates that providing auxiliary aids and services for individuals with disabilities includes ensuring that such services are available in languages appropriate for an individual with limited English proficiency (LEP). We urge the adoption of these provisions in the final rule.
Finally, we recommend that § 92.202(a) explicitly parallel the language in § 92.201(b) by stating that auxiliary aids and services must be provided free of charge, be accurate and timely and protect the privacy and the independent decision making of the individual with a disability. While those requirements and others are incorporated through § 92.202(a)'s reference to 28 CFR 35.160 through 35.164, smaller covered entities that are creating 1557 policies and procedures without necessarily obtaining legal advice may struggle to fit § 92.201 and 92.202 noting the seeming difference in language between the subsections. OCR's provision of technical assistance that addresses specifically and in plain language what is required under 28 CFR 35.160 to 35.164, in conjunction or with what is required under § 92.201 of the proposed rule will also be helpful.

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2. Expand on "availability of language assistance services and auxiliary aids and services" to include plain language and screen reader capabilities. Information pertaining to health is not typically provided in an easily understood format which leads to confusion when accessing and utilizing health care services. The use of plain language in healthcare should be at the forefront of all healthcare communication. Furthermore, all information presented on a virtual platform needs to be accessible for a screen-reader. Understanding health information is critical for people with disabilities to fully access accurate health care.

We also applaud the requirement that covered entities provide reasonable modifications for individuals with disabilities and appropriate auxiliary aids and services, thereby helping protect against discrimination and ensure equal access.

(b)(5)

U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Disability Rights Maine

The Arc of Pennsylvania

The Colorado Health Foundation

(b)(5)

While we support §§ 92.10 and 92.11 including a revised notice requirement that does not require a 1557 notification to be sent out with every patient/member contact and requires the notice of auxiliary services and supports in a specific list of significant communications we make the following additional recommendations to ensure that the proposed notice requirement is as effective as intended:• The § 92.10 and § 92.11 notices should be posted not only in locations where individuals seeking services will be able to see or hear them but also be posted prominently where front line employees can see them and be trained to use them to communicate the rights described to these individuals with communication or cognitive disabilities who face evident barriers to seeing hearing or understanding the notice without auxiliary aids or services or other means of assistance.• Covered entities must inquire about the communication needs of members/beneficiaries and record their needed auxiliary aid or service in the electronic health record so that they can consistently receive effective communication from the covered entity.• The § 92.11 Notice should be visually distinguishable through the use of large sans serif print that is a minimum of size 18 font.• The regulation itself should explicitly clarify that any required for all written communications to be rendered in alternative formats or in LEP languages necessarily include but are not limited to the list of significant communications in subsection 92.11(c)(5).• The critical importance of clear communication in health care settings warrants the inclusion of a requirement that covered entities in determining what is an appropriate auxiliary aid or service should give primary consideration to the requests of the person with a disability.

In addition to a number of technical requirements that improve access Sections 92.203 and 92.205 of the proposed rule preserve prior existing requirements for structural accessibility and the provision of reasonable modifications. We support these sections and additionally recommend incorporating existing standards relating to accessible medical and diagnostic equipment that were developed by the United States. [Footnote 8: See Medical Diagnostic Equipment Accessibility Standards U.S. Access Board https://www.access-board.gov/mde/.] These provisions including these additional recommendations are critical especially considering that people with disabilities routinely report feeling unable to convey their medical needs to physicians or having those needs dismissed.

The proposed rule facilitates access to health care services for people with disabilities We are pleased that the proposed rule creates standards that seek to create equity in quality of care for all patients including those with disabilities who often experience stigma bias and discrimination in the health care system that adversely affects their ability to access needed care and can lead to missed delayed or inaccurate diagnosis and treatment sometimes with deadly consequences. [Footnote 11: See e.g. National Council on Disability Unfortunate Accessible Medical Equipment Standards: A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities (May 20 2021).] The proposed rule ensures that those with disabilities including mobility impairments are not excluded from complete health care based on a facility's physical design ensures that people are informed of the accommodations available to them and requires that covered entities provide auxiliary aids for those with sensory manual or auditory disabilities.

[Bold: C. The NPRM's proposed provisions for access to facilities and proposed integration provision are essential protections for people with disabilities.] We support § 92.203 and § 92.205 which preserve prior existing requirements for structural accessibility and the provision of reasonable modifications to ensure access to facilities for people with disabilities. However we strongly recommend that the final rule incorporate existing standards relating to accessible medical and diagnostic equipment that were developed by the U.S. Access Board and finalized in 2017. [Footnote 120: US ACCESS BOARD Medical Diagnostic Equipment Access bility Standards https://www.access-board.gov/mde/ (Last visited Oct. 3 2021).] For some people with disabilities equipment accessibility is as necessary to equitably effective health care as the accessibility of buildings and facilities and is equally linked to requests for reasonable modifications in a covered entity's policies and procedures.

Justice in Aging endorses the Consortium for Constituents with Disabilities (CCD) comments with respect to Effective communication for individuals with disabilities (§ 92.202) Accessibility for buildings and facilities (§ 92.203) Accessibility of information and communication technology for individuals with disabilities (§92.204) and Requirement to make reasonable modifications (§ 92.205). Given that more than one third of older adults have at least one disability these provisions are very important to ensuring that people can access quality health care and LTSS as they age. We urge HHS to ensure these provisions and the provisions with respect to language access work together to ensure that older adults and others with disabilities and LEP have meaningful access.

[Bold: The ways in which provider networks limit or deny access to care for individuals on the basis of race color national origin sex age or disability. This includes the extent to which the lack of availability of accessible medical diagnostic equipment in a provider network constitutes discriminatory benefit design or network inadequacy and/or limits or denies access to care for people with disabilities.] Medical providers must be more accessible to people with disability which should already happen because of the ADA's Titles. Hyperlink: II. https://www.ada.gov/ada_title_II_stat.htm (pertaining to state and local government entities) and Hyperlink: III. https://www.ada.gov/ada_title_III_stat.htm (pertaining to Public Accommodations and Commercial Facilities). There are several ways that medical providers can address environmental concerns. Facilities can have Hyperlink: medically accessible equipment: https://www.ada.gov/medicare_mobility_ca/medicare_ta.html such as an adjustable exam tables that would be used by patients with mobility impairments and accessible scales. Facilities can also provide sensory carts and/or have sensory rooms to accommodate patients with sensory problems. They could also not have loud TVs in waiting rooms. Many of these adjustments would help many other patients not just people with IDD. Facilities should also allow accompaniment by care partners and other support personnel.

No comments are associative with this rule.

(b)(5)

Disability Rights Maine

The Leadership Conference on Civil and Human Rights

U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Center for Reproductive Rights

Justice in Aging

(b)(5)

wears the number of children living with disabilities has tripled largely as the result of health care advances that have allowed their survival. Despite these changing demographics the health care system continues to use an outdated approach that emphasizes acute illness and well-child care and de-emphasizes long-term management of chronic conditions and disabilities. Children with disabilities and special health care needs disproportionately lack access to a comprehensive medical home despite evidence that receiving care in a medical home can profoundly improve outcomes for these children increased access to subspecialty care fewer missed days of school and decreased family financial burden. [Footnote xxxiv: https://pdfs.semanticscholar.org/6dea/d6aacc0d2e71995101701aee2234b75d4244.pdf The AAP supports provisions in the proposed rule requiring effective communication for individuals with disabilities and accessibility standards including the requirements for websites and electronic and information technology. As was demonstrated during the COVID-19 pandemic inaccessible websites or online portals resulted in access barriers for individuals with disabilities. Requiring covered entities to provide individuals with disabilities with accessible health programs and activities provided through information and communication technology can help reduce barriers to care. These protections will enable more children to benefit from the care coordination and other benefits of a medical home. Despite protections in the ACA insurers still seek to avoid high cost populations such as people with disabilities or chronic conditions and others with high health needs. One example of this is denying organ transplants to otherwise eligible children with disabilities. [Footnote xxxv: Stallings MB Norris G AAP Committee on Bioethics Council on Children with Disabilities Children With Intellectual and Developmental Disabilities as Organ Transplantation Recipients. Pediatrics. 2021; 148(5): e2021008825]
[Bold: Effective and Accessible Communication] DRM supports §§ 92.202 and 92.204 on effective communication and accessible information and communication technology (ICT) requirements for people with disabilities.

(b)(5)

Institute for Exceptional Care

American Academy of Pediatrics

Disability Rights Maine

Effective Communication for Individuals with Disabilities [§92.202) and Accessibility of Information and Communication Technology for Individuals with Disabilities [§92.204)WPHCA supports §§ 92.202 and 92.204 on effective communication and access able information and communication technology (ICT) requirements for people with disabilities. Community Health Centers are the largest primary care network in the United States and 1 in 5 Medicaid beneficiaries is a Community Health Center patient. Medicaid is the primary insurer for people with disabilities making Community Health Centers a primary site for all populations to access those services. Primary care providers at Community Health Centers take the time to build a relationship with patients over time allowing them to be well-positioned to provide whole person targeted care and address overall personal health needs. Community Health Centers always strive to meet patients where they are depending on their abilities and health needs and will continue to utilize communication services and make information easily available and accessible to patients with disabilities. WPHCA has engaged with various technical resources to improve digital health literacy for patients including patients of all abilities. These trainings help Community Health Centers meet the needs of their patients aided by effective use of tools such as remote monitoring telehealth patient portals and more.

(b)(5)

Wisconsin Primary Health Care Association

[Bold: Effective Communication for Individuals With Disabilities [§92.202) and Accessibility of Information and Communication Technology for Individuals With Disabilities [§92.204)]. [Bold: TPCA supports §§ 92.202 and 92.204 on effective communication and access able information and communication technology (ICT) requirements for people with disabilities. Health centers are the largest primary care network in the United States and 1 in 5 Medicaid beneficiaries is a health center patient. Medicaid is the primary insurer for people with disabilities making health centers a primary site for all populations to access those services. Primary care providers at health centers take the time to build a relationship with patients over time allowing them to be well-positioned to provide whole person targeted care and address overall personal health needs. Health centers always strive to meet patients where they are depending on their abilities and health needs and will continue to utilize communication services and make information easily available and accessible to patients with disabilities.

Tennessee Primary Care Association

[Bold: Effective Communication for Individuals With Disabilities [§92.202) and Accessibility of Information and Communication Technology for Individuals With Disabilities [§92.204)] MNACHC supports §§ 92.202 and 92.204 on effective communication and access able information and communication technology (ICT) requirements for people with disabilities. Health centers are the largest primary care network in the United States and 1 in 5 Medicaid beneficiaries is a health center patient. Medicaid is the primary insurer for people with disabilities making health centers a primary site for all populations to access those services. Primary care providers at health centers take the time to build a relationship with patients over time allowing them to be well-positioned to provide whole person targeted care and address overall personal health needs. Health centers always strive to meet patients where they are depending on their abilities and health needs and will continue to utilize communication services and make information easily available and accessible to patients with disabilities.

Minnesota Association of Community Health Centers

We support the proposed rule's provisions to address issues at the nexus of disability rights and technology ensuring that web-based and mobile-based services are accessible to those with disabilities.

U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

[Bold: III. Effective and Accessible Communication] [Bold/Italics: Effective communication for individuals with disabilities [§ 92.202)Accessibility of information and communication technology for individuals with disabilities (§ 92.204)] The Tennessee Disability Coalition supports §§ 92.202 and 92.204 on effective communication and accessible information and communication technology (ICT) requirements for people with disabilities. So often people with disabilities are confronted by health care services that do not address the needs for effective communication. As a result the person's understanding and knowledge of what has been said/shared is significantly reduced.

Tennessee Disability Coalition

[Bold: Ensuring Access to Telehealth] We support the proposed provisions on telehealth and the recognition of it as a tool to improve access for individuals who for various reasons are unable or prefer to receive services in person. As telehealth has expanded during the COVID-19 pandemic access has not been equitable for LEP individuals and people with disabilities due to the telehealth platforms themselves being inaccessible. Therefore we recommend that HHS require telehealth platforms to allow a third-party interpreter or use of auxiliary aids and services. Second all of the communication about telehealth that occurs prior to a telehealth appointment (e.g. scheduling system requirements testing connections appointment reminders and log-on instructions) must be accessible to people with LEP and people with disabilities. Similarly platforms should be adopted to meet the needs of older adults and people who are autistic deaf or hard of hearing blind/deaf/hard of movement impaired or otherwise have difficulty in communicating via traditional telehealth modes.

Center for Elder Law & Justice

Individuals with Disabilities (§92.204) Under this section covered entities must ensure that their health programs provided through ICT including websites and mobile apps are accessible to individuals with disabilities unless doing so would result in undue financial or administrative burden or a fundamental alteration in the nature of the program or activity. HHS seeks comment on whether the Proposed Rule should require covered entities to comply with a specific accessibility standard and if so which version and what timeline is necessary for covered entities to come under compliance with required standards? In addition HHS asks for comments on whether it should provide a safe harbor for covered entities that are in compliance with existing published standards. Recommendation: BCBSA also recommends HHS allow covered entities to comply with the Web Content Accessibility Guidelines (WCAG) 2.1 Level AA. Covered entities that are compliant with WCAG 2.1 Level AA should be deemed to be in compliance with Section 1557 proposals in this rule. BCBSA recommends HHS require compliance with the most recent edition of the WCAG Level AA standard but allow covered entities at least 18 months to comply with and/or receive attestation from providers and third-party vendors that they comply with the new standard. BCBSA also recommends HHS require providers and third-party vendors to provide issuers with a Voluntary Product Accessibility Template (VPAT) document indicating compliance with Section 508 accessibility standards. Rationale: WCAG is a widely known published accessibility standard that is updated every three years to address changing technology. The current version includes recommendations for making web content more accessible for those with disabilities such as blindness hearing loss limited movement speech disabilities learning disabilities and cognitive limitations. The guidelines address accessibility of web content on desktops laptops tablets and mobile devices. HHS should not hold covered entities liable for violations of Sec. 1557 in addition to improvements to language access this proposed rule provides clear standards for effective communications and reasonable modifications that benefit the disability community [Footnote 17: 87 Fed. Reg. at 47917 (Proposed § 92.204)]. Specifically the proposed rule's clarification of the scope of discrimination prohibited under Section 1557 to include telehealth and the accessibility of information and communication technology would reduce the barriers to care for people with disabilities. While there have been advancements in health care access for people with disabilities entities still deny care or fail to provide the necessary supports and accommodations to people with disabilities. Therefore we ask that the rule consider incorporating the U.S. Access Board's standards related to accessible medical diagnostic equipment [Footnote 18: U.S. Access Board Medical Diagnostic Equipment Accessibility Standards https://www.access-board.gov/mde/]

(b)(5)

Blue Cross Blue Shield Association

(b)(5)

Senate Democrats

(b)(5)

Disability Protection Organizations strongly support the proposed rule and commend the Administration for protecting people with disabilities. NCFA's HelpLine often speaks with Massachusetts residents who are deaf and/or blind and need accessible information to access health coverage and care. Through our work with and advocacy alongside Massachusetts residents with disability and organizations know the number of physical financial and technological barriers that prevent patients with disabilities from receiving the care they needs.We support the provisions related to effective communication and accessible information and communication technology (ICT) requirements for people with disabilities. As technology used in health care develops and evolves it must continue to consider the user experience of individuals with disabilities. With regard to accessibility to buildings and facilities we support these provisions that preserve prior existing requirements for structural accessibility and the provision of reasonable modifications. However we strongly recommend incorporating within the proposed rule existing standards relating to accessible medical and diagnostic equipment that were developed by the U.S. Access Board and finalized in 2017 [Footnote 9: Medical Diagnostic Equipment Accessibility Standards: https://www.access-board.gov/mde/]. For some people with disabilities equipment accessibility is as necessary to equally effective health care as the accessibility of buildings and facilities. Equipment accessibility is also equally linked to requests for reasonable modifications to a covered entity's policies and procedures.

We also agree with the inclusion of mobile applications within § 92.204(b) which will hopefully be a spur greater awareness among software developers of the need for mobile applications that are fully accessible to people with disabilities and compatible with mobile devices and internet platforms that are favored for accessibility reasons.

Individuals with Disabilities (§92.204) Under this section covered entities must ensure that their health programs provided through ICT including websites and mobile apps are accessible to individuals with disabilities unless doing so would result in undue financial or administrative burden or a fundamental alteration in the nature of the program or activity. HHS seeks comment on whether the Proposed Rule should require covered entities to comply with a specific accessibility standard and if so which version and what timeline is necessary for covered entities to come under compliance with required standards? In addition HHS asks for comments on whether it should provide a safe harbor for covered entities that are in compliance with existing published standards.Recommendation: BCBSA also recommends HHS allow covered entities to comply with the Web Content Accessibility Guidelines (WCAG) 2.1 Level AA. Covered entities that are compliant with WLAG 2.1 Level AA should be deemed to be in compliance with Section 1557 proposals in this rule. BCBSA recommends HHS require compliance with the most recent edition of the WCAG Level AA standard but allow covered entities at least 18 months to comply with and/or receive attestation from providers and third-party vendors that they comply with the new standard. BCBSA also recommends HHS require providers and third-party vendors to provide issuers with a Voluntary Product Accessibility Template (VPAT) document indicating compliance with Section 508 accessibility standards.Rationale: WCAG is a widely known published accessibility standard that is updated every three years to address changing technology. The current version includes recommendations for making web content more accessible for those with disabilities such as blindness hearing loss limited movement speech disabilities learning disabilities and cognitive limitations. The guidelines address accessibility of web content on desktops laptops tablets and mobile devices. HHS should not hold covered entities liable for violations of Section 1557.

Additionally we agree with the inclusion of mobile applications within § 92.204(b). Mobile applications need to be accessible for all which means that they are compatible with all mobile devices and internet platforms.

Individuals with Disabilities (§92.204) Under this section covered entities must ensure that their health programs provided through ICT including websites and mobile apps are accessible to individuals with disabilities unless doing so would result in undue financial or administrative burden or a fundamental alteration in the nature of the program or activity. HHS seeks comment on whether the Proposed Rule should require covered entities to comply with a specific accessibility standard and if so which version and what timeline is necessary for covered entities to come under compliance with required standards? In addition HHS asks for comments on whether it should provide a safe harbor for covered entities that are in compliance with existing published standards.Recommendation: BCBSA also recommends HHS allow covered entities to comply with the Web Content Accessibility Guidelines (WCAG) 2.1 Level AA. Covered entities that are compliant with WCAG 2.1 Level AA should be deemed to be in compliance with Section 1557 proposals in this rule. BCBSA recommends HHS require compliance with the most recent edition of the WCAG Level AA standard but allow covered entities at least 18 months to comply with and/or receive attestation from providers and third-party vendors that they comply with the new standard. BCBSA also recommends HHS require providers and third-party vendors to provide issuers with a Voluntary Product Accessibility Template (VPAT) document indicating compliance with Section 508 accessibility standards.Rationale: WCAG is a widely known published accessibility standard that is updated every three years to address changing technology. The current version includes recommendations for making web content more accessible for those with disabilities such as blindness hearing loss limited movement speech disabilities learning disabilities and cognitive limitations. The guidelines address accessibility of web content on desktops laptops tablets and mobile devices. HHS should not hold covered entities liable for violations of Section 1557.

(b)(5)

The public health crisis brought to light that public health issues which disproportionately and negatively impact people with disabilities in many situations – telehealth facility/equipment access and crisis care alarming. North Dakota is a rural state and telehealth is an innovative way to deliver healthcare to rural populations and compensate for provider shortages in these rural areas. It is dependent on the provider technology being compliant with accessible web standards. P&A would like to see covered entities responsible for complying with WCAG 2.1 guidelines. Technology is changing at a rapid pace and requiring the most recent web accessibility standards is necessary for entities to provide the most accessibility to people with disabilities.

[illegible] applications and medical diagnostic equipment.Plain language easy read and graphic language should always be used. Key aspects of [Hyperlink: plain language; https://www.plainlanguage.gov/about/definitions/] include use of active voice brief sentences and paragraphs common words and design features like [illegible] headings and tables). [Hyperlink: Text in Easy Read, https://www.learningdisabilities.org.uk/learning-disabilities/a-z/e/easy-read] is accessible to people with learning and other disabilities. Prevalent Easy Read rules are the use of brief sentences images representing each sentence simplified language large font simple fonts and minimal design elements. Easy Read documents tend to be longer than non-Easy Read materials. Graphic illustrations can allow people with IDD to better understand concepts. Bold. Steps HHS can take to be a covered entities meet their language access and effective communication responsibilities.HHS should not just focus on Limited English proficiency. HHS should use Plain Language and Easy Read. It should also ensure that people with IDD can communicate in the way they would like (Verbal AAC device Low-Tech).

Lastly we recommend that § 92.202(b) explicitly parallel the language in § 92.201(b) by stating that auxiliary aids and services must be provided free of charge be accurate and timely and protect the privacy and the independent decision making of the individual with a disability. Although this language is incorporated through § 92.202(a)'s reference to 28 CFR 35.160 through 35.164 smaller covered entities that are creating 1557 policies and procedures without necessarily obtaining legal advice may simply look to §§ 92.201 and 92.202 not noting the seeming difference in language between the subsections.

(b)(5)

Health Care For All

Disability Rights Maine

Blue Cross Blue Shield Association

Tennessee Disability Coalition

(b)(5)

Blue Cross Blue Shield Association

ND Protection & Advocacy Project

Institute for Exceptional Care

Tennessee Disability Coalition

(b)(5)

In addition to further improvements to language access this proposed rule provides clear standards for effective communications and reasonable modifications that benefit the disability community [Footnote 17: 87 Fed. Reg. at 47917 (Proposed § 92.204)]. Specifically, the proposed rule's clarification of the scope of discrimination prohibited under Section 1557 to include telehealth and the accessibility of information and communication technology would reduce the barriers to care for people with disabilities. While there have been advancements in health care access for people with disabilities, it still can be difficult to provide the necessary supports and accommodations to people with disabilities. Therefore, we ask that the rule consider incorporating the U.S. Access Board's standards related to accessible medical diagnostic equipment [Footnote 18: U.S. Access Board Medical Diagnostic Equipment Accessibility Standards https://www.access-board.gov/mde/]

Disability Protection Organizations strongly support the proposed rule's nondiscrimination protections for people with disabilities. HCFA's HelpLine often speaks with Massachusetts residents who are deaf and/or blind and need accessible information to access health coverage and care. Through our work with and advocacy alongside Massachusetts residents with disability, our organizations know the number of physical, financial, and technological barriers that prevent patients with disabilities from receiving the care they needs. We support the provisions related to effective communication and accessible information and communication technology (ICT) requirements for people with disabilities. As technology used in health care develops and evolves, it must continue to consider the user experience of individuals with disabilities. With regard to accessibility to buildings and facilities, we support these provisions that preserve prior existing requirements for structural accessibility and the provision of reasonable modifications. However, we strongly recommend incorporating within the proposed rule existing standards relating to accessible medical and diagnostic equipment that were developed by the U.S. Access Board and finalized in 2017. [Footnote 9: Medical Diagnostic Equipment Accessibility Standards https://www.access-board.gov/mde/] For some people with disabilities, equipment accessibility is as necessary to equally effective health care as the accessibility of buildings and facilities. Equipment accessibility is also equally linked to requests for reasonable modifications in a covered entity's policies and procedures.

No comments are associated with this issue.

In addition to a number of technical requirements that improve access, Sections 92.203 and 92.205 of the proposed rule preserve prior existing requirements for structural accessibility and the provision of reasonable modifications. We support these sections and additionally recommend incorporating existing standards relating to accessible medical and diagnostic equipment that were developed by the United States. [Footnote 8: See Medical Diagnostic Equipment Accessibility Standards U.S. Access Board https://www.access-board.gov/mde/.] These provisions including these additional recommendations are critical, especially considering that people with disabilities routinely report feeling unable to convey their medical needs to physicians or having those needs dismissed.

b. The MRCT Center strongly endorses the assertion that the revised Rule clarifying Section 1557 should establish that one standard of nondiscrimination applies and that standard is the most protective of those who have been or are subject to discrimination on the bases of race, color, national origin, disability, age, or sex. It should clarify that one standard exists for health care for all categories and to reject an that are disadvantaged group is afforded preference or right above another. That disparate impact beyond and/or those of disparate treatment is a standard or should be the single applicable standard. In addition, the Rule should clarify that reasonable accommodations are an exception and must be provided to demonstrate compliance with the Rule.

[Bold. Structural accessibility and reasonable modifications. We support the provisions that preserve prior existing requirements for structural accessibility and the reasonable modifications. However, we strongly recommend HHS incorporate the U.S. Access Board's accessible medical and diagnostic equipment standards in the final rule. [Footnote 12: Medical Diagnostic Equipment Accessibility Standards U.S. Access Board https://www.access-board.gov/mde/ (2012).] Equipment accessibility is as necessary to equally effective healthcare as the accessibility of buildings and facilities and is equally linked to requests for reasonable modifications in a covered entity's policies and processes. [Footnote 13: Id.]

[Bold. C. The NPRM's crossover provisions for access to facilities and proposed integration provision are essential protections for people with disabilities. [We support § 92.203 and § 92.205 which preserve prior existing requirements for structural accessibility and the provision of reasonable modifications to ensure access to facilities for people with disabilities. However, we strongly recommend that the final rule incorporate existing standards relating to accessible medical and diagnostic equipment that were developed by the U.S. Access Board and finalized in 2017. [Footnote 120: US ACCESS BOARD Medical Diagnostic Equipment Access bility Standards https://www.access-board.gov/mde/ (Last visited Oct. 3 2021).] For some people with disabilities, equipment accessibility is as necessary to equally effective health care as the accessibility of buildings and facilities and is equally linked to requests for reasonable modifications in a covered entity's policies and procedures.

Justice in Aging endorses the Consortium for Constituents with Disabilities' (CCD) comments with respect to Effective communication for individuals with disabilities (§ 92.202), Accessibility for buildings and facilities (§ 92.203), Accessibility of information and communication technology for individuals with disabilities (§92.204), and Requirement to make reasonable modifications (§ 92.205). Given that more than one-third of older adults have at least one disability, these provisions are very important to ensuring that people can access quality health care and LTSS as they age. We urge HHS to ensure these provisions and the provisions with respect to language access work together to ensure that older adults and others with disabilities and LEP have meaningful access.

The Americans with Disabilities Act and Rehabilitation Act both prohibit discrimination against people living with disabilities though Section 1557 strengthens these anti-discrimination protections. First, the Proposed Rule requires covered entities to proactively ensure patients living with disabilities are provided with reasonable accommodations. For example, the Department clarifies that a covered entity must provide modifications in the absence of a request when it has knowledge of an individual's disability or when the individual's disability is obvious. Next, in addition to a number of technical requirements that improve access, Section 92.205 of the Proposed Rule requires covered entities to develop written procedures for making reasonable accommodations. This is critical where people of color routinely report feeling unable to convey their medical needs to physicians or having those needs dismissed.

[Bold: § 92.205 - Requirement to make reasonable modifications] We urge the Department to strengthen the section by adding language to clarify that modifications to add medically necessary care for individuals with disabilities or eliminating exclusions of medically necessary services are not considered fundamental alterations to the nature of the health program.

No comments are associated with this issue.

We suggest strengthening the language pertaining to providers complying with state or local law as a justification for denying gender-affirming care to state unequivocally that section 1557 as federal law preempts any such state or local law restricting access to this care.

HHS has not and cannot demonstrate need and a substantial evidentiary basis for such a self-contradictory and unnecessary Proposed Rule. This is nothing more than arbitrary and capricious rulemaking by the Department driven by an unscientific ideology that will permanently disfigure the practice of medicine if finalized.

(b)(5)

Senate Democrats

Health Care For All

The Leadership Conference on Civil and Human Rights

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Center for Elder Law & Justice

Center for Reproductive Rights

Justice in Aging

Alliance of Multicultural Physicians

National Disability Rights Network

Colors+

Ethics & Public Policy Center

(b)(5)

Equal Program Access on the Basis of Sex (§ 92.206)We strongly support the inclusion of this section which will help address the myriad forms of harmful discrimination described above. It is important to clarify that while providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient they may not refuse gender-affirming care based on a personal belief that such care is never clinically appropriate. We suggest strengthening the language pertaining to providers complying with a state or local law as a justification for denying gender-affirming care to state

unequivocally that Section 1557 as federal law preempts any such state or local law restricting access to this care

disease defined by the failure to achieve a successful pregnancy after 12 months or more of appropriately timed unprotected intercourse or therapeutic donor insemination." Many health plan policies for ART coverage are based on this definition. Others use a definition of infertility based solely on failure to achieve pregnancy after a period of unprotected heterosexual intercourse. Both of these definitions used in this context place an undue burden on non-heterosexual individuals and couples who wish to reproduce. Health plans using these definitions often impose significant extra costs or complete exclusions of coverage of fertility treatments for LGBTQI+ people. We believe these pervasive policies that focus on cisgender heterosexual couples are inherently discriminatory and HHS should clarify in the Final Rule that ART coverage should not be offered without regard to sexual orientation or gender identity (sex characteristics (including intersex traits) or any other factors protected by Section 1557. ART includes several methods for facilitating reproduction in the case of medical or social infertility. These include intrauterine insemination (IUI) in vitro fertilization (IVF) and surrogacy. Denying such services based on an individual's couple's inability to have unprotected procreative sexual intercourse is inherently discriminatory against LGBTQI+ individuals and couples particularly for the vast majority of same-sex couples for whom sexual intercourse cannot lead to pregnancy. For example this discriminatory to deny IUI to a couple composed of two cisgender women based on their inability to engage in procreative sexual intercourse with each other. In [Italic red: Bostock] the Supreme Court considered whether LGBTQI+ workers who were fired from their jobs for their sexual orientation or gender identity were discriminated against on the basis of sex. The Court held 6-3 that the Civil Rights Act's protection against employment discrimination on the basis of sex applied and that a plain reading of the protection extends to discrimination based on sexual orientation or gender

(b)(5)

Congressman Mike Quigley

[Bold and Italics Equal Program Access on the Basis of Sex (§ 92.206)] [Bold The AAMC supports the proposed additional clarifications to ensure equal access to health programs and activities without discrimination on the basis of sex.' We agree with the Department that additional regulatory clarity specific to sex discrimination in health programs and activities is prudent These additional clarifications pertain to (1) a general prohibition on the denial or limitation of services to an individual based on the individual's sex assigned at birth gender identity or gender otherwise recorded (2) prohibition of covered entities' denial or limitation of a health care professional's ability to provide health services or the basis of a patient's sex assigned at birth gender identity or gender otherwise recorded (3) prohibition of sex-specific health programs or activities that subjects any individual to more than [de minimis harm and (4) prohibition of denial or limitation of gender affirming care if the denial is based on the patient's sex assigned at birth gender identity or gender otherwise recorded. The AAMC believes that the proposed protections are supported by decades of peer reviewed research showing that access to positive health care for LGBTQI+ people and access to gender affirming care is essential for living healthy and happy lives. Footnotes 9 and 10: See Diana M. Tordoff et. al JAMA Pediatrics Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender Affirming Care (February 2022) finding that receipt of gender-affirming care among young people was associated with 60% lower odds of depression and 73% lower odds of suicidality over a 12 month follow-up ; See Jaime Swan et al Journal of Gay & Lesbian Mental Health Mental health and quality of life outcomes of gender affirming surgery A systematic literature review (February 2022) finding through a review of 53 studies and indication of reduced rates of suicide attempts anxiety depression and symptoms of gender dysphoria along with higher levels of life satisfaction after gender-affirming surgery]

(b)(5)

Association of American Medical Colleges (AAMC)

based "standards of care"): The entire rule is premised on gender ideology a gender-dominated belief system that is unproven lacks empirical support and is highly controversial And yet the rule makes clear that medical providers and healthcare institutions are expected to endorse the "gender identity" belief system to use ideological terminology (such as "cisgender" and "sex assigned at birth") instead of fact-based scientific terms (such as male or female) and to provide "gender affirming care" or "transition" care on demand. Otherwise they risk becoming the subject of a discrimination claim. As discussed elsewhere in these comments HHS leaves little room for the exercise of professional-based or medical judgment based refusals to provide "gender affirming care" to anyone who seeks it. The Proposed Rule relies on WPATH's purported "standards" and the Endocrine Society's clinical practice guidelines for "gender affirming care" even though the cited guidelines are controversial and the evidentiary basis for those guidelines is of "low" quality Although the Rule states that "[g]ender-affirming care like all medical care should follow clinical practice guidelines and professional standards of care" it is clear that HHS has made an arbitrary determination far outside its competence as a government regulatory agency that only ideological-tainted "guidelines" or "standards" will be court Footnote 108: 87 Fed Reg 47868 | (The HHS attempt to impose an arbitrary standard of care through the regulatory process is addressed more at length below.)

Ethics & Public Policy Center

Equal Program Access of the Basis of Sex (§ 92.206)We strongly support this proposed section for the reasons discussed by the National Center for Lesbian Rights. This provision will help to address the numerous forms of discrimination described above and clarifies that while providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient they may not refuse gender-affirming care based on a personal belief that such care is never clinically appropriate

Justice in Aging

(numerated in the Proposed Rules] We appreciate HHS' enumeration of specific forms of sex discrimination that are prohibited in the Proposed Rule Section 92.206 importantly clarifies that while providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient they may [Bold. not] refuse gender affirming care to a patient based on a personal or religious belief that such care is never clinically appropriate The restoration of protections for gender-affirming care is an essential component of the proposed rule as denials of access to and insurance coverage for such care are among the most common manifestations of discrimination against the LGBTQI+ community Relatedly we suggest strengthening the language of § 92.206(b) and 92.207(b) to prevent covered entities from using state or local laws that bar or restrict access to gender-affirming care as well as broader reproductive and sexual health care as a justification to deny such care.In light of [Italics: Dobbs] we also urge you to add specific examples of discrimination relative to pregnancy and related conditions See e.g. minimal or related to pregnancy and related conditions a pervasive in our health care system. Access to sexual and reproductive health care such as contraception or fertility care abortion gender-affirming care and maternity care is often barred by discriminatory policies or practices For example pregnant Black Indigenous Latina/x Asian American and Pacific Islander and all people of color who live at the intersections of Section 1557's protected identities are often subjected to discrimination throughout pregnancy and the postpartum period including mistreatment [embedded hyperlink text (https://reproductive health

journal.biomedcentral.com/articles/10.1186/s12978-019-0729-2)] during labor and delivery People with disabilities often experience multiple barriers [embedded hyperlink text

Physicians for Reproductive Health

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8/65596/)] to sexual and This section would also be strengthened by including specific examples of what constitutes discrimination based on pregnancy or related conditions such as discriminating against someone because they had previously had an abortion or denying medically necessary care because it could prevent complicate or end a patient's fertility or pregnancy

(b)(5)

Eating Disorders Coalition for Research, Policy & Action

(b)(5)

Eating Disorders Coalition for Research, Policy & Action

(b)(5)

• More Explicitly Prohibiting DiscriminationHHS focuses much of this rule on restoring nondiscrimination protections that were eliminated in the 2020 rule. HHS reiterates that Section 1557 provides a general prohibition on discrimination on the basis of race sex national origin age or disability under health programs or activities Additionally HHS clarifies that the term "on the basis of sex" includes sex stereotypes sex characteristics including intersex traits pregnancy or related conditions sexual orientation and gender identity [Footnote 7 Consistent with legal conclusions reached in Price Waterhouse v Hopkins 490 U S 228 [1989] [sex discrimination includes discrimination based on sex stereotypes] and Bostock v Clayton County 140 S Ct 1731 1742 [2020] (sex discrimination includes discrimination based on sexual orientation and gender identity)" This broader definition will require covered entities to provide equal access to health programs and activities without the threat of discrimination on the basis of sex and will be prohibited from denying or limiting health services for gender-affirming care on the basis of an individual's sex assigned at birth gender identity or gender otherwise recorded This clarification will also prohibit discrimination on the basis of sex race color national origin age and disability in the provision and administration of health insurance coverage

[2] Specific Applications to Health Programs and Activities [Title IX Equal Program Access on the Basis of Sex [§92 206)] Bold TPCA supports the proposed rule's §92 206 that ensures patients have equal program opportunity on the basis of sex.' We also strongly agree with its extension to nondiscrimination in the coverage of gender affirming and transition related care. For years studies have shown disparities in accessing care for Transgender individuals Transgender and Gender Diverse individuals commonly face insurance-related obstacles to obtain clinically appropriate care These disparities only multiply for Black Indigenous and other Transgender People of Color as well as Transgender People with disabilities. By finalizing this provision this will help address health disparities among the LGBTQI community by prohibiting denials in programs based on their gender

Program Access of the Basis of Sex [§ 92.206)We strongly support the inclusion of this section which will help to address the myriad forms of harmful discrimination described above. Importantly it clarifies that providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient but may [talic: not] refuse gender affirming care based on a personal belief that such care is never clinically appropriate. While we are in favor of the inclusion of this section we also suggest strengthening the language retaining the provisions requiring compliance with a state or local law as a justification for denying gender affirming care More specifically we would recommend that HHS states clearly and unequivocally that Section 1557 of the ACA which is federal law preempts [talic: any] such state or local law that seeks to restrict access to gender affirming care As an agency we are strongly in favor of this addition as it will increase protections for transgender non-binary and gender expansive people who may otherwise encounter additional and unnecessary barriers to culturally humble healthcare.As with section 92.101(a)(2) above we suggest that "transgender status" be added to sections 92.206(a)(1) (a)(2) and (b)[4). We also believe that the policy language of section (b)[2] would be clearer if it was shortened as indicated below. In addition we recommend deleting the indicated language in (b)[4] as it could enable a provider to engage in a discriminatory denial of care [even if a claimant cannot show that the care in question was on other occasions provided for other purposes] In short these suggested changes would be reflected in §2 206 as follows:' In providing access to health programs and activities a covered entity must not :(1) Deny or limit health services including those that are offered exclusively to individuals of one sex to an individual based upon the individual's sex assigned at birth gender identity [including the individual transgender status' or gender otherwise recorded;(2) Deny or limit a health care professional's ability to provide health services on the basis of an

Indeed the Proposed would contradict and render an [inconsistent ruling] Voluntary Resolution Agreement OCR entered into with Michigan State University under Section 1557 regarding the Larry Nassar gymnast sex abuse scandal [Footnote 23: Voluntary Resolution Agreement between HHS OCR and Michigan State University et al. [Aug. 5 2019)," the Patient's wishes and comfort should determine the sex of the chaperone"]. https://www.hhs.gov/sites/default/files/ocr-between-msu-and-ocr.pdf] That resolution requires Michigan State medical facilities to offer patients chaperones of the sex of the patients' choice when doctors conduct intimate examinations of them. This resolution was negotiated with the input of a parents' representative of the gymnast victims. It would be a revictimization of those women and girls to say they must allow a biological man who identifies as women to see them in a vulnerable state including gynecological exams when their presence is not necessary for treatment and when they have requested a female chaperone. The preamble to the Proposed Rule makes it abundantly clear whose side HHS will take in such conflicts when it declares without any scientific basis that some men can get pregnant) that "experience significant forms of discrimination stigma and erasure" in pregnancy care This necessitating the Proposed Rule [Footnote 24 87 Fed. Reg. 47855.] Under the Proposed Rule biological women who identify as men must always be treated and addressed as "pregnant men" while biological men who identify as women must always be allowed to comply with biological women because to do otherwise would be more than [italics de minimis] harm over compliance requirements and rights of people to be free from discrimination an protected bases [We recommend revising the indicated language in Section § 92 206 (b)[4] as a provider could engage in a discriminatory denial of care even if a claimant cannot show that the care in question was on other occasions provided for other purposes. For example there are certain procedures that trans people seek for medically necessary gender affirming care that may technically be seen as cosmetic procedures for the general population. This can sometimes cause denial of care for trans people trying to access these services with the current regulatory language These suggested changes would be reflected in §2.206 as follows:"In providing access to health programs and activities a covered entity must not /1} Deny or limit health services including those that are offered exclusively to individuals of one sex to an individual based upon the individual's sex assigned at birth gender identity or gender otherwise recorded;(2) Deny or limit a health care professional's ability to provide health services on the basis of an individual's sex assigned at birth gender identity or gender otherwise recorded if such denial or limitation has the effect of excluding individuals from participation in denying them the benefits of or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity;(3) Deny or limit health services sought for purposes of gender transition or other gender affirming care if the denial or limitation is based on a patient's sex assigned at birth gender identity including transgender status or gender otherwise recorded [Italic: Unaddressed discrimination on the basis of race (ulor national origin [including limited English proficiency and primary language) sex [including pregnancy sexual orientation gender identity and sex characteristics) age and disability as applied to State and Federally facilitated Exchanges with any data used supporting information or facts surveys audits or reports [The addition of intersectional discrimination is much

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discrimination by providers and insurers in the aftermath of the Dobbs decision some patients have been denied access to needed medical care based on the pharmacist's belief that the drug would be used for an abortion [Footnote 25: Laura Weiss "Pharmacists and Patients Are Freaking Out Over New Medication Restrictions Post-Roe" The New Republic July 27 2022 https://newrepublic.com/article/167165/dobbs-pharmacists-walgreens-methotrexate] Denying these patients their prescribed medication is inappropriate and should be seen as sex discriminat ory under section 1557 as well. The finalized rule should amend section 92.206(b) to include the following new language for providers [a] Adopt or apply any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than de minimis harm including by adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity [Bold and Italics: or subjects pregnant people to discriminatory treatment during childbirth including rough handling harsh language or undertreatment of pain [4] Deny or limit health services sought for purpose of gender transition or other gender-affirming care fertility care or any health services that the covered entity would provide to an individual for other purposes if the denial or limitation is based on a patient's sex assigned at birth gender identity or gender otherwise recorded. [5] Deny or limit services or a health care professional's ability to provide services on the basis of pregnancy or related conditions including termination of pregnancy contraception miscarriage management fertility care maternity care or other health services; [6] Deny or limit services based on an individual's reproductive or sexual health care decisions or history including termination of pregnancy miscarriage or adverse pregnancy outcome; and [7] Deny or limit services or a health care professional's ability to provide services

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In 2020 OCR reviewed all available evidence and found no denials of access based on gender ty remotely sufficient to justify regulatory intervention. Let's not be coy about this rule's real goals: to require doctors to perform experimental gender-transition surgeries and treatments on adults and minors and to require everyone's insurance plans to pay for them. Because neither law policy nor science support such an extreme inversion of medicine we request the Agency abandon all efforts at amending the Section 1557 Rule

The Century Foundation

We urge the Department to include broader reproductive and sexual health care in its language around prohibited sex discrimination. Specifically the "equal program access" section of the regulatory text should include clear prohibitions on denying or limiting services or the ability for professionals to provide services for pregnancy or related conditions including contraception or termination of pregnancy miscarriage management fertility care maternity care and other health services [Footnote 31 Id at 47858 47916 (Proposed § 92 206)] This is especially important as people of color immigrants LGBTQIA+ people low-income people and people from rural areas face insurmountable barriers and stigma to reproductive health care in the wake of the Dobbs decision and the ongoing attacks on abortion

Ethics & Public Policy Center

As with section 92 101[a][2] above we suggest that "transgender status" be added to sections 92 206[b][1] [b][2] and [b][4] We also believe that section [b][2] would be clearer if shortened as indicated below In addition we recommend deleting the indicated language in [b][4] as a provider could engage in a discriminatory denial of care even if a claimant cannot show that the care in question was on other occasions provided for other purposes These suggested changes would be reflected in 92 206 as follows "In providing access to health programs and activities a covered entity must not:(1) Deny or limit health services including those that are offered exclusively to individuals of one sex to an individual based upon the individual's sex assigned at birth gender identity [bold underline transgender status] or gender otherwise recorded,[?] Deny or limit a health care professional's ability to provide health services on the basis of an individual's sex assigned at birth gender identity [bold underline transgender status] or gender otherwise recorded [4] Deny or limit health services sought for purpose of gender transition or other gender-affirming care if the denial or limitation is based on a patient's sex assigned at birth gender identity [bold underline transgender status] or gender otherwise recorded "This section would also be strengthened by including specific examples of what constitutes discrimination based on pregnancy or related conditions such as discriminating against someone because they had previously had an abortion or denying medically necessary care because it could prevent complications or end a patient's fertility or pregnancy

Senate Democrats

Program Access of the Basis of Sex [§ 92.206)] We strongly support the inclusion of this section which will help to address the myriad forms of harmful discrimination described above It is important to clarify that while providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient they may not refuse gender-affirming care based on a personal belief that such care is never clinically appropriate We suggest strengthening the language pertaining to providers complying with a state or local law as a justification for denying gender-affirming care to state unequivocally that section 1557 as federal law preempts any such state or local law restricting access to this care As with section 92 101[a][2] above we suggest that "transgender status" be added to sections 92.206[b][1] [b][2] and [b][4]. We also believe that section (b)[2] would be clearer if shortened as indicated below In addition we recommend deleting the [illegible] language in [b][4] as a provider could engage in a discriminatory denial of care even if a claimant cannot show that the care in question was on other occasions provided for other purposes. These suggested changes would be reflected in 92 206 as follows "In providing access to health programs and activities a covered entity must not: [1] Deny or limit health services including those that are offered exclusively to individuals of one sex to an individual based upon the individual's sex assigned at birth gender identity [Bold transgender status] or gender otherwise recorded;[2] Deny or limit a health care professional's ability to provide health services on the basis of an individual's sex assigned at birth gender identity [Bold transgender status] or gender otherwise recorded; [strikethrough: if such denial or limitation has the effect of excluding individuals from participation in denying them the benefits of or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity.;[4] Deny or limit health services sought for purpose of gender transition or other gender-affirming care [strikethrough: that the covered entity would provide to an individual for other purposes] if the denial or limitation is based on a patient's sex assigned at birth gender identity [underlined/Bold: transgender status] or gender otherwise recorded."

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SIECUS: Sex Ed for Social Change

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Eating Disorders Coalition for Research, Policy & Action

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Center for Reproductive Rights

Tennessee Primary Care Association

Minnesota Association of Community Health Centers

Endocrine Society

Health Care For All

Concerned Women for America

Ethics & Public Policy Center

|Bo d. A. The final rule should enumerate these specific forms of discrimination in sections §92 206 and §92 207 |Clear nondiscrimination protections related to pregnancy ur related conditions including termination of pregnancy fert ty care contraception and prenatal b thing and postpartum care are critica y necessary in this moment of crisis for reproduct ve health care access. We support the Department's enumeration of specific forms of sex discrimination prohibited in § 92 206(b)(1) and § 92 207(b)(1). We encourage the Department to strengthen these provisions by including examples related to pregnancy and pregnancy-related conditions in these sections. Accordingly we propose the following additions to § 92 206(b) '[Under the (b) Adopt or apply any policy or practice that subjects people to discriminatory treatment during pregnancy childb rth or postpartum care including coerced or unconsented treatment verbal or physical abuse denied or delayed care and violations of privacy;(6) Deny delay or limit services or a health care professional's ability to provide services on the basis of pregnancy or related conditions including termination of pregnancy contraception miscarriage management fertility care maternity care or any health services.;7) Deny delay or limit services based on an individual's reproductive or sexual health care decisions or history including termination of pregnancy miscarriage or adverse pregnancy outcome; or(8) Deny delay or limit services or a health care professional's ability to provide services that may prevent cause complications to or end fertility or pregnancies including medications or treatments for disabilities or emergency medical conditions under 42 U S C § 1395dd

discrimination on the basis of gender identity by |A Adding "transgender status" in sections 92 206(b)(1) (b)(2) and (b)(4) "Transgender status" and "gender identity" are often used interchangeably, however there have been cases where people seeking to discriminate have sought to distinguish between these two terms. |Footnote 1: See e.g. "Making Admission or Placement Determinations Based on Sex in Facilities Under Community Planning and Development Housing Programs" Proposed Rule 85 Fed Reg 41811 (July 24 23201) We recommend that "transgender status" be included alongside other mentions of gender identity in the proposed rule.B. Omitting the indicated language below in section 92.206(b)(4) as a provider could partake in a discriminatory denial of care even if a claimant can not prove that the care was provided in other cases for other purposes C. Omitting the indicated language below in section 92 206(b) in order to provide a clearer explanation of gender identity discrimination.The suggested changes are reflected as follows "In providing access to health programs and activities a covered entity must not ;1) Deny or limit health services including those that are offered exclusively to individuals of one sex to an individual based upon the individual's sex assigned at birth gender identity |Build transgender status| or gender otherwise recorded;(2) Deny or limit a health care professional's ability to provide health services on the basis of an individual's sex assigned at birth gender identity transgender status or gender otherwise recorded If such denial or limitation has the effect of excluding individuals from participation in denying them the benefits of or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity;(4) Deny or limit health services sought for purpose of gender transition or other gender affirming care that the covered entity would provide to an individual for other purposes if the denial or limitation is based on a patient's sex assigned at birth gender identity transgender status or gender otherwise recorded."

deny or limit services based on "gender identity." Is there any claim for service that could be denied? At any age? The Department must answer whether "gender affirming care" is for any claim related to one's identity and if not provide the specific objective criteria that defines the limits of such treatments. If the Department is unable to clearly delineate the provision of services required by this further proof that this Rule is arbitrary and capricious.The Department must answer these questions: What specific exhaustive list of treatments and procedures constitute "gender affirming care?" Does it cover any cosmetic plastic surgery for any individual to change body appearance or alter body parts and alter sexual function? Does it include coverage for breast binders for youth mastectomies and hysterectomies for teenage girls cosmetic surgeries for feminizing or masculinizing characteristics prosthetic penises or breast augmentation for male bodies and female bodies? Without an exhaustive list of procedures and the objective enforceable criteria for when these procedures are mandated under the Rule's "gender affirming care" mandate this Rule is arbitrary and capricious Because the Rule is entirely vague it is necessary for the Department to establish clearly whether "gender affirming care" includes all manner of health care treatments behavioral mental and physical that might affirm an individual's actual sex including realigning with that sex in addition to any desired features functions thoughts and appearance of sex. To deny coverage services and procedures designed to assist an individual to align with his or her bodily sex and function would be sex discrimination The requirement for nondiscriminatory care cannot go one way This Rule must obligate covered entities for any health service or procedure that he os an individual conform to his or her natural sex and sexual function. To be nondiscriminatory it must also include any desired appearance that is consistent with a person's sex Nothing can be denied including all cosmetic surgeries and elective procedures

Program Access of the Basis of Sex |§ 92.206)We strongly support the inclusion of this section which will help to address the myriad forms of harmful discrimination described above. It importantly clarifies that providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient but may |talic: not| refuse gender affirming care based on a personal belief that such care is never clinically appropriate.While we are in favor of the inclusion of this section we also suggest strengthening the language pertaining to providers complying with a state or local law as a justification for refusing to provide gender affirming care. More specifically we would recommend that HHS states clearly and unequivocally that Section 1557 of the ACA which is federal law preempts |talic: any| such state or local law that seeks to restrict access to gender affirming care As an agency we are strongly in favor of this addition as it will increase protections for transgender non-binary and gender expansive people who may otherwise encounter additional and unnecessary barriers to culturally humble healthcare.As with section 92.101(a)(4) above we suggest that "transgender status" be added to sections 92 206(b)(1) (b)(2) and (b)(4). We also believe that the policy language of section (b)(2) would be clearer if it was shortened as indicated below. In addition we recommend deleting the indicated language in (b)(4) as it could enable a provider to engage in a discriminatory denial of care even if a claimant can not show that the care in question was on other occasions provided for other purposes In short these suggested changes would be reflected in 92 206 as follows "In providing access to health programs and activities a covered entity must not ;1) Deny or limit health services including those that are offered exclusively to individuals of one sex to an individual based upon the individual's sex assigned at birth gender identity |Include transgender status| or gender otherwise recorded;(2) Deny or limit a health care professional's ability to provide health services on the basis of an

We also appreciate the Department's inclusion of equal program access which explicitly includes services or that programs may not deny or limit services based on sex assigned at birth gender identity or gender . Fed Reg at 47918 |Proposed § 92.206|. This provision includes protections for gender transition or gender affirming care which clarifies that a provider's beliefs are not a sufficient basis for judgement that health services are not clinically appropriate. LGBTQIA+ people experience barriers to accessing health care from providers refusing care based on the actual or perceived gender identity to discriminatory attacks on gender affirming care as well as illegal or regarding employer coverage of care These changes will better ensure that health providers insurers and other programs and activities cannot refuse care or provide discriminatory care or treatment

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Center for Reproductive Rights

38 Members of Congress

Concerned Women for America

(b)(5)

Equitas Health

Senate Democrats

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SIECUS: Sex Ed for Social Change

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Eating Disorders Coalition for Research, Policy & Action

Center for Reproductive Rights

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[Bold: HRSA recommends also including "transgender status" in § 92.206(b)(1) (b)(2) and (b)(4) and in § 92.207(b)(4).]
[Bold: MNACHC recommends also including "Transgender status" in § 92.206(b)(1) (b)(2) and (b)(4) and in §92.207(b)(4)

Impact on Access to Care] Finalizing the proposed rule will codify protections against discrimination on the basis of sex to include discrimination on the basis of sexual orientation and gender identity. The rule specifies that covered entities could not: • Deny or limit health services based on individual's sex assigned at birth, gender identity or gender otherwise recorded; • Deny or limit a health care professional's ability to provide health services on the basis of a patient's sex assigned at birth, gender identity or gender otherwise recorded;• Apply a policy or practice that treats individuals differently or separates them on the basis of sex in a manner that subjects them to more than de minimis harm, and• Deny or limit access to gender transition or gender affirming care that it would otherwise provide to someone else based on the sex assigned at birth, gender identity or gender otherwise recorded. The Endocrine Society supports this expansion of Section 1557 nondiscrimination protections which restores the protections based on sexual orientation and gender identity and specifically protects gender transition and gender affirming care.

Protections against Discrimination on Basis of Sex]Sex discrimination disproportionately impacts women of color, LGBTQ+ people, and individuals living at the intersections of multiple identities. This frequently results in access to less affordable health coverage and lower quality healthcare, including more frequently receiving inaccurate diagnoses, being provided less effective treatment, and sometimes being denied care altogether. As the first broad prohibition against sex discrimination in health care, § 1557 is crucial to ending gender-based discrimination by health care providers and health insurers. Gender Identity and Sexual Orientation]We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law, including Price Waterhouse v. Hopkins and Bostock v. Clayton County, makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity, including transgender status. It is essential that this rule track those decisions to provide assurance to participants, beneficiaries and enrollees, and notice to covered entities that these bases are unequivocally included. We also support the explicit inclusion of discrimination based on sex characteristics, including intersex traits, as such discriminatory or inherently sex-based. While the terms "gender identity" and "transgender status" are often used interchangeably, there have been instances in which those seeking to permit discrimination against transgender people have attempted to by drawing distinctions between the two concepts. Therefore, explicit language is needed to prevent this discriminatory and consistently throughout. The final rule is important. We therefore recommend also including "transgender status" in § 92.206(b)(1) (b)(2) and (b)(4) and in §92.207(b)(4)

[illegible] discrimination on the basis of gender identity by:[A] Adding "transgender status" in sections 92.206(b)(1) (b)(2) and (b)(4). "Transgender status" and "gender identity" are often used interchangeably; however, there have been cases where people seeking to discriminate have sought to distinguish between these two terms. [Footnote 1] See e.g. "Making Admission or Placement Determinations Based on Sex in Facilities Under Community Planning and Development Housing Programs," Proposed Rule, 85 Fed Reg 44811 (July 24, 2020).] We recommend that "transgender status" be included alongside all other mentions of gender identity in the proposed rule.B. Drafting the "indicated" language below in section 92.206(b)(4) as a prohibition could partake in a discriminatory denial of care even if a claimant can not prove that the care was provided in other cases for other purposes.C. Offering the indicated language below in section 92.206(b) in order to provide a clearer explanation of gender identity discrimination. The suggested changes are reflected as follows: "In providing access to health programs and activities a covered entity must not: [1] Deny or limit health services including those that are offered exclusively to individuals of one sex to an individual based upon the individual's sex assigned at birth, gender identity [Bold: transgender status] or gender otherwise recorded; [2] Deny or limit a health care professional's ability to provide health services on the basis of an individual's sex assigned at birth, gender identity, transgender status or gender otherwise recorded if such denial or limitation has the effect of excluding individuals from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity; [4] Deny or limit health services sought for purpose of gender transition or other gender-affirming care that the covered entity would provide to an individual for other purposes if the denial or limitation is based on a patient's sex assigned at birth, gender identity, transgender status or gender otherwise recorded."

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The Proposed Rule's claim that it would still allow "the practice of assigning patients to dual-occupancy rooms in hospitals and in-patient treatment facilities on the basis of sex" [Footnote 23: to [] is grossly misleading if not outright subterfuge. While under the Proposed Rule a hospital may perhaps continue to nominally assign "women" to shared rooms they cannot exclude biological males who merely identify as women or asexual or non-binary or two-spirit [italics, etc.] While doctors, nurses and ordinary people will keep using the word women to mean biological women, HHS would respond as Inigo Montoya by saying "I do not think it means what you think it means." [Footnote 22: The Princess Bride, 20th Century Fox (1987).] In fact, the point of these provisions is not to address real social, cultural, biological or psychological differences between men and women that are relevant to healthcare and merit special treatment, but to allow people who identify as transgender or non-binary or asexual or two-spirit [italics, etc.] to force the families of [italics, their] choices regardless of how people around them feel about it.

Functionally, a provider must treat a patient or a customer according to their self-identified sex in all respects and at all times [which includes the counter-scientific "recognition" and "affirmance" that men can get pregnant] without any requirement that a person so identifying has undergone any "transition" treatments or surgeries, dresses or acts in any particular manner, has any diagnosis of gender dysphoria, or has procured a legal name or birth certificate change. The expected changes in the Proposed Rule are not about addressing people being barred from receiving healthcare due to irrelevant immutable characteristics such as race. Those issues were properly addressed by the 2020 Rule. Rather, if the Proposed Rule as expected redefines sex discrimination to include discrimination on the basis of sexual orientation and gender identity then the Proposed Rule would not be about discrimination in any traditional sense because LGBT persons are not being denied healthcare based solely on their self ascribable identity or self-declared status as "transgender." Statements and actions from HHS confirm that this Proposed Rule is intended to smuggle in a new purported standard of care based on subjective self-identification into medicine and to impose a requirement for coverage of and participation in gender transition procedures under cover of nondiscrimination.

The Rule would require pregnant women who identify as men to be treated "consistent with the individual's gender identity" [Footnote 4: Proposed § 92.206(b)(5).] which can and has led to disaster. As documented in the preamble to the 2020 Rule, a biological female with abdominal pain had her pregnancy complication misdiagnosed because the hospital treated her consistent with her preferred gender identity of "male-assisting" and stillbirth of the child. [Footnote 6: 85 FR 37188, 37190.]

Impact on Access to Care] Finalizing the proposed rule will codify protections against discrimination on the basis of sex to include discrimination on the basis of sexual orientation and gender identity. The rule specifies that covered entities could not: • Deny or limit health services based on individual's sex assigned at birth, gender identity or gender otherwise recorded; • Deny or limit a health care professional's ability to provide health services on the basis of a patient's sex assigned at birth, gender identity or gender otherwise recorded;• Apply a policy or practice that treats individuals differently or separates them on the basis of sex in a manner that subjects them to more than de minimis harm, and• Deny or limit access to gender transition or gender affirming care that it would otherwise provide to someone else based on the sex assigned at birth, gender identity or gender otherwise recorded. The Endocrine Society supports this expansion of Section 1557 nondiscrimination protections which restores the protections based on sexual orientation and gender identity and specifically protects gender transition and gender affirming care.

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Tennessee Primary Care Association

Minnesota Association of Community Health Centers

Endocrine Society

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As cited in HHS's 2020 Rule on Section 1557 and referenced above in an actual case from 2019 a person who was admitted to an emergency room with severe abdominal pain was tracked according to a preferred male gender identity. Unbeknownst to the triage staff the patient was actually a woman in late-stage labor. The result was the stillbirth of a very real human child who possibly could have been saved but for gender-identity policies distorting the truth of the situation. According to HHS "this case is not based on speculation. Rather it involved the actual death of an unborn child and attendant trauma and anguish for those involved all potentially because of a misdiagnosis resulting from a reliance on stated gender identity as opposed to sex." Given that life-and-death decisions are frequently made in healthcare settings and often in urgent circumstances this story serves as an example of the consequences that could result from the confusion caused by the ... mandate to treat individuals 'consistent with' stated gender identity." [Footnote 87: 85 FR 37178] HHS also found that using non-discrimination mandates to impose a gender identity ideology risked masking clinically relevant and sometimes vitally important information by requiring providers and insurers to switch from a scientifically valid and biologically based system of tracking sex to one based on subjective self-identification according to gender identity." [Footnote 88: Id.]

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The arbitrary decision by HHS to reframe "discrimination" through the prism of "gender identity" jeopardizes essential aspects of care that depends on recognizing the reality of biological sex. Instead under the Proposed Rule each of these elements is suddenly a vulnerability a potential fact pattern for a claim of discrimination on the basis of gender identity. The Rule is an astonishing display of bureaucratic arrogance in furtherance of an ideological goal which attempts to supplant and dictate medical judgments of skilled healthcare providers and institutions. [Italic: Scientific assumptions (facts of nature)," HHS has arbitrarily decided that a medical provider who acknowledges undeniable facts of nature—e.g. only females get pregnant and give birth— is making discriminatory assumptions. For example it states that "transgender men who are pregnant experience significant forms of discrimination stigma and erasure' when navigating pregnancy and prenatal care particularly because pregnancy and childbirth are often treated as something exclusively experienced by cisgender women." [Footnote 100: 87 Fed. Reg. 47867.] Further unpacking spells out the discriminatory nature of "incorrect [factual] assumptions" noting that "[p]roviders and insurers frequently formulate [has a] 'incorrect assumptions' about transgender and gender non-conforming individuals' bodies when assessing medical necessity for sex-specific preventive care." [Footnote 101: 87 Fed. Reg. 47871 n.451 (emphasis added).]

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[Bold: Sex based clinical trials.] Even though the NIH mandates all clinical trials to specify the biological sex of clinical subjects in every clinical trial HHS indicates that it is willing for ideological purposes [producing no evidence that sex-based distinctions in clinical trials cause discriminatory harm] to pressure clinical researchers and organizations to disregard sex based distinctions for fear of inviting a gender-identity discrimination claim. The rule states: "Similarly sex-specific clinical trials may be permissible based upon the scientific purposes of the study (i.e. trials based on a particular sex-characteristic(s) such as those that test treatments for specific conditions or that evaluate differences in responses to treatment regimens among individuals with different sex characteristics). In evaluating a complaint of discrimination challenging a covered entity's sex-specific health program or activity OCR may consider a variety of factors relevant to the particular health program or activity. In particular this provision would prohibit the adoption of a policy or engaging in a practice that prevents any individual from participating in a covered entity's health program or activity consistent with their gender identity." In other words even though the NIH says that every clinical trial must include sex-specific recruitment and labeling of subjects because sex is a biological variable HHS is laying down an insidious marker that sex specific clinical trials can only be justified in limited circumstances (e.g. trial of a prostate cancer drug is limited to males who have prostates) but not generally. Instead a person must be granted access to clinical trials on the basis of gender identity absent a showing of particular relevance. [Footnote 115: 87 Fed. Reg. 47866.] This is a step backwards and of particular harm to females who were long excluded from clinical trials on the presumption that sex based differences did not matter in the evaluation of diseases and treatments. Until some recognized the impact of "sex as a biological variable" that must be taken into account if medicine is to benefit females in particular.

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Specific Applications to Health Programs and Activities - Equal Program Access on the Basis of Sex [§92.206(WPHCA supports the proposed rule's §92.206 that ensures patients have equal program opportunity on the basis of sex. We also strongly agree with its extension to nondiscrimination in the coverage of gender affirming and transition-related care. For years studies have shown disparities in accessing care for transgender individuals. Transgender and gender-diverse individuals commonly face insurance-related obstacles to obtain clinically appropriate care. These disparities only multiply for Black Indigenous and other transgender people of color as well as transgender people with disabilities. By finalizing this provision this will help address health disparities among the LGBTQ community by prohibiting denials to programs based on their gender.

Wisconsin Primary Health Care Association

The Proposed Rule explicitly rejects the U.S. Constitution's Equal Protection Clause standard for sex discrimination claims which allows [and sometimes requires] men and women to be treated differently based on inherent differences in biology when such differences are real relevant and not based on stereotypes [Footnote 16: United States v. Virginia 518 U.S. 515 (1996).] By contrast under the Proposed Rule discrimination "on the basis of sex" includes "deriving] or limiting] health services including those that are offered exclusively to individuals of one sex to an individual based upon the individual's ... gender identity or gender otherwise recorded" [Footnote 17: Proposed § 92.206. See also proposed § 92.101(a)(2).] without any room for deviation—no constitutional intermediate scrutiny as under the 2020 Rule nor even allowance for an "exceedingly persuasive justification" as under the 2016 version of the Rule. [Footnote 18: See former § 92.101(b)(3)(iv) (2016) (repealed and replaced by 2020 Rule).] Indeed the Proposed Rule goes beyond denial or limitations on health services and outlaws "[italics: any] policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than [the] de minimis] harm." [Footnote 19: Proposed § 92.206(b)(3) (emphasis added). See also 87 Fed. Reg. 47866.] The Proposed Rule clarifies that this includes "adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity." [Footnote 20: Id.] Thus the Proposed Rule would prohibit health care professionals medical facilities and insurance companies from using any sex-based distinction or biological fact unless they can prove it "does not cause more than [the] de minimis harm." And even that narrow practically nonexistent exception does not apply if the sex based distinction results in a denial or limitation of services.

(b)(5)

Ethics & Public Policy Center

We strongly support the additional guidance provided by proposed sections 92.206 and 92.207 regarding equal program access and equal insurance coverage. The terms of discrimination highlighted in proposed sections 92.206(b)(3) and (b)(4) and 92.207(b)(3)-(5) in particular affect many intersex people some of whom are also transgender and some of whom are not. For example intersex people who are cisgender or transgender sometimes are arbitrarily denied clinically appropriate preventive screenings or support services typically associated with one sex because of their perceived or assigned or recorded gender.

InterACT: Advocates for Intersex Youth

Lying the hands of America's health care system and any of many flawed health providers with a sweeping mandate that anything less than accommodating self-defined gender identity could violate "more than [italics: de minimis] harm" proves this Rule is the work of bureaucratic activists not an objective accountable agency that has an obligation to protect public health and the public trust. This Rule is nothing short of weaponizing ideology for the purposes of promoting a gender orthodoxy that is confusing the minds and destroying the bodies of our children.

Concerned Women for America

(b)(5)

|Bold. Medical Inquiries | HHS states that while it recognizes that medical providers "need to make inquiries about a patient's sex-related medical history, health status or physical traits related to sex in the course of providing care" it considers "a sex-stereotypical when such inquiries result in more than 'de minimis harm.'" |Footnote 105. 87 Fed. Reg 47887 | In response to an allegation of discrimination HHS (OCR) "may consider whether a provider's inquiries may be evidence of discrimination" by assessing whether the inquiries "have a relationship to the care provided or [whether] they are made in a manner that is harassing, hostile or evinces disregard for a patient's privacy." |Footnote 106: 87 Fed. Reg 47888 | Put differently if a healthcare provider asks the wrong question or uses an inappropriate question in the wrong "manner" then the provider is likely to face a claim of discrimination on the basis of "gender identity." The Proposed Rule states that "[w]here relevant, OCR will consider the totality of the circumstances in determining whether overbroad, irrelevant or hostile inquiries may constitute evidence of discrimination." |Footnote 107: 87 Fed. Reg 47888.| This amounts to an arbitrary and capricious extension of the grounds for sex discrimination claims.

|Underline. Mandating "gender identity" to redefine "sex" imposes a new form of discrimination on the basis of sex|Sections 92.10 92.101 92.206 147 154 155 120 and 156.200 of this Rule establish a new category of sex as "gender identity" that is entirely subjective personally determined and evolving. By overriding the meaning of sex as the scientific and undeniable presence of XX or XY chromosomes in every cell of the human body this Rule imposes a new form of discrimination against individuals based on their actual sex. The Rule cherry picks a Title IX court decision to justify a fabricated standard of "more than |Italics: de minimis| harm" as the basis for adjudicating "gender identity" claims."However the Department may still find that a covered entity violates Section 1557 if it implements the sex-based distinction in a way that constitutes discrimination by imposing more than |Italics: de minimis| harm upon a particular individual. This is what Title IX requires." This is false. By statute or regulation Title IX has never required sex to be recognized as anything but objectively biologically based. Covered entities should never be in violation of Section 1557 for recognizing or providing care to men and women on the basis of their sex as male and female. In fact effective healthcare demands treatment according to sex.

Enumeration in the Proposed Rules| We appreciate HHS' enumeration of specific forms of sex discrimination that are prohibited in the Proposed Rule. Section 92.206 importantly clarifies that while providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient they may |bold: not| refuse gender affirming care to a patient based on a personal or religious belief that such care is never clinically appropriate. The restoration of protections for gender-affirming care is an essential component of the proposed rule as denials of access to and insurance coverage for such care are among the most common manifestations of discrimination against the LGBTQI+ community. Below we suggest strengthening the language of § 92.206(a)(2) and 92.207(b)(4) to prevent covered entities from using state or local laws that bar or restrict access to gender-affirming care as well as broader reproductive and sexual health care as a justification to deny such care. In light of |Italics: Dobbs| we also urge you to add specific examples of discrimination related to pregnancy and related conditions. Sex discrimination related to pregnancy and related conditions is pervasive in our health care system. Access to sexual and reproductive health care such as contraception or fertility care abortion gender-affirming care and maternity care is often barred by discriminatory policies or practices. For example pregnant Black Indigenous Latina/x Asian American and Pacific Islander and all people of color who live at the intersections of Section 1557's protected identities are often subjected to discrimination throughout pregnancy and the postpartum period including mistreatment (embedded hyperlink text (https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-019-0729-2)) during labor and delivery. People with disabilities often experience multiple barriers (embedded hyperlink text (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8765596/)) to sexual and

The Prupused Rule explicitly rejects the U.S. Constitution's Equal Protection Clause standard for sex discrimination claims which allows (and sometimes requires) men and women to be treated differently based on inherent differences in biology when such differences are real relevant and not based on stereotypes |Footnote 16: United States v. Virginia 518 U.S. 515 (1996).| By contrast under the Proposed Rule discrimination "on the basis of sex" includes "deriving or limiting] health services including those that are offered exclusively to individuals of one sex to an individual based upon the individual's . . . gender identity or gender otherwise recorded" |Footnote 17: Proposed § 92.206. See also proposed § 92.101(a)(2)[.]] without any room for deviation—no constitutional intermediate scrutiny as under the 2020 Rule nor even allowance for an "exceedingly persuasive justification" as under the 2016 version of the Rule. |Footnote 18. See former § 92.101(b)(3)(v) (2016) (revoked and replaced by 2020 Rule).| Indeed the Proposed Rule goes beyond denial or limitations on health services and outlaws "|Italics: any| policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than |harm de minimis| harm." |Footnote 19. Proposed § 92.206(b)(3) (emphasis added). See also 87 Fed. Reg. 47886 | The Proposed Rule clarifies that this includes "adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity." |Footnote 20: Id.| Thus the Proposed Rule would prohibit health care professionals medical facilities and insurance companies from using any sex-based distinction biological or otherwise unless they can prove it "does not cause more than |harm de minimis harm.| And even that narrow practically nonexistent exception does not apply if the sex-based distinction results in a denial or limitation of services

Pregnancy Access on the Basis of Sex|§ 92.206|We strongly support the inclusion of this section which will help to address the myriad forms of harmful discrimination described above. It importantly clarifies that providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient but may |italic: not| refuse gender affirming care based on a personal belief that such care is never clinically appropriate.While we are in favor of the inclusion of this section we also suggest strengthening the language pertaining to providers complying with a state or local law as a justification related to denying gender affirming care. More specifically we would recommend that HHS states clearly and unequivocally that Section 1557 of the ACA which is federal law preempts |italics: any| such state or local law that seeks to restrict access to gender affirming care. As an agency we are strongly in favor of this addition as it will increase protections for transgender non-binary and gender expansive people who may otherwise encounter additional and unnecessary barriers to culturally humble healthcare. As with section 92.101(a)(2) above we suggest that "transgender status" be added to sections 92.206(a)(1) (a)(2) and (b)(4). We also believe that the policy language of section (b)(2) would be clearer if it was shortened as indicated below. In addition we recommend deleting the indicated language in (b)(4) as it could enable a provider to engage in a discriminatory denial of care "even if a claimant cannot show that the care in question was on other occasions provided for other purposes).In short these suggested changes would be reflected in 92.206 as follows:" In providing access to health programs and activities a covered entity must not:¦(1) Deny or limit health services including those that are offered exclusively to individuals of one sex to an individual based upon the individual's sex assigned at birth gender identity |and body| transgender status| or gender otherwise recorded.;(2) Deny or limit a health care professional's ability to provide health services on the basis of an

We strongly support the additional guidance provided by proposed sections 92.206 and 92.207 regarding equal program access and equal insurance coverage. The forms of discrimination highlighted in proposed sections 92.206(b)(5) and (b)(4) and 92.207(b)(3)-(5) in particular affect many intersex people some of whom are also transgender and some of whom are not. For example intersex people who are cisgender or transgender sometimes are arbitrarily denied clinically appropriate preventive screenings or support services typically associated with one sex because of their perceived birth assigned or recorded gender

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Ethics & Public Policy Center

Concerned Women for America

Physicians for Reproductive Health

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InterACT: Advocates for Intersex Youth

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InterACT: Advocates for Intersex Youth

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The Leadership Conference on Civ and Human Rights

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Concerned Women for America

SIECUS: Sex Ed for Social Change

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Center for Reproductive Rights

The Heritage Foundation

Eating Disorders Coalition for Research, Policy & Action

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Center for Reproductive Rights

Tennessee Primary Care Association

Minnesota Association of Community Health Centers

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[Bold: Defining Gender-Affirming Care] Pennie generally supports the proposed rule's prohibition of categorical coverage exclusions or limitations for all health services related to gender transition or other gender-affirming care. Notwithstanding Pennie's general agreement with the proposed rule Pennie urges HHS to provide a comprehensive definition of "gender-affirming care" within the regulations itself as opposed to only in the preamble. This regulatory definition is necessary for Pennie to properly assess whether the benefit offered within an insurance plan meet the baseline standard. This definition will allow Pennie and the issuers operating on the Pennsylvania exchange to appropriately display the new "gender-affirming care" benefit category. Without this definition insurers will be left to define this category individually making this a new benefit category inconsistent across plans and potentially misleading for consumers shopping for coverage on the exchange. Pennie does not wish to limit the definition of gender affirming care within the final rule, however a federal definition is necessary for Pennie to include this as a benefit category in a way that supports clear consumer access to these services. Ideally this definition would include the array of services that support an individual throughout their transition including services such as hormone therapy gender reassignment surgeries and behavioral health care

Pennsylvania Health Insurance Exchange Authority d/b/a Pennie

Impact on Access to Care[1] Finalized the proposed rule will codify protections against discrimination on the basis of sex to include discrimination on the basis of sexual orientation and gender identity. The rule specifies that covered entities could not:• Deny or limit health services based on an individual's sex assigned at birth gender identity or gender otherwise recorded.• Deny or limit a health care professional's ability to provide health services on the basis of a patient's sex assigned at birth gender identity or gender otherwise recorded,• Apply a policy or practice that treats individuals differently or separates them on the basis of sex in a manner that subjects them to more than de minimis harm; and• Deny or limit access to gender transition or gender affirming care that it would otherwise provide to someone else based on the sex assigned at birth gender identity or gender otherwise recorded. The Endocrine Society supports this expansion of Section 1557 nondiscrimination protections which restores the protections based on sexual orientation and gender identity and specifically protects gender transition and gender affirming care

Endocrine Society

Protections against Discrimination on Basis of Sex[2] Sex discrimination disproportionately impacts women of color LGBTQ+ people and individuals living at the intersections of multiple identities. This frequently results in access to less affordable health coverage and lower quality health care, including more frequently receiving inferior care, services being provided less effective treatment and sometimes being denied care altogether. As the first broad prohibition against sex discrimination in health care § 1557 is crucial to ending gender-based discrimination by health care providers and health insurers. Gender identity and sexual orientation We ask that HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law including Price Waterhouse v. Hopkins and Bostock v. Clayton County makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity including transgender status. It is essential that this rule track those decisions to provide assurance to participants beneficiaries and enrollees and notice to covered entities that these bases are unequivocally included. We also support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discrimination is inherently sex based. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have just cited to by dressing distinctions between the two concepts. Therefore explicit language is needed to prevent this discrimination and consistency throughout the final rule is important. We therefore recommend also including "transgender status" in §§ 92.206(b)(1), (b)(2), and (b)(4) and in §92.207(b)(3).

Health Care For All

because [1] it claims that "sex" means "gender identity" and [2] people who experience a mismatch of "gender identity" and sexed body often desire medical or surgical interventions to facilitate a change in appearance or to maintain the body's natural function that consequently there is no ethical basis for refusing to accede to the "gender-identity"-based treatment demands of an individual. No covered entity or provider is permitted to refuse on ethical moral or medical judgment grounds to fabricate an individual's gender identity based request for medical or surgical interventions. This amounts to giving the person experiencing "gender dysphoria" by identifying as transgender a "super-right" to a "gender transition" entitling them to insist that any and every physician facility or provider capable of complying with their demands must comply or risk an anti-discrimination complaint. For example HHS states that "the proposed rule [would not] require a pediatrician to prescribe hormone blockers for a prepubescent gender-nonconforming minor if that health care provider concluded pursuant to a non-discriminatory bona fide treatment decision that social transition was the clinically indicated next step for that child." This example communicates HHS's expectation that every provider is expected to endorse "gender affirming care." The only non-discriminatory basis for refusing hormone blockers is the desire or to pursue a different "gender-affirming" pathway (social transition). HHS's explicitly states that a provider's categorical refusal to prescribe or offer "gender affirming care" constitutes discrimination. "[A] provider's view that no gender transition or other gender affirming care can ever be beneficial for such individuals for example in compliance with a state or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not medically appropriate." An ethical judgment that "gender affirming" care for minors including recommending a psychosocial transition is never ethically justifiable is not considered to be "a legitimate nondiscriminatory basis for the [] challenged action [] even if a number of well-respected physicians about the propriety of "gender reassignment" operations should give the Department pause before forcing individuals physicians hospitals and insurers to participate in or cover such procedures. There are a variety of reasonable medical opinions about the best treatment for gender dysphoria a deep-seated desire to appear and be treated as a member of the opposite sex. Permanently altering resecting or amputating well functioning organs of the human body is a controversial form of treatment. Indeed several European countries who adopted such treatments early including the UK Sweden and Finland are now urging caution. This would be an inopportune time for the federal government to take a side in these debates through a sole court able agency action and then coercively impose that judgment on all medical professionals. Paul McHugh MD a University Distinguished Service Professor of Psychiatry at the Johns Hopkins University School of Medicine and former Psychiatrist-in-Chief at Johns Hopkins University Hospital has written extensively about the serious medical and psychological questions surrounding sex-reassignment surgery. When Dr. McHugh arrived at Johns Hopkins in the 1970s the hospital had become one of the leading centers for sex reassignment surgery in the country. Yet few follow-up studies were being conducted with patients receiving sex-reassignment operations as treatment for gender identity disorder [now called gender dysphoria in the [Italics: Diagnostic and Statistical Manual of Mental Disorders]. McHugh encouraged Jon Meyer who was a colleague psychiatrist and psychoanalyst to conduct research on the psychological well being of patients after sex-reassignment surgery to see if the procedure led to any improvements. The results as McHugh describes them left much to be desired. [Meyer] found that most of the patients he tracked down some years after their surgery were contented with what they had done and that only a few regretted it. But in every other respect they were little changed in their

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The Heritage Foundation

This is especially troubling because the HHS analysis ["Equal Program Access on the Basis of Sex[4] 92.206[] appears to anticipate including access to gender-affirming care and other undefined "services" [Footnote 132: 87 Fed. Reg. 47,860.] on the basis of a broad range of undefined identities as well as to require healthcare providers to grant "access" to sex specific medical care regardless of the person's identity.

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medical standard of care when there is not medical consensus. |The Proposed Rule attempts to force medical providers and institutions to accept "gender-affirming care" as the prevailing and authoritative "standard of care" covering treatments for an ever-expanding group of people including those not previously considered appropriate candidates for "gender-affirming care." Although "gender dysphoria" is the DSM-V diagnosis that the American Psychological Association links to "gender-affirming care," the Proposed Rule defines "gender-affirming care" as an appropriate treatment beyond the diagnosis of "gender dysphoria" without citing any evidence to support its arbitrary decision to include persons who are not diagnosed with "gender dysphoria" but merely seek "support" for a "gender transition" as well as individuals with "intersex" conditions seeking "treatment for gender dysphoria." |Footnote 133, 87 Fed. Reg. 47834 n.139.|The Rule states: "For purposes of this preamble the term 'gender-affirming care' refers to care for transgender individuals [including those who identify using other terms for example nonbinary or gender nonconforming] that may include but is not necessarily limited to counseling hormone therapy surgery and other services designed to treat gender dysphoria or to support gender affirmation or transition. Gender-affirming care may also be but is not necessarily referred to as 'gender affirming health services' or 'transition-related care.' The terms 'gender affirming care' or 'transition related care' also include care sought by individuals with intersex conditions who seek treatment for gender dysphoria." Footnote 134, 87 Fed. Reg. 47834 n.130." HHS grounds its claims about "gender-affirming care" in publications by the World Association for Transgender Health [WPATH] and the Endocrine Society in spite of the weak evidentiary basis of those documents (a point addressed in subsequent paragraphs). "Footnote 135, 87 Fed. Reg. 47834 n.139 [citing World Prof. Ass'n for Transgender Health Standards of Care for the Health of Transsexual

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However HHS's arbitrary decision to use the Proposed Rule as a means to establish the "gender affirming" protocol as a medically appropriate treatment or even the only medically appropriate treatment for gender dysphoria exceeds statutory authority and the intent of Section 1557. In addition the Rule's framing of "gender affirming care" as appropriate and "medically necessary" to treat anything other than a diagnosis of "gender dysphoria" has no basis in science and is a patently arbitrary and capricious exercise of regulatory power. In fact there is no consensus within the medical profession regarding an authoritative standard of care for gender dysphoria or transitioning treatments. This lack of medical consensus is reflected historically internationally and in actions by the federal government and various states and the continuing public controversy surrounding the use of transitioning treatments on minors.

We strongly support the proposed rule which will help to address the myriad forms of harmful discrimination described above. It importantly clarifies that while providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient they may not refuse gender-affirming care based on a personal belief that such care is never clinically appropriate. We suggest strengthening the language pertaining to providers complying with a state or local law as a justification for denying gender-affirming care to state unequivocally that section 1557 as federal law preempts any such state or local law restricting access to this care.

Ethics & Public Policy Center

Enumerated in the Proposed Rules| We appreciate HHS' enumeration of specific forms of sex discrimination that are prohibited in the Proposed Rule. Section 92.206 importantly clarifies that while providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient they may [bold: not] refuse gender affirming care to a patient based on a personal or religious belief that such care is never clinically appropriate. The restriction of protections for gender-affirming care is an essential component of the proposed rule as denials of access to and insurance coverage for such care are among the most common manifestations of discrimination against the LGBTQ+ community. Below we suggest strengthening the language of § 92.206(b) and 92.207(b) to prevent covered entities from using state or local laws that bar or restrict access to gender-affirming care as well as broader reproductive and sexual health care as a justification to deny such care. In light of [Italics: Dobbs] we also urge you to add specific examples of discrimination related to pregnancy and related conditions. Several terminated or related to pregnancy and related conditions is pervasive in our health care system. Access to sexual and reproductive health care such as contraception or fertility care abortion gender-affirming care and maternity care is often barred by discriminatory policies or practices. For example pregnant Black Indigenous Latina/x Asian American and Pacific Islander and all people of color who live at the intersections of Section 1557's protected identities are often subjected to discrimination throughout pregnancy and the postpartum period including mistreatment [embedded hyperlink text (https://reproductive health journal.biomedcentral.com/articles/10.1186/s12978-019-0729-2)] during labor and delivery. People with disabilities often experience multiple barriers [embedded hyperlink text (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8765596/)] to sexual and reproductive specific services in healthcare systems and accurate. [Italics: Equal Program Access on the Basis of Sex §92.206][Bold: TPCA supports the proposed rule's §92.206 that ensures patients have equal program opportunity on the basis of sex.' We also strongly agree with its extension to nondiscrimination in the coverage of gender affirming and transition related care. For years studies have shown disparities in accessing care for Transgender individuals. Transgender and Gender Diverse individuals commonly face insurance-related obstacles to obtain clinically appropriate care. These disparities only multiply for Black Indigenous and other Transgender People of Color as well as Transgender People with disabilities. By finalizing this provision this will help address health disparities among the LGBTQ community by prohibiting denials to programs based on their gender.

Physicians for Reproductive Health

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[Italics: "Conversion" or "Reparative" Therapy]42 U.S. Code § 18114 guarantees individuals "access to therapies." It directly addresses the Department of Health and Human Services saying Notwithstanding any other provisions of this Act the Secretary of Health and Human Services shall not promulgate any regulation that: (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs. [Footnote 19: 42 U.S. Code § 18114]As such any ban on talk therapy would violate both the First Amendment and U.S. Code. To require or compel health insurance companies and medical providers to provide medical or hormonal treatments for those struggling with gender dysphoria while forcing to cover talk therapy coverage is an equal rights anti-discriminatory violation. Additionally to the extent coverage of transitioning treatments is required or compelled Section 1557 should provide for certain limits.

Tennessee Primary Care Association

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Specific Applications to Health Programs and Activities - Equal Program Access on the Basis of Sex §92.206|WPHCA supports the proposed rule's §92.206 that ensures patients have equal program opportunity on the basis of sex. We also strongly agree with its extension to nondiscrimination in the coverage of gender affirming and transition related care. For years studies have shown disparities in accessing care for transgender individuals. Transgender and gender-diverse individuals commonly face insurance-related obstacles to obtaining clinically appropriate care. These disparities only multiply for Black Indigenous and other transgender people of color as well as transgender people with disabilities. By finalizing this provision this will help address health disparities among the LGBTQ community by prohibiting denials to programs based on their gender.

The Heritage Foundation

Wisconsin Primary Health Care Association

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Minnesota Association of Community Health Centers

(b)(5)

Concerned Women for America

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NCPA

designed to improve health for specific populations such as Chronic Condition Special Needs Plans (C-SNPs) that restrict enrollment to special needs individuals with specific chronic conditions would not be considered discriminatory for purposes of Section 1557.Rationale:There are several programs designed to improve health for specific populations such as chronic condition C-SNPs that restrict enrollment to special needs individuals with specific chronic conditions Programs such as these do not have a discriminatory intent but rather are designed to provide tailored care more efficiently to particularly vulnerable populations. The rules implementing the PHSA's prohibition on discrimination based on health status (see e.g. PHSA section 2705) similarly explicitly permit treating individuals with adverse health conditions more favorably (see e.g. 45 CFR 146.121(g)). BCBSA applauds HHS' stated goal of advancing health equity and reducing disparities based on race national origin disability gender sexual orientation and other protected classes. BLBSA and its Plans strongly agree with HHS that it is critical to progress beyond consideration of broad demographic categories in all health equity programs and to identify and address disparities within and among subgroups. Through health equity data collection and analysis and evidence-based studies our members are already striving to identify health disparities within specific subgroups and in specific geographic areas; and to develop focused strategies to close care gaps and address unique needs.We are concerned that the new proposed regulations may unintentionally limit our Plans' ability to develop effective programs and initiatives to reduce health disparities. Specifically where our Plans have identified a disparity within a population subgroup and/or in a specific geography they need the flexibility to pursue focused programs to address the need. Such programs may include but are not limited to individual outreach to members of a subgroup through the care management process tailored marketing to a subgroup to address a particular

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Blue Cross Blue Shield Association

none discriminatory decisions regarding individual care or coverage. HHS rightly draws this distinction which courts have recognized and which protects patients from discriminatory harm without interfering with professional medical judgment and individualized care. We also share HHS's concern that covered entities not be permitted to mask discrimination behind clinical policies criteria or categories that simply repackage unlawful sex based distinctions. We therefore recommend the following clarifications to the regulatory text in § 92.206: [c] Nothing in this section requires the provision of any health service where the covered entity has a legitimate nondiscriminatory reason for denying or limiting that service to an individual including where the covered entity typically declines to provide the any comparable health care services to any individual [Strikethrough: or where the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual.] However a provider's belief that gender transition [Strikethrough: or] other gender-affirming care [Underline: or reproductive health care] including but not limited to termination of pregnancy] can never be beneficial for such individuals for its compliance with a state or local law that reflects a similar judgment] is not a [Strikethrough: sufficient basis for a judgment that a health service is not clinically appropriate] [Underline: legitimate nondiscriminatory reason for denying or limiting the health service.]In § 92.207 [c] Nothing in this section requires coverage of any health service where the covered entity has a legitimate nondiscriminatory reason for determining that such health service fails to meet applicable coverage requirements [Strikethrough: such as medical necessity requirements] in an individual case [Underline: provided that the coverage requirements or medical necessity standards are not discriminatory themselves or applied in a discriminatory manner.] We further encourage HHS state clearly in the final rule that the familiar but-for causation test applies to establishing a violation of Section 1557;

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InterACT Advocates for Intersex Youth

[illegible] coverage to gender affirming care and ending other common forms of discrimination against the LGBTQI+ community. Therefore the NPRM's purpose to restore protections for gender-affirming care are essential. We support the explicit inclusion of examples in §92.206 and §92.207 of the types of discrimination that are prohibited to ensure covered entities have clear guidance about their obligations to provide and cover this essential care. Importantly §92.206(c) clarifies that while providers may exercise clinical judgment in determinations regarding the appropriate services for an individual patient they may not refuse gender affirming care to a patient based on a personal belief that such care is never clinically appropriate. We also support the clarification in §92.206(c) that a provider's compliance with a state or local law that reflects a judgment that such care is never appropriate is "not sufficient basis for a judgment that a health service is not clinically appropriate." [Footnote 69: 87 Fed. Reg. 47918 (Aug. 4 2022).] We recommend that the Department further strengthen this language by stating unequivocally that Section 1557 as federal law preempts any such state or local law restricting access to gender-affirming care.

Center for Reproductive Rights

Regulation in Section 1557 will interact with state laws that is how Section 1557 (a federal agency ruling) may or will preempt conflicting state laws. Courts could include state laws protecting minors from sterilizing and irreversible gender transition interventions or state conscience and religious freedom protection laws. It is unclear how strings attached to federal financial assistance could unilaterally preempt incompatible state laws in place of the standard dispensation of federal funds from entities that are unable to comply either by overarching choice or due to a state law. [Footnote 48: Morrison "HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate on Health Care" https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-on-health-care-3]Again judging from the 2016 Rule the proposed regulation would apply to any "health programs or activities any part of which receives federal financial assistance administered by HHS" as well as any health programs or activities administered by HHS or those established under Title of the ACA including federally facilitated and state based insurance exchanges. [Footnote 49: 80 Federal Register 54718 (proposed September 8 2015) "This includes any "hospital health clinic group health plan health insurance issuer physician's practice community health center nursing facility residential or community based treatment facility or other similar entity" that receives HHS funds. [Footnote 50: Ibid. 54716.] The proposed regulation would therefore apply to Approximately 153000 health care facilities, "Almost all practicing physicians in the United States because they accept some form of Federal remuneration or reimbursement." - All state Medicaid programs; and All the businesses and activities of a private insurer if any of its businesses receive any federal financial assistance either directly (such as through a Medicaid managed care contract) or indirectly (through subsidies provided to its customers as is the case with Medicare Advantage and exchange

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The Heritage Foundation

Additionally we support the changes that require that providers inquire about a patient's medical history health status or physical traits when providing care be limited to the relationship to the underlying condition and not asked in a manner that is hostile or disregards patient privacy.

Endocrine Society

[illegible] Department's motivation intent and guidance conflict with the law and policy of the State of Arkansas and puts the State's most vulnerable residents at risk of harm. The Arkansas General Assembly enacted Act 626 of 2021 which prohibits the provision of gender transition treatment to children under the age of 18. Each state serves as a policy through the legislative arm of its duly elected representatives the executive branch of the state must act accordingly. However if a state does not follow the Department's proposed rules it is at risk of losing millions of dollars of federal healthcare funding that protects its most vulnerable residents. This is an untenable situation that inherently coerces states such as Arkansas to follow federal policy determined by administrative fiat and not by Congressional action. Such coercion is unconstitutional and renders the proposed rules invalid.

Arkansas Department of Human Services

With respect to the language regarding providers complying with a state or local law as a justification for denying gender-affirming care we recommend strengthening this provision to state unequivocally that Sec. 1557 as federal law preempts any such state or local law restricting access to this care.

Justice Along

(b)(5)

Recommended Changes to the Proposed Rule While the protections outlined in the proposed rule are an exceptional leap forward in ensuring all patients receive the dignified and quality healthcare they deserve we urge the Department to further strengthen the rule by: 1. [Bold: Stating explicitly that Section 1557 as interpreted in this rule preempts inconsistent state and local laws and actions.] Some actors continue to make the argument that based on personal belief gender-affirming care is never clinically appropriate. While providers are permitted to exercise clinical judgment as to whether a particular service is appropriate for an individual patient the rule must unambiguously clarify that providers cannot argue that outright refusal of care is appropriate because it is in compliance with a discriminatory state or local law.
No comments are associated with this issue

(b)(5)

48 Members of Congress

Further restricting access to comprehensive and quality reproductive healthcare services is tied to disparities in health outcomes and persistent inequities in several reproductive health measures including maternal health [footnote 11 Sutton M. Y. Anachebe N. F. Lee R. & Skanes H. (2021). Racial and Ethnic Disparities in Reproductive Health Services and Outcomes 2020. Obstetrics and gynecology 137(2) 225–233. https://doi.org/10.1097/AOG.0000000000004224] Longitudinal research shows that people restricted from abortions face increased life-threatening delivery complications greater economic hardship and economic insecurity. [Footnote 12: APA 2022 February] APA supports the Administration's plan to advance data collection standardization transparency and research with respect to maternal health and urges the Department to examine the connection between nondiscrimination in health care civil rights compliance and maternal behavioral health outcomes. [Footnote 13: Executive Office of the President. (2022 June). White House Blueprint for Addressing the Maternal Health Crisis. https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf]

American Psychological Association

The proposed rules can be compared to the Department's actions at issue in Burwell v. Hobby Lobby 573 U.S. 682 (2014) and the Department clearly ignores the Court's decision in that case. In Hobby Lobby the Court found that the government's compelling interest in protecting women's health could be accomplished in a less restrictive manner. Likewise the Department is free to provide gender transition procedures without coercing the states to follow federal policy in conflict with their own laws and policies.
No comments are associated with this issue

Arkansas Department of Human Services

The Proposed Rule Addresses Various Forms of Systemic Racism in Health Care The Department properly notes that racial health disparities in the United States are directly attributable to "persistent bias and racism" in the healthcare system. Both intentional and unintentional race discrimination serve as barriers to care lead to lower quality care and drive worse health outcomes for communities of color. Discrimination in health care is often systemic — deeply embedded within the policies procedures and practices of covered entities to say nothing of the social determinants of health outside of healthcare systems. The Proposed Rule addresses several major drivers of systemic racism including antiscrimination policies and procedures algorithmic discrimination and discriminatory health insurance networks. Each of these are a critical step toward addressing the ways in which racism manifests systematically in health care.

Alliance of Multicultural Physicians

Similarly the finalized rule should amend section 92.207(b)(1) to include the following new language for health insurers: "[4] Have or implement a categorical coverage exclusion or limitation for all services related to gender transition or other gender-affirming care. [Bold and Italics: Termination of pregnancy contraception fertility care miscarriage management pregnancy loss maternity care other reproductive and sexual health services or any health services] if such denial limitation or restriction results in discrimination on the basis of sex. "[5] Otherwise deny or limit coverage deny or limit coverage of a claim or impose additional cost-sharing or other limitations or restrictions on coverage for specific health services related to gender transition or other gender-affirming care [Bold and Italics: termination of pregnancy contraception fertility care miscarriage management pregnancy loss maternity care other reproductive and sexual health services or any health services] if such denial limitation or restriction results in discrimination on the basis of sex. [Bold and Italics: "[7] Deny or limit coverage deny or limit coverage of a claim or impose additional cost sharing or other limitations on coverage for health services that may prevent cause complications to or end fertility or pregnancies if such denial limitation or reversion results in discrimination on the basis of sex. [Including these new provisions in the finalized rule will ensure that patients are not denied their needed medications. The burden of this denial of care will fall most harshly on patients of color and disabled patients as we have already seen since the Dobbs decision and this chilling effect will only worsen as more states ban abortion care.

The Century Foundation

6. [Bold: Clarifying how the Department will handle intersectional claims.] Some claimants will have intersecting claims of discrimination in healthcare. We encourage the Department to unambiguously state the inclusion of protections for intersectional cases in section 92.101(a)(1) and sections 92.207(a) (b)(1) and (b)(7).

(b)(5)

48 Members of Congress

Discrimination Prohibited [§ 92.101(a)] It is encouraging to see the Department recognize in the preamble to the NPRM that people may experience discrimination in health care on more than one basis. It would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. We propose the following change to sect on 92.101(a)(1): "except as provided in Title I of the ACA an individual may not on the basis of race color national origin sex age or disability [,build/underlined] or any combination thereof] be excluded from participation in be denied the benefits of or otherwise be subjected to discrimination under any health program or activity operated by a covered entity." This language should also be added to sections 92.207(a) (b)(1) and (b)(2).

(b)(5)

Eating Disorders Coalition for Research, Policy & Action

Nondiscrimination on the Basis of Association [§ 92.209]We are pleased that this NPRM restores explicit protections against discrimination on the basis of association. This is consistent with longstanding interpretations of other antidiscrimination laws which cover discrimination based on an individual's own characteristics or those of someone with whom they are associated or with whom they have a relationship. As noted in the NPRM preamble certain protected populations including LGBTQI people are particularly susceptible to discrimination based on association. An individual in a same-sex relationship or marriage could be subjected to discrimination based on their own and the spouse or partner's sex whereas that same individual might not be similarly mistreated were they not in a same-sex relationship. It is important that the final rule make clear that this kind of associational discrimination is within the ambit of the rule's protections.

Colors+

HHS should finalize the proposal that ensure covered entities when providing or administering health related services or coverage do not discriminate on the basis of race color national origin sex age disability or gender identity and specifically transgender individuals. This includes denying cancelling limiting or refusing to issue or renew a health insurance plan or policy, denying or limiting coverage of a claim, or imposing additional cost sharing to such individuals. It is also important the covered entity also not engage in marketing practices or benefit designs that discriminate against such individuals.

JBAC

[Bold: II. The Proposed Rule Addresses Various Forms of Systemic Discrimination in Health Care and Methods of Prevention.] The department properly notes that health disparities in the United States are directly attributable to persistent bias in the health care system. Both explicit and implicit discrimination serve as barriers to care lead to lower quality care and drive worse health outcomes for communities. Discrimination in health care is often systemic — deeply embedded within the policies procedures and practices of covered entities. The proposed rule addresses several major drivers of systemic discrimination including antidiscrimination policies and procedures and algorithmic discrimination. The proposed rule takes a critical step toward addressing the ways in which discrimination manifests systemically in health care.

The Leadership Conference on Civil and Human Rights

(b)(5)

|Bold and Italics: Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage (§ 92.207)| Bold: The AAMC strongly supports proposals to prohibit discrimination in health insurance coverage.' We support the Department's proposal to reinstate the provision from the 2016 Rule to prohibit discrimination on the basis of race color national origin sex age or disability in the provision or administration of health insurance coverage and other health-related coverage. We also support the proposal to apply this provision to all federally funded health plans including the Department's administration of its own health-related coverage programs. HHS proposes to apply this provis on inclusive of all an insurer's health programs and activities including short-term limited duration insurance and to an insurer's or other entity's operations related to third party administrative services to ensure all individuals have the protections Congress intended when it enacted the Affordable Care Act. We support this inclusive and broad approach to prohibiting discrimination in health insurance coverage.

Related Coverage (§92.207)]WPHCA is supportive of the proposal in §92.207 as this would prohibit discrimination against patients with Medicaid Medicare Part D and coverage through the federal marketplace. For decades Community Health Centers have developed extensive partnerships with state Medicaid agencies and nearly 48% of Community Health Center patients nationwide are Medicaid beneficiaries. Additionally about 11% of patients have Medicare and 20% have private insurance. In Wisconsin 55% of patients are Medicaid enrollees 17% are uninsured 18% have private insurance and 10% are insured through Medicare. While benefits for Medicaid and Medicare are continuing to become more robust and inclusive beneficiaries have limited options for providers facilities and services depending on which state they are located in. Medicare and Medicaid beneficiaries deserve access to equitable quality health care regardless of their income or location. The combination of discrimination and social determinants of health can discourage patients from seeking primary care and routine services. WPHCA appreciates HHS taking steps to protect patients with insurance coverage that falls under the definition of Federal Financial Assistance. This includes the design of health insurance benefits marketing practices and coverage provisions.Community Health Centers across the country waive away millions of dollars of "bad debt" for those who lack the financial means to pay for the care they need. This frequently happens when patients seek care that falls outside of their insurance coverage because of their gender identity or reproductive status. Oftentimes Medicare and Medicaid patients cannot afford to pay out of pocket this is preventing them from receiving necessary services. However patients know they can receive the care they need at their local Community Health Center. Living true to the Community Health Center mission our patients do not have to choose whether they can afford paying for the care they need or paying for life essentials such as food housing or transportation.

Association of American Medical Colleges [AAMC]

Wisconsin Primary Health Care Association

|Bold: TPCA encourages HHS to finalize §92.207 to provide equal protections to all patients and create equitable antidiscrimination protections for all types of health insurance coverage.| Historically health plans and insurance companies have implemented discriminatory practices that impact applicants and employees based on sex race color national origin age and other intersecting identities. For example private and public insurers have been found to discriminate based on relationship status and sexual orientation through policies that require single people or those in non-heterosexual relationships to pay out of pocket for certain reproductive health services. Given these circumstances patients face difficult decisions on where to obtain care and have little recourse if they experience discrimination in seeking care.

Tennessee Primary Care Association

|Bold: HHS should finalize the proposals that ensure covered entities when providing or administering health-related services or coverage do not discriminate on the basis of race color national origin sex age or disability.| This includes denying canceling limiting or refusing to issue or renew a health insurance plan or policy; denying or limiting coverage of a claim; or imposing additional cost-sharing to LGBTQI+ individuals. We also believe it is important that the covered entity does not engage in marketing practices or benefit designs that discriminate against such individuals

Association of American Medical Colleges [AAMC]

|Bold: TPCA also strongly supports CCIIO's proposal to treat Medicare Part B payments as federal financial assistance [FFA] and Part B providers and suppliers as recipients under 1557 Title IV Title IX Section 504 and the Age Act.] This change in interpretation is well-supported by how the Part B program has evolved the fact that most Part B providers are already receiving other forms of FFA and the clear intent of the 1557 statute itself. Eliminate confusion for older adults and people with disabilities and help ensure that people with Medicare have the same protections and rights regardless of the Medicare provider they choose the Medicare covered service they are receiving or whether they are in Original Medicare or Medicare Advantage. Bringing all Medicare providers under this rule will also help increase access to quality health care for underserved communities who face the most discrimination and there are as many Medicare providers serve people with other forms of insurance TPCA agrees with HHS' judgment that the statutory text of Sect on 1557 is clear: Congress intended that the law apply to these entities and address these issues. |Bold: Thus TPCA strongly supports HHS' proposal on of and improvements to § 92.207 by using its inclusion of specific forms of prohibited discrimination.|

(b)(5)

Tennessee Primary Care Association

related coverage have long discriminated against applicants and enrollees on the basis of sex and intersecting identities. For example some insurance companies refuse to cover [embedded hyperlink: "ok text (https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/)] certain types of care that are traditionally used by women such as in vitro fertilization (IVF). Private and public insurers often discriminate based on relationship status and sexual orientation with policies that require single people or those in non-heterosexual relationships to pay out of pocket for a predetermined number of failed intrauterine insemination cycles before providing them coverage when different sex couples do not have to meet the same standard. The high cost and lack of coverage for fertility treatment including IVF are large barriers for people who experience multiple and intersecting forms of bias and discrimination including provider bias and harmful preconceptions about their desire and need for fertility treatment. Women of color have a long history of forced sterilization and reproductive coercion in this country and continue to report [embedded hyperlink (https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/disparities_in_access_to_effective_treatment_for_infertility_in_the_us-pdfmembers.pdf)] that providers do not take their fertility concerns seriously instead "emphasizing] birth control over procreation."As the [italics: Dobbs' case eliminated the constitutional right to abortion it also undermined the right to privacy and concurring opinions attacked related rights to contraception consensual sexual contact and same-sex marriage. Many individuals already struggled to get full coverage or services for contraception but especially emergency contraception. Some state legislatures have banned emergency contraception [embedded hyperlink text: [https://www.guttmacher.org/state-policy/explore/emergency-contraception)] from their state family planning

Physicians for Reproductive Health

The States support these changes because among other reasons ensuring that a broader swath of entities refrain from discrimination in the healthcare system will reduce adverse health outcomes the costs of which would otherwise be borne by the States' public health systems. In addition limiting the scope of Section 1557 as the 2020 Rule sought to do increases the burden on the States to monitor and enforce nondiscrimination laws. For similar reasons the States also support HHS's proposal to add specific new antidiscrimination requirements in health insurance coverage and other health-related coverage as discussed further below

Attorneys General of California, New York, Massachusetts, and nineteen other States

It is encouraging to see the Department recognize in the preamble to the NPRM that people may experience discrimination that is simultaneously related to multiple identities. However I would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. As such we propose the following change to section 92.101[a)(1):"Except as provided in Title I of the ACA an individual must not on the basis of race color national origin sex age or disability [italics: or any combination thereof] be excluded from participation in be denied the benefits of or otherwise be subjected to discrimination under any health program or activity operated by a covered entity."Should this addition be adopted this revised language should also then be added to sections 92.201[a) [b)(1) and [b)(4) to ensure consistency

Equitas Health

(b)(5)

We also strongly support the Department's removal of and improvements to § 92.207 including the inclusion of specific forms of prohibited discrimination. We recommend that the Department further strengthen the text of proposed § 92.207 to address sex discrimination in insurance coverage related to pregnancy or related conditions including discrimination related to abortion fertility care and contraception. Accordingly we urge the Department to amend proposed § 92.207(b) as follows: (4) Have or implement a categorical coverage exclusion or limitation for all services related to gender transition or other gender-affirming care [U]nderline: termination of pregnancy contraception fertility care miscarriage management pregnancy loss maternity care other reproductive and sexual health services or any health services] if such denial limitation or restriction results in discrimination on the basis of sex.[5] Otherwise deny or limit coverage deny or limit coverage of a claim or impose additional cost-sharing or other limitations or restrictions on coverage for specific health services related to gender transition or other gender affirming care [Underline: termination of pregnancy contraception fertility care miscarriage management pregnancy loss maternity care other reproductive and sexual health services or any health services]' if such denial limitation or restriction results in discrimination on the basis of sex; or. . .[7] [Underline: Deny or limit coverage deny or limit coverage of a claim or impose additional cost sharing or other limitations or coverage for health services that may prevent cause complications to or end fertility or pregnancies if such denial limitation or restriction results in discrimination on the basis of sex.]	(b)(5)	Center for Reproductive Rights
[Bold: Clarifying how the Department will handle intersectional claims] Some claimants will have intersecting claims of discrimination in healthcare. We encourage the Department to unambiguously state the inclusion of protections for intersectional cases in section 92.101(a)(1) and sections 92.207(a) (b)(1) and (b)(2).		38 Members of Congress
HHS should finalize the proposals that ensure covered entities when providing or administering health-related services or coverage do not discriminate on the basis of race color national origin sex age disability or gender identity and specifically transgender individuals. This includes denying cancelling limiting or refusing to issue or renew a health insurance plan or policy; denying or limiting coverage of a claim, or imposing additional cost sharing to such individuals. It is also important the covered entity also not engage in marketing practices or benefit designs that discriminate against such individuals.		URAC
[Bold: Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage [§ 92.207]:] It is essential that this provision be adopted in the final rule to clarify that pursuant to the text of the ACA the protections of 1557 do apply to insurance		Eating Disorders Coalition for Research, Policy & Action
[Bold: MNACHC encourages HHS to finalize 92.207 to provide equal protections to all patients and create equitable discrimination protections for all types of health insurance coverage]. Historically health plans and insurance companies have implemented discriminatory practices that impact applicants and enrollees based on sex race color national origin age and other intersecting identities. For example private and public insurers have been found to discriminate based on relationship status and sexual orientation through policies that require single people or those in non-heterosexual relationships to pay out of pocket for certain reproductive health services. Given these circumstances patients face difficult decisions on where to obtain care and have little recourse if they experience discrimination in seeking care		Minnesota Association of Community Health Centers
The Department's proposal to once again recognize Section 1557's application to private insurance continues the aim of properly implementing Congress' intent when drafting Section 1557 to encompass all forms of healthcare access. According to data in a new report from the Center for American Progress (Hyperlink: https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtq-communities/) transgender and nonbinary people at-large experience significant discrimination when seeking insurance coverage for medical care. Key findings include that in the past year: • 20 percent of transgender or nonbinary respondents including 47 percent of transgender or nonbinary respondents of color reported experiencing one form of denial by a health insurance company. • 28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported a denial of coverage for gender-affirming hormone therapy and • 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported a denial of coverage for gender-affirming surgery		38 Members of Congress
WPHCA encourages HHS to finalize §92.207 to provide equal protections to all patients and create equitable discrimination protections for all types of health insurance coverage. Historically health plans and insurance companies have implemented discriminatory practices that impact applicants and enrollees based on sex race color national origin age and other intersecting identities. For example private and public insurers have been found to discriminate based on relationship status and sexual orientation through policies that require single people or those in non-heterosexual relationships to pay out of pocket for certain reproductive health services. Given these circumstances patients face difficult decisions on where to obtain care and have little recourse if they experience discrimination in seeking care		Wisconsin Primary Health Care Association
Impact on Insurance Coverage and Benefit DesignUnder the proposed rule the definition of a covered entity will expand to include every health program or activity that receives federal financial assistance and all health programs within HHS including the Indian Health Service Centers for Medicare & Medicaid Services and the National Institutes of Health. Consequently all health plans offered by an insurer that participates in the Marketplace will be subject to Section 1557. Additionally all providers who participate in Medicare and Medicaid which would meet the federal financial assistance requirement will be subject to these provisions if finalized. The Endocrine Society supports expanding the definition of covered entity and believes that the provisions in Section 1557 will have the most impact when applied to the broadest range of federal health programs and activities possible. If finalized the proposed rule will prohibit discrimination in insurance issuance coverage cost sharing marketing and benefit design. This provision will ensure that transgender individuals can access preventive services and medical care that aligns with their gender identity and their sex assigned at birth. It is well known that preventive medical care reduces risk for diseases disabilities and death. In vulnerable communities access to preventive services can help reduce health disparities. As previously mentioned transgender individuals are at higher risk for numerous health problems and we believe that improving their access to the full spectrum of preventive care will improve their health outcomes.	(b)(5)	Endocrine Society
[Bold: Insurance Coverage] We strongly support the proposed provisions to prohibit discriminatory plan benefit design and marketing practices by insurers. Particularly we support the following provisions: • Covered entities could not—on the basis of race color national origin sex age or disability—deny cancel limit or refuse to issue or renew coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage; • Covered entities could not adopt marketing practices or benefit designs that discriminate on the basis of race color national origin sex age or disability, and • Covered entities also could not have or implement benefit designs that do not provide or administer coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities. An example of this would be if a plan required utilization management for someone in the community but not for someone in an institution		National Health Council

(b)(5)

|Bold. The proposed rule will improve access to mental health coverage|Unequal coverage of mental health services and discriminatory benefit design have historically prevented people with mental health conditions from accessing needed services. Application of Section 1557 to marketing and benefit design is essential to protecting people with mental health conditions from insurers who will find roundabout ways to discourage the enrollment and undermine the protections for people with other pre-existing conditions under the ACA. Specifically we would like to highlight the significance of proposed paragraph (b)(2) which would prohibit marketing practices or benefit designs that discriminate on the basis of race color national origin sex age or disability. As the proposed rule states, "By clarifying that health insurance and other health-related coverage must not employ discriminatory benefit design or marketing practices proposed paragraph (a)(2) would further the ACA's goals of expanding access to affordable and quality health care and would be consistent with existing departmental regulations governing health insurance and other health-related coverage that similarly prohibit such discriminatory practices." We believe these changes would further help prevent health insurers inappropriately excluding important benefits or designing benefits in a way that limits access to medically necessary care for those with mental illness while cherry-picking healthier enrollees.

The Proposed Rule Clarifies and Expands the Scope of Nondiscrimination in Health Programs and Activities. We applaud HHS for clarifying that the scope of Section 1557 covers an expansive range of programs and activities consistent with Congressional intent. We support the Department's proposal to return to the 2016 interpretation that applies Section 1557 to all health programs and activities receiving funding from the Department or administered by the Department such as state or federally facilitated Exchanges health insurance issuers that receive federal financial assistance and third-party administrators (e.g. Pharmacy Benefits Managers). [Footnote 1: Nondiscrimination in Health Programs and Activities 87 Fed. Reg. 47824 47838 (proposed Aug. 4 2022) (to be codified at 42 CFR Parts 438 440 457 and 460)]. We also support the proposed rule's expanded enforcement of nondiscrimination in health insurance coverage to include discriminatory health plan designs adopted by group health plans as well as marketing practices. [Footnote 2: 87 Fed. Reg. at 47876 47912 (Proposed § 92.4)].

|Bold: § 92.207(a)(2) Benefit Design|We agree with the Department that the 2020 rule resulted in less protection for people who need health care and who are protected by Section 1557 against discrimination. We strongly support the application of Section 1557 to health insurance coverage especially health benefit designs.

The application of benefit design under 1557 is an important expansion of protections. Too often barriers to health care can be baked in those decisions. Assuring that plan design practices support equitable access to health care will benefit patients. Without these provisions patients could be subject to discriminatory benefit designs. Examples of plan design elements that we hope would be eliminated through 1557 protections include placing all or most prescription drugs used to treat a specific condition on a health plan's highest cost formulary tier; applying age limits to services that have been found to be clinically effective at all ages or requiring prior authorization or step therapy for all or most medications in drug classes regardless of medical evidence.

We support strong regulatory protections prohibiting discriminatory plan benefit design and marketing practices. For example the coverage of Durable Medical Equipment can be problematic for children. Children need more frequent wheelchair and other mobility device replacement due to their rapid growth and development. Limitations that prohibit children from receiving new equipment according to these needs are problematic. Relatedly children with disabilities also often need to access habilitation services which the Centers for Medicare and Medicaid Services defines as "health care services that help a person keep learn or improve skills and functioning for daily living." These services are often times hard for children and their families to access but are important for children who are delayed in walking or talking or need to learn other muscular skills for their lives. Covered entities should not be able to deny or limit health services based on an individual's disability.

b. |Bold: Clarifying how the Department will handle intersectional claims.| Some claimants will have intersecting claims of discrimination in healthcare. We encourage the Department to unambiguously state the inclusion of protections for intersectional cases in section 92.101(a)(1) and sections 92.207(a) (b)(1) and (b)(2).

HHS should finalize the proposals that ensure covered entities when providing or administering health-related services or coverage do not discriminate on the basis of race color national origin sex age disability or gender identity and specifically transgender individuals. This includes denying canceling limiting or refusing to issue or renew a health insurance plan or policy; denying or limiting coverage of a claim, or imposing additional cost sharing to such individuals. It is also important the covered entity also not engage in marketing practices or benefit designs that discriminate against such individuals.

|Bold: Prohibiting Discrimination in Benefit Design|We strongly support the proposed provisions to prohibit discriminatory plan benefit design and marketing practices. Older adults are more likely to have chronic conditions and disabilities and therefore have higher health care needs. Despite established protections for people with pre-existing conditions insurers continue to discriminate against people with costlier conditions and greater needs by persuading them from enrolling or shifting more out-of-pocket costs to people with certain conditions. [Footnote 14: How Much Does Health Spending Eat Away at Retirement Income? Center for Retirement Research at Boston College https://crr.bc.edu/wp-content/uploads/2022/07/IB_22-12.pdf (2022).] Further the gap between coverage and high drug prices forces many older adults to rely on coverage assistance programs to pay for medications necessary to survive. One lady stated that her life-sustaining drug to treat her cancer costs more than $18000 per month and she utilizes the assistance program to cover her fee. [Footnote 15: Seniors Face Crushing Drug Costs as Congress Stalls on Capping Medicare Out-Of-Pockets KHN https://khn.org/news/article/seniors-face-crushing-drug-costs-as-congress-stalls-on-capping-medicare-out-of-pockets/ (2021)]. We particularly support the proposal to incorporate the integration mandate in HHS's Sec. 504 regulations into Sec. 1557. This provision is necessary to help ensure people with disabilities including older adults are able to get the health coverage they need to live in the community and are not unjustly institutionalized. We agree that the proposed prohibition on not providing or administering coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities should apply both to benefit design and to implementation of a benefit design.

(b)(5)

|Bold: Benefits determinations.| The Proposed Rule prohibits "benefit designs that impermissibly limit coverage based on a person's sex at birth gender identity or gender otherwise recorded." [Footnote 103: 87 Fed. Reg. 47870.] HHS asserts that discrimination "against transgender people in health insurance and other benefits related coverage remains pervasive especially for individuals who experience intersectional discrimination such as individuals who experience both transphobia and racism." [Footnote 110: 87 Fed. Reg. 47820.] HHS provides insufficient evidence to show that "transgender" and "gender-diverse" individuals (or the many other descriptive labels covered by the proposed rule) have suffered "pervasive" discrimination. Instead it appears to rely on self-reported discrimination that equates denial of demanded services with presumptive discrimination. As reported in a 2020 study of self-identified LGBTQ adults 38 percent of transgender respondents and 52 percent of transgender respondents of color—said that they had been denied hormone therapy coverage by their health insurer and 43 percent reported being denied coverage for surgery for their transition." [Footnote 111: 87 Fed. Reg. 47870.]

(b)(5)

National Alliance on Mental Illness

Senate Democrats

National Disability Rights Network

National Health Council

American Academy of Pediatrics

38 Members of Congress

URAC

(b)(5)

Center for Elder Law & Justice

Ethics & Public Policy Center

(b)(5)

[Bold: Healthcare entities' limits on provider care.] Healthcare institutions might limit for a variety of reasons [such as risk management or ethics] a provider's ability to perform certain procedures or to use particular medical treatments in their facilities. One example of this is a set of ethical constraints on Catholic hospitals called the Ethical and Religious Directives [ERDs] for Catholic Health Care Services. The ERDs prohibit for ethical reasons Catholic Health Care entities from performing, providing or referring for certain treatments, notably abortions, sterilizations, and medical or surgical interventions for purposes of gender transition. The Proposed Rule takes direct aim at Catholic and other faith-based hospitals that impose ethical limits on their providers stating "restrictions by covered entities on the ability of providers to prescribe or provide care based on their patient's gender identity or sex assigned at birth would likely constitute prohibited discrimination in violation of this rule." [Federal Register 112 87 Fed. Reg 47846]. In fact Catholic healthcare entities do not discriminate on the basis of a person's identity but because they view "gender-affirming" treatments as unethical and harmful they prohibit their affiliated providers from conducting those treatments. The Rule thus attempts to force healthcare entities to be in the business of providing "gender-affirming care" regardless of their concerns over benefit to patient safety or even malpractice risks.

None of the material on Health Insurance and Other Health-Related Activities (§ 92.207) Justice in Aging supports the proposed provisions in this section to prohibit discriminatory plan benefit design and marketing practices. Older adults are more likely to have chronic conditions and disabilities and therefore have higher health care needs. Despite established protections for people with pre-existing conditions insurers continue to discriminate against people with costlier conditions and greater needs by dissuading them from enrolling or shifting more out-of-pocket costs to people with certain conditions.

Impact on Insurance Coverage and Benefit Design. Under the proposed rule the definition of a covered entity will expand to include every health program or activity that receives federal financial assistance and all health programs within HHS including the Indian Health Service, Centers for Medicare & Medicaid Services, and the National Institutes of Health. Consequently all health plans offered by an insurer that participates in the Marketplace will be subject to Section 1557. Additionally all providers who participate in Medicare and Medicaid which would meet the federal financial assistance requirement will be subject to these provisions if finalized. The Endocrine Society supports expanding the definition of covered entity and believes that the provisions in Section 1557 will have the most impact when applied to the broadest range of federal health programs and activities possible. If finalized the proposed rule will prohibit discrimination in individuals' insurance coverage, cost-sharing, marketing, and benefit design. This provision will ensure that transgender individuals can access preventive services and medical care that aligns with their gender identity and their sex assigned at birth. It is well known that preventive medical care reduces risk for diseases, disabilities and deaths. Insulnerable communities access to preventive services can help reduce health disparities. As previously mentioned transgender individuals are at higher risk for numerous health problems and we believe that improving their access to the full spectrum of preventive care will improve their health outcomes.

[Bold: Insurance Coverage.] We strongly support the proposed provisions to prohibit discriminatory plan benefit design and marketing practices by insurers. Particularly we support the following provisions: • Covered entities could not—on the basis of race, color, or national origin, sex, age, or disability—deny, cancel, limit, or refuse to issue or renew coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage. • Covered entities could not adopt marketing practices or benefit designs that discriminate on the basis of race, color, or national origin, sex, age, or disability; and • Covered entities also could not have implement benefit designs that do not provide or administer coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities. An example of this would be if a plan required utilization management for someone in the community but not for someone in an institution.

We support HHS's effort to ensure that everyone has access to health care and health coverage. However we object to language in the proposed regulations that can be read to require the provision and coverage of procedures that are medically ineffective or cause harm, violate professional and evidence-based judgments as to an appropriate course of treatment or conflict with the religious and moral convictions of health care providers, insurers, plan sponsors, and other stakeholders. We agree with and support the Department's proposal to apply the regulation only to health programs and activities and its proposed treatment of notices for non-English speakers.

WPHCA appreciates OCR's clarification in paragraph [III.C] of [IV.C (1)], that prohibits discrimination on the basis of sex stereotypes; sex characteristics including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity. While the terms "gender identity" and "transgender status" are often used interchangeably, there have been instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between the two concepts. Therefore, explicit language is needed to prevent this discrimination and consistency throughout the final rule is important. WPHCA recommends adding including "transgender status" in § 92.206(b)(1), (b)(2), and (b)(4), and in § 92.207(b)(3).

3. [Bold: Clarifying the prohibition on categorical coverage exclusion of services related to gender transition or other gender affirming care.] Currently section § 92.207(b)(4) can be misread as only applying if an insurer excludes all health services related to gender transition or gender affirming care. We recommend deleting the word "all" to make clear that the exclusion of any such services is prohibited. We also encourage OCR to clarify in the preamble to the final rule that "gender affirming care" is care that affirms an individual's self-identified gender, is responsive to their self-reported needs and goals, and is provided with informed consent or assent of the individual. That "conversion" practices such as sexual orientation and gender identity change efforts and medical interventions intended to "normalize" a child's variations in sex characteristics in accordance with the sex assigned or assigned sex are distinct from gender affirming care and other health services related to gender transition, and that the rule should not be interpreted as prohibiting the adoption or application of any nondiscriminatory policies, practices or requirements that ensure that the intended recipient of a non-emergent medical intervention or other health service has the opportunity to provide or withhold their informed consent or assent to the proposed intervention or service.

We strongly support the additional guidance provided by proposed sections § 92.206 and § 92.207 regarding equal program access and equal insurance coverage. The terms of discrimination highlighted in proposed sections § 92.206(b)(3) and (b)(4) and § 92.207(b)(3)-(5) in particular affect many intersex people some of whom are also transgender and some of whom are not. For example intersex people who are cisgender or transgender sometimes are arbitrarily denied clinically appropriate preventive screenings or support services typically associated with one sex because of their perceived or assigned or recorded gender.

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Ethics & Public Policy Center

Justice in Aging

Endocrine Society

National Health Council

Kansas Catholic Conference

Wisconsin Primary Health Care Association

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88 Members of Congress

InterACT: Advocates for Intersex Youth

None sex mirat on in Health nsurance Coverage and Other Health Related Coverage If§ 92 237)It is essent a that this provision be adopted n the final rule to c a r y that pursuant to the text of the ACA the protections of Section 1557 do app y to nsurance p ans and Coverage Cons stent with our recommendations above we strongly suggest adding "transgender status" to section 92.207(b)(4):"A covered entity must not n providing or admin stering health insurance coverage or other health- related coverage (4) De y or limit coverage de y or limit coverage of a c a m or m ake addit on a cost sh r ng or other limitat ons or restrict ons or cove age to an ndividual based upon the ind vidual's sex at birth gender identity |italic gold: transgender status| or gender otherwise recorded."Add t onal y we recommend a s ght mod f cat on to sect on 92 237(b)[4] w hich bans 'categor ca coverage exclusions' of services related to gender transit on or other gender affirming care. As currently drafted it could be nterpreted to |italic: only| apply if an insurer excludes a ' health services related to gender transition or other gender affirming care services, however we be ieve the true nterest is to proscribe ex clusions of "any" such services.To clarify this language and to protect access to ge der affirm ng care we strongly p ecomm de et ng the word "all" from this paragraph such t hat the final text reads:"A covered entity must not n providing or admin stering health insurance coverage or other health- related coverage: ... [4] Have or im plement a categor cal coverage exclusion or limitat on for 'str iketh rough. all' health services related to gender transition or other ge nder-affirming care "Furthermore Section 92 207(b)(5) would be clearer f shortened:"A covered ent ty must not n provid ng or admin stering health insurance coverage or other health related coverage: ... [5] Otherwise deny or mit coverage deny or l mit coverage of a claim or impose addit ona cost sharing or other lim tations or restrict ons on coverage for spec fic health services related to gender transition or other gender-affirming care."

struggling with identity|Sect on 92.207 mandates a broad class of new health care coverage obligations based on a person's "gender dentity" w th no dent fier or or reporting of documented associated r sks and no lim tation regarding age So-called "standards of care" in this field are based on nur-empir cal self-reporting s rveys and are high y controvers a Calls for review have been s lenced by nf uential medical associations like the American Academy of Pe atr cs International trans promoting organizations specifically WPATH are defining "standards of care" that have no objective verification. The Food and Drug Administration (FDA) has documented adverse event reports from the off-label use of puberty blockers – powerful drugs that remain unapproved to this day |see https://www fda.gov/drugs/questions and answers fdas-adverse event reporting system-faers/january- march-2017-potential-signals-serious-risks-new-safety information-identified-fda-adverse| Recent y the FDA added warnings about the potential harmful effects of puberty blocking d ugs including brain swelling and vis on loss |see https://www.formularywatch.com/view/study jak inh bitors may have different side effects|.A new review in the ournal of Sex and Marital The apy evaluating the "Dutch protocol" wh ch has been used to defend the use of puberty-blocking d ugs and more severe forms of treatment or youth ca not be ignored |see https://www.tandfonline.com/doi/full/10.1080/0092623X.2022.2121258| The Department m ust be able to answer these questions What evidence underlies the require ments for treating minors under "gender affirm ng care"? Are there any age limitat ons on t eatment? Who determines t his? The Rule cannot ignore the evidence of bod y and psychological harm that use of unapproved drugs cause especially for you ng people yet that is what the Rule requires by defin ng any withholding of "gender affirming" treatment an act of discrimination. Gender t ansition regret is only grow ng wh ch w ll substantially add to costs of repairing

Add tionally we support proposed Sect on 92.207's prohibition of discrimination in the coverage of gender affirming and transit on related care Transgender and gender d verse peop e face signific ant barriers to health care access such as coverage ex clusions wa ting periods high cost sharing lack of access to providers and determinat ons t hat gender affirming care is cos metic or not medically necessary. These barriers to care are further heightened for B ack Indigenous and other t ransgender people of color as well as transgender people with disabi ities The proposed rule aims to protect transgende nonbinary nterse x and gende diverse people from d sc mir atory benefit design and other pract ces by insurers that are contrary to well estab ished standards of care and reaf rms regulatory protections with the med cal standards of care put forth by m ajor med cal associations

Nond sc mir at on in Health nsurance Coverage and Othe Health-Related Coverage (§ 92 207)It is essent a that this provision be adopted n the final rule to c a r y that pursuant to the text of the ACA the protections of 1557 do apply to nsurance Consistent with our recommendations above we suggest adding "transgender status" to section 92 207(b)(4) "A covered entity must not n prov ding or administer ng health insurance cove age or other health-related coverage: ... [4] Deny or mit coverage deny or mit coverage of a claim or mpose additiona cost shar ng or other limitat ons or restrictions on coverage to an individual based upon the ndividual's sex at birth gender identity hold underline: transgender status| or gender otherwise recorded "We recommend a slight modif cation to section 92 207(b)(4) which bans categorica coverage exclusions of services related to gender transition or other gender aff rming care. As drafted t could be nterpreted to only apply if an insurer excludes "all" health services related to gender transition or other gender affirming care whereas we believe the true inte t is to proscribe exclusions of "any" such services Thus we propose deleting the word "all" from this paragraph such that the final text reads:" A covered ent ty must not in providing or administer ng health insurance coverage or other health re ated coverage (4) Have or im plement a categor cal coverage exclu or or lim tation for a ho d ll health services related to gende transition or other gender-affirming care "Section 92 207(b)(5) wou d be clearer if shortened "A covered entity must not in prov ding or administer ng health insurance coverage or other health related coverage (5) Otherwise deny or mit coverage deny or mit coverage of a claim or impose add tional cost sharing or other lim tations or restrict ons or coverage for spec fic health services related to gender transit on or other gender-affirm ng care."

justifies the use and safety of pu berty blockers cross sex hormones and "gender confirm ng" surge es for the purpose of gender t ans tion of minors? What proof that these interventions "do no harm" exists to ustify mandating coverage as a matter of "non discrimination"? Mandating coverage for "gender aff rming care" for a teen girl want ng to remove her breasts is tantam m nt to requiring mastectomies for anorexic Cosmetic reconstruction and hormone treatments will never make a female/woman a male/man The dea that children could be "born n the w ong body" is unscient fic - as scientifically preposterous as saying the earth is flat. To affirm a child's v ew of himself as "her" and to rreversible sex reassignment "health care" is nd ect deceptive Mutilating a youth's body for "gende exploration" causing long-term health r sks including loss of IQ decrease in bone density increased risk of cancer v sion im pairment and sterilization is noth ng short of child abuse. No ethical medical pract ce should be engaged in such practice and no nsurer forced to cover the evolving "n ation" and "gender fl d" ideology that would give anyone a claim to such med cal services and fuel an insatiable market dem nd ng scarce medical resources for cosmetic claims to "affirm" a person's physica appearance.Does the Rule's nond sc mir at on requ rement allow for health services and nsurance coverage related to sexua attract on fluidity exploration in therapy (SAFE T) and other sexua orientation change efforts? Does the Ru e's nondiscrimination requirement forbid d sc mina ng against SAFE-T health care? Is SAFE-T part of the full spect um of hea th care options re ated to a person's sexual or entation? If not why not especially n light of the em pirica research cited in this study of sexua ity attraction fluid ty and well be ng in the |italics: Journa of Human Sexuality|

https://www.journalofhumansexuality.com/_files/ugd/ec16e3_d0708a0dc62e4d a78e0258eb96dc1467.pdf?

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Concerned Women for America

The Leadership Conference on Civ and Human Rights

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Concerned Women for America

insurance issuers for the first time. As recently as the 2020 Section 1557 rule the department reasoned that health insurance providers are not "principally engaged in the business of providing health care." Footnote 40: The Department of Health and Human Services "SELECT 1557: Frequently Asked Questions" question #17, https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html| Now however under the proposed rule the department is changing their stance to include health insurance issuers. This means that health insurance issuers will be subject to Section 1557's redefinition of sex pregnancy and abortion as a consequence of receiving federal funds. This is a hefty departure from previous rulings and will have far-reaching conclusions for health insurance issuers. The Department considered any explicit or categorical exclusions of coverage for "gender transition" treatment as "unlawful on its face." |Footnote 41: Any "covered entity shall not" among other things "[c]ategorically or automatically exclude from coverage or limit coverage for all health services related to gender transition" or "[o]therwise deny or limit coverage or deny a claim for specific health services related to gender transition if such denial or limitation results in discrimination against a transgender individual." Id. d. 54180 and 54220. Although the Department claimed that the proposed regulations would not "affirmatively require" |Footnote 42: Id. 54190.| coverage of such treatment this claim was undercut by the Department's more concrete statements on the matter. In evaluating whether it is discriminatory to deny or limit a request for coverage of a particular service for an individual seeking the service as part of transition-related care OCR will start by inquiring whether and to what extent coverage is available when the same service is not related to gender transition. If for example a health plan or State Medicaid agency denies a claim for coverage of a hysterectomy that a patient's provider says is medically necessary to treat gender dysphoria OCR would ask

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The Heritage Foundation

|Bold: Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage |§ 92.207|. It is essential that this provision be adopted in the final rule to clarify that pursuant to the text of the ACA the protections of 1557 do apply to insurance. Consistent with our recommendations above we suggest adding "transgender status" to section 92.207(b)(5):"A covered entity must not in providing or administering health insurance coverage or other health-related coverage ...(5) Deny or limit coverage deny or limit coverage of a claim or impose additional cost sharing or other limitations or restrictions on coverage to an individual based upon the individual's sex at birth gender identity |Bold: transgender status| or gender otherwise recorded. "We recommend a slightly modification to section 92.207(b)(4) which bars categorical coverage exclusions of services related to gender transition or other gender-affirming care. As drafted it could be misconstrued to only apply if an insurer excludes "all" health services related to gender transition or other gender-affirming care whereas we believe the true intent is to prosecute exclusions of "any" such services. Thus we propose striking the word "all" from this paragraph such that the final text reads:"A covered entity must not in providing or administering health insurance coverage or other health-related coverage: ...(4) Have or implement a categorical coverage exclusion or limitation for [Bold/struck through: all] health services related to gender transition or other gender affirming care;"Section 92.207(b)(5) would be clearer if it contained "A covered entity must not in providing or administering health insurance coverage or other health-related coverage: ...(5) Otherwise deny or limit coverage deny or limit coverage of a claim or impose additional cost sharing or other limitations or restrictions on coverage for specific health services related to gender transition or other gender affirming care

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NCLGBTQIA+ Task Force

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NCLGBTQIA+ Seeked for Social Change

Center for Reproductive Rights

characteristic and should use consistent language throughout the rule in reference to protected characteristics.|While the terms "gender identity" and "transgender status" are frequently used interchangeably at times people have sought to justify discrimination against transgender people by highlighting distinctions between the two terms. |Footnote 76: See e.g. "Making Admissions and Placement Determinations Based on Sex in Facilities Under Community Planning and Development Housing Programs" Proposed Rule 85 Fed Reg 44811 (July 24 2020).| Therefore we recommend that the Department use both terms in the regulatory text. We propose that this change be made in sections 92.206(b)(1)(b)(2) and (b)(4) and in section 92.207(b)(3) as well as in §92.101(a)(2) as follows:§92.101(a)(2) Discrimination on the basis of sex includes but is not limited to discrimination on the basis of sex stereotypes sex characteristics including intersex traits, pregnancy or related conditions, sexual orientation, |Under the transgender status,| and gender identity. The NPRM's proposal that covered entities should develop and implement written policies and procedures to ensure compliance with this rule and that the procedural requirements apply to all covered nondiscrimination bases is an important addition. We also support the notice requirements in §92.10. However the description of prohibited sex discrimination in §92.8 |Policies and Procedures| and §92.10 |Notice of nondiscrimination) differs from the language of §92.101 (Discrimination prohibited). While the differences are not extensive we recommend the Department use consistent language throughout the rule to avoid confusion. Using the more expansive definition in §92.101. Relatedly we support the Department's proposal to restore protections for sexual orientation and gender identity that were arbitrarily and capriciously removed from §147.104 §155.120 §155.220 §156.200 and §156.125 by the 2020 rule. However because the proposed language of these protections differs from the language proposed under §92.we

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Center for Reproductive Rights

Extending section 1557 protections to benefit designs is important for people with mental illness and for people with other serious and chronic conditions where the likelihood of co-occurring mental illness is higher and the prospect of similar discrimination is greater. They can also help address the pervasive discrimination that LGBTQ communities often face in health care and coverage. While the uninsured rate for LGBTQ adults has considerably as the ACA was implemented individuals continue to face considerable discrimination and poorer access to quality health care services. For example transgender people are more likely to encounter insurance discrimination as exclusions deny transgender people coverage for medically necessary health care services related to gender transition such as mental health counseling. When transgender-specific exclusions in insurance plans are removed however it improves mental health and reduces suicide risk. Therefore NAMI supports the clear prohibitions on discrimination in connection with health services related to medically necessary care including gender-affirming care

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National Alliance on Mental Illness

The proposed rule is critical to our very existence. We must not be denied the health care we need because of discrimination based on our gender identity and/or sexual orientation. This rule will make it easier for us to access the care we need and will help protect us from discrimination not only in our medical providers' offices but also from our insurers. Additionally it recognizes our right to gender affirming care. By directing the Office for Civil Rights to enforce nondiscrimination protections based on gender identity and sexual orientation it will serve as a deterrent and a means for recourse from healthcare discrimination targeting us.

Sam & Devonan Foundation for Transgender Youth

|Bold: TPCA recommends also including "transgender status" in § 92.206(b)(1)(b)(2) and (b)(4) and in §92.207(b)(3).|

Tennessee Primary Care Association

|Bold: MNALHC recommends also including "transgender status" in § 92.206(b)(1)(b)(2) and (b)(4) and in §92.207(b)(3)|

Minnesota Association of Community Health Centers

Consistent with our recommendations above we suggest adding "transgender status" to section 92.207(b)(4): "A covered entity must not in providing or administering health insurance coverage or other health-related coverage. ... (5) Deny or limit coverage deny or limit coverage of a claim or impose additional cost sharing or other limitations or restrictions on coverage to an individual based upon the individual's sex at birth gender identity [bold/underlined transgender status] or gender otherwise recorded." We recommend a slight modification to section 92.207(b)(4) which bars categorical coverage exclusions of services related to gender transition or other gender-affirming care. As drafted it could be misconstrued to unlawfully if an insurer excludes "all" health services related to gender transition or other gender affirming care whereas we believe the true intent is to proscribe exclusions of "any" such services. Thus we propose deleting the word "all" from this paragraph such that the final text reads: "A covered entity must not in providing or administering health insurance coverage or other health-related coverage: ... (4) Have or implement a categorical coverage exclusion or limitation for [add/strikethrough: all] health services related to gender transition or other gender affirming care." Sect or 92.207(b)(5) would be clearer if shortened: "A covered entity must not in providing or administering health insurance coverage or other health-related coverage ... (5) Otherwise deny or limit coverage deny or limit coverage of a claim or impose additional cost sharing or other limitations or restrictions on coverage for specific health services related to gender transition or other gender affirming care [shortenough: if such denial limitation or restriction results in discrimination on the basis of sex."]

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ating Disorders Association for Research Policy & Action

Protections against Discrimination on Basis of SexSex discrimination disproportionately impacts women LGBTQ+ people and individuals living at the intersections of multiple identities. This frequently results in access to less affordable health coverage and lower quality health care ranging more frequently receiving improper diagnoses being prevented lawful effective treatment and sometimes being denied care altogether. As the first broad prohibition against sex discrimination in health care § 1557 is crucial to ending gender-based discrimination by health care providers and health insurers. Gender identity and sexual orientationWe applaud HHS for articulating clear and expansive explanation of discrimination on the basis of sex. Supreme Court cases like including Price Waterhouse v. Hopkins and Bostock v. Clayton County makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity including transgender status. It is essential that this rule track those decisions to provide assurance to participants beneficiaries and enrollees and notice to covered entities that these bases are unequivocally included. We also support the explicit inclusion of discrimination based on sex characteristics including intersex traits as such discriminatory and inherently sex-based. While the terms "gender identity" and "transgender status" are often used interchangeably there have been instances in which those seeking to permit discrimination against transgender people have just cited to by pressing distinctions between the two concepts. Therefore explicit language is needed to prevent this discriminatory and consistently throughout the final rule is important. We therefore recommend also including "transgender status" in § 92.206(b)(1) (b)(2) and (b)(4) and in §92.207(b)(3)

ealth Care For All

[Bold: Relevance of sex based distinctions [and sex based language]:] The proposed rule's arbitrary exclusion from coverage determinations or service provision of sex-based language and sex-based clinical treatments puts patients in a precarious position. It is undisputed the medical fact that certain kinds of care are appropriate only for individuals of a particular sex. Providers should not be forced to ignore the relevance of sex based distinctions but this is clearly what is intended under the proposed rule's "gender identity" regime. The Rule provides the example of a "health plan that excludes coverage for surgery such as a vaginoplasty and penile metoidioplasty for any enrollee whose sex assigned at birth is male while providing coverage for such medically necessary surgery for enrollees whose sex assigned at birth is female is discriminatory on its face." [Footnote 105: "For example a health plan that excludes coverage for surgery such as a vaginoplasty and penile metoidioplasty for any enrollee whose sex assigned at birth is male "while providing coverage for such medically necessary surgery" for enrollees whose sex assigned at birth is female" is discriminatory on its face." Similarly the Rule includes a general prohibition on the denial or limitation of health services including those that are offered exclusively to individuals of one sex to any individual based on the individual's sex assigned at birth gender identity or gender otherwise recorded." [Footnote 104: 87 Fed. Reg. 47865.]

thics & Public Policy Center

The Department's proposal to once again recognize Section 1557's application to private insurance continues the aim of properly implementing Congress' intent when drafting Section 1557 to encompass all forms of healthcare access. According to data in a new report from the Center for American Progress [Hyperlink: https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtq-communities/] transgender and nonbinary people at large experience significant discrimination when seeking insurance coverage for medical care. Key findings include that in the past year: 30 percent of transgender or nonbinary respondents, or among 47 percent of transgender or nonbinary respondents of color reported experiencing one form of denial by a health insurance company;• 28 percent of transgender or nonbinary respondents including 29 percent of transgender or nonbinary respondents of color reported a denial of coverage for gender-affirming hormone therapy; and• 22 percent of transgender or nonbinary respondents including 30 percent of transgender or nonbinary respondents of color reported a denial of coverage for gender-affirming surgery.

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8 Members of Congress

relative coverage have long discriminated against applicants and enrollees on the basis of sex and intersecting identities. For example some insurance companies refuse to cover [embedded hyperlink text (https://www.kff.org/womens-health-policy/issue-brief/coverage and use of fertility services in the u s/)] certain types of care that are traditionally used by women such as in vitro fertilization [IVF]. Private and public insurers often discriminate based on relationship status and sexual orientation with policies that require single people or those in non-heterosexual relationships to pay out of pocket for a predetermined number of failed intrauterine insemination cycles before providing them coverage when different sex couples do not have to meet the same standard. The high cost and lack of coverage for fertility treatments including IVF are large barriers for people who experience multiple and intersecting forms of bias and discrimination including provider bias and harmful preconceptions about their desire and need for fertility treatment. Women of color have a long history of forced sterilization and reproductive coercion in this country and continue to report [embedded hyperlink text (https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-

up notions/disparities in access to effective treatment for infertility in the us-adfmembers.pdf)] that providers do not take their fertility concerns seriously instead "emphasizing] birth control over procreation." As the [Italics, Bolds] case eliminated the constitutional right to abortion it also undermined the right to privacy and cumbering other protected related rights to contraception consensual sexual contact and same-sex marriage. Many individuals already struggled to get full coverage or services for contraception but especially emergency contraception. Some state legislatures have banned emergency contraception [embedded Hyperlink text (https://www.guttmacher.org/state-policy/explore/emergency-contraception)] from their state family planning

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Endocrine Society

Pulmonary Fibrosis Foundation

National Disability Rights Network

The Leadership Conference on Civil and Human Rights

California Department of Health Care Services

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Multi Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

National Disability Rights Network

|Bold: Prohibiting Discrimination in Benefit Design|We strongly support the proposed provisions to prohibit discriminatory plan benefit design and marketing practices. Older adults are more likely to have chronic conditions and disabilities and therefore have higher health care needs. Despite established protections for people with pre-existing conditions insurers continue to discriminate against people with costlier conditions and greater needs by persuading them from enrolling or shifting more out-of-pocket costs to people with certain conditions |Footnote 14: How Much Does Health Spending Eat Away at Retirement Income? Center for Retirement Research at Boston College https://crr.bc.edu/wp-content/uploads/2022/07/IB_22-17.pdf (2022)| |Further the gap between coverage and high drug prices forces many older adults to rely on coverage assistance programs to pay for medications necessary to survive. One lady stated that her life-sustaining drug to treat her cancer costs more than $18000 per month and she utilizes the assistance program to cover her fee. |Footnote 15: Seniors Face Crushing Drug Costs as Congress Stalls on Capping Medicare Out Of Pockets KHN https://khn.org/news/article/seniors-face-crushing-drug-costs-as-congress-stalls-on-capping-medicare-out-of-pockets/ (2021)| |We particularly support the proposal to incorporate the integration mandate in HHS's Sec. 504 regulations into Sec. 1557. this provision is necessary to help ensure people with disabilities including older adults are able to get the health coverage they need to live in the community and are not unjustly institutionalized. We agree that the proposed prohibition on not providing or administering coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities should apply both to benefit design and to implementation of a benefit design

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Center for Elder Law & Justice

[§92.207]: The section prohibits covered entities from having or implementing a benefit design that does not provide or administer health insurance coverage or other health-related coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities |The specific prohibitions on discrimination proposed subsection 92.101(b)(1) also incorporates existing Section 504 regulations at 45 CFR Part 84 including 45 CFR 84.4(b)(2).)|Recommendation: BLBSA recommends that the final rule clarify that the most integrated setting requirement does not require changing the nature of the program or otherwise require services that are not clinically appropriate. Specifically we recommend that the language underlined below be added to §92.207(b)(6).|6| Have or implement benefit designs that do not provide or administer health insurance coverage or other health-related coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities |underlined| unless| |modifying the benefit design would fundamentally alter the nature of the health insurance coverage or other health-related coverage or|a| the care setting is clinically appropriate for the benefit design.|Rationale: Providing coverage to qualified individuals with disabilities in the most integrated setting appropriate should not be done in a way that unnecessarily increases costs for all enrollees. Specifically this provision should not prohibit routine and nuanced ministerial medical management strategies such as prior authorization or step therapy for outpatient settings. This proposed clarification would be consistent with 45 CFR 84.4(b)(2) which explicitly provides that "For purposes of this part, aids benefits and services to be equally effective are not required to produce the identical result or level of achievement for handicapped and nonhandicapped persons but must afford handicapped persons equal opportunity to obtain the same result to gain the same benefit or to reach the same level of achievement in the most integrated setting appropriate to the

Blue Cross Blue Shield Association

We also strongly support the proposed rule's § 92.207(b)(6) which explicitly requires covered entities to provide or administer health insurance coverage or other health-related coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities. This aligns the rule with governing Supreme Court precedent in |Italics| Olmstead v. L.C. ex rel. Zimring| |Footnote 17| Olmstead v. L.C. ex rel. Zimring, 527 U.S. 581 (1999). | and allows patients with disabilities and disability advocates to highlight the increased risk of isolation unmet health care needs and lost functional capacity when public and private insurance providers and policies place arbitrary restrictions on when and where services or treatments may be provided

Center for Reproductive Rights

|Bold: Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage §92.207| |Bold: TPCA is supportive of the proposal in §92.207 as this would prohibit discrimination against patients with Medicaid Medicare Part B and coverage through the federal marketplace.| For decades health centers have developed extensive partnerships with state Medicaid agencies and nearly 88% of health center patients are Medicaid beneficiaries. Additionally about 11% of patients have Medicare and 20% have private insurance.While benefits for Medicaid and Medicare are continuing to become more robust and inclusive beneficiaries have limited options for providers facilities and services depending on which state they are located in. Medicare and Medicaid beneficiaries deserve access to equitable quality health care regardless of their income or location. The combination of discriminatory and social determinants of health can discourage patients from seeking primary care and routine services. TPCA appreciates HHS taking steps to protect patients with insurance coverage that falls under the definition of Federal Financial Assistance this includes the design of health insurance benefits marketing practices and coverage provisions.Health centers across the country write away millions of dollars of "bad debt" for those who lack the financial means to pay for the care they need. This frequently happens when patients seek care that falls outside of their insurance coverage because of their gender identity or reproductive status. Oftentimes Medicare and Medicaid patients cannot afford to pay out of pocket thus prevent ing them from receiving necessary services. However patients know they can receive the care they need at their local health center. Living true to the health center mission our patients do not have to choose whether they can afford paying for the care they need or paying for life essentials such as food housing or transportation

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Tennessee Primary Care Association

|Bold: Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage §92.207| MNACHC is supportive of the proposal in §92.207 as this would prohibit discrimination against patients with Medicaid Medicare Part B and coverage through the federal marketplace.| For decades health centers have developed extensive partnerships with state Medicaid agencies and nearly 88% of health center patients are Medicaid beneficiaries. Additionally about 11% of patients have Medicare and 20% have private insurance. While benefits for Medicaid and Medicare are continuing to become more robust and inclusive beneficiaries have limited options for providers facilities and services depending on which state they are located in. Medicare and Medicaid beneficiaries deserve access to equitable quality health care regardless of their income or location. The combination of discriminatory and social determinants of health can discourage patients from seeking primary care and routine services. MNACHC appreciates HHS taking steps to protect patients with insurance coverage that falls under the definition of Federal Financial Assistance this includes the design of health insurance benefits marketing practices and coverage provisions. Health centers across the country write away millions of dollars of "bad debt" for those who lack the financial means to pay for the care they need. This frequently happens when patients seek care that falls outside of their insurance coverage because of their gender identity or reproductive status. Oftentimes Medicare and Medicaid patients cannot afford to pay out of pocket thus preventing them from receiving necessary services. However patients know they can receive the care they need at their local health center. Living true to the health center mission our patients do not have to choose whether they can afford paying for the care they need or paying for life essentials such as food housing or transportation

Minnesota Association of Community Health Centers

|Italics: Integration Mandate|We strongly support the proposal in § 92.207(b)(6) to explicitly incorporate the Sec. 504 integration mandate into Sec. 1557 and are pleased to see the examples that HHS is contemplating this provision would apply to particularly Medicare Advantage and Medicaid. This is an important and necessary step to root out the deeply imbedded institutional biases in our health care and LTSS systems

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Justice in Aging

the most integrated setting appropriate to the needs of qualified individuals with disabilities should apply both to benefit design and to implementation of a benefit design. We offer these additional examples that we believe this rule can help address: Medicare's current narrow reading of the statutory requirement that durable medical equipment must be used in the home results in denials of coverage for items like wheelchairs which an individual may not need to move around their house but which they do need in order that are necessary for individuals to live successfully at home in the community—to go shopping attend a religious service attend congregate social activities or engage in other essential activities of community life. Federal Medicaid policy that prohibits federal matching dollars for retroactive coverage of HCBS [except for federal funds being paid for retroactive coverage of nursing facility costs] leaves many older adults who need LTSS with no choice but to enter a nursing facility even if their needs could be met at home or in another more integrated community setting. Policies that limit the number or types of services that can be delivered in a single run nation ofs t impose particular barriers on people with disabilities who often have more medical care needs. For example we have heard of state Medicaid programs denying reimbursement for treatment of more than one diagnosis in the same office visit or limiting the number of "procedures" per visit. These types of limits do not exist in institutional settings. For someone who does not have access to reliable transportation or for Native elders who live in remote locations and have to travel multiple hours to reach providers these types of limits can prevent them from getting the care they need while living at home. They also disproportionately negatively impact individuals with mental health conditions such as anxiety or depression who find even a single trip outside the home difficult to manage or those who need to coordinate trips with the schedule of an accompanying caregiver. - Poor quality non-emergency medical transportation

[Bold. TPCA also strongly supports CCR's proposal to treat Medicare Part B payments as federal financial assistance (FFA) and Part B providers and suppliers as recipients under Title VI, Title IX Section 504 and the Age Act.] This change in interpretation is well-supported by how the Part B program has evolved the fact that most Part B providers are already receiving other forms of FFA and the clear intent of the 1557 statute itself. eliminate confusion for older adults and people with disabilities and help ensure that people with Medicare have the same protections and rights regardless of the Medicare provider they choose the Medicare covered service they are receiving or whether they are in Original Medicare or Medicare Advantage. Bringing all Medicare providers under this rule will also help increase access to quality health care for underserved communities who face the most discrimination and there are many Medicare providers serve people with other forms of insurance. TPCA agrees with HHS' judgment that the statutory text of Section 1557 is clear: Congress intended that the law apply to these entities and address these issues. [Bold. This TPCA strongly supports HHS' restoration of and improvements to § 92.207, re ecting its inclusion of specific forms of prohibited discrimination.]

[Bold. Design features that result in unnecessary segregation or institutionalization of individuals with disabilities or place them at serious risk of institutionalization or segregation. HEC opposes institutionalization. It is ideal for people with IDD to be in the community not in institutions. There has been a [Hyperlink history of mistreatment: https://oxfordre.com/socialwork/view/10.1093/acrefore/9780199975839.001.0001/acrefore-9780199975839-e-1493?rskey=KVI3G8&result=2] of institutionalized individuals. New Hyperlink York's Willowbrook State School: https://timeline.com/willowbrook-the-institution-that-shocked-a-nation-into-changing-its-laws-c847acb44e0d] for many patients with mental disabilities spurred the deinstitutionalization movement. Soon after it opened in 1947 this facility was overfilled and understaffed. At full capacity in the mid 1950s there were widespread hepatitis infection among patients and employees. In 1960 a measles outbreak caused 60 patient deaths. Although this facility was named a school teaching occurred for only a small number of students for approximately two hours each day. The institution's patients were neglected. Some were in inhumanly waste remains. Sexual and physical abuse and disease were common

[Bold: Examples of how state Medicaid agencies can avoid creating incentives for institutional services over home and community-based services through policies on reimbursement scope of services service authorization and the like] Four fifths of a million people with IDD use HCBS. [Hyperlink As of 2020, https://www.kff.org/health-reform/state-indicator/participants-by-hcbs-waiver-type/?activeTab=map&activeTimeframe=0&selectedDistributions=idd&sortModel=%7B%22colId%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D] 813,000 people with IDD [Hyperlink] waiver participants comprising 42.39 percent of total waiver participants. [Hyperlink However people with IDD, https://www.kff.org/health-reform/state-indicator/waiting-lists-for-hcbs-waivers/?activeTab=map&activeTimeframe=0&selectedDistributions=total-waiting list enrollment&sortModel=%7B%22colId%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D] are disproportionately on HCBS waiver waitlists. [Hyperlink As of 2020, https://www.kff.org/health-reform/state-indicator/waiting-lists-for-hcbs-waivers/?activeTab=map&activeTimeframe=0&selectedDistributions=total-waiting list enrollment&sortModel=%7B%22colId%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D] 464538 people with IDD represent 29.00 percent of the total 865015 people who are on the 1915(c) and Section 1115 HCBS Waivers waitlists. HHS should ensure better financing of HCBS. It should consider making part of HCBS coverage an essential plan benefit so commercial insurers will also support these services. Medicaid cannot finance all of HCBS.

[Bold: Insurance Coverage.] We strongly support the proposed provisions to prohibit discriminatory plan benefit designs and marketing practices by insurers. Particularly we support the following provisions:• Covered entities could not—on the basis of race color national origin sex age or disability—deny cancel limit or refuse to issue or renew coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage,• Covered entities could not adopt marketing practices or benefit designs that discriminate on the basis of race color national origin sex age or disability; and• Covered entities also could not have benefit plan design that do not provide or administer coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities. An example of this would be if a plan required utilization management for someone in the community but not for someone in an institution.

As described in the proposed rule, certain utilization management can include prior authorization step therapy (or "fail first") and durational or quantity limits. While CMS states that utilization management controls "are standard industry practices that are permitted under Section 1557," we are pleased that you have added [Italics] "...as long as they are applied in a neutral nondiscriminatory manner and are not otherwise prohibited under other applicable Federal and state law. Excessive use or administration of utilization management tools that target a particular condition that could be considered a disability or other prohibited basis could violate Section 1557. For example prescription drug formularies that place utilization management controls on most or all drugs that treat a particular condition regardless of the reasons without placing similar utilization management controls on most or all drugs used to treat other conditions may be discriminatory under this section. Similarly benefit designs that place utilization management controls on most or all services that treat a particular disease or condition but not others may raise concerns of discrimination. Where there is an alleged discriminatory practice or action the covered entity would be expected to provide a legitimate non-discriminatory reason based on clinical evidence for the practice."]

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Justice in Aging

Tennessee Primary Care Association

Institute for Exceptional Care

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Institute for Exceptional Care

National Health Council

National Health Council

none str minatory decisions regarding individual care or coverage |HHS rightly draws this distinction which courts have recognized and which protects patients from discriminatory harm without interfering with protected medical judgment and individualized care. We also share HHS's concern that covered entities not be permitted to mask discrimination behind categorical policies criteria or categories that simply repackage unlawful sex based distinctions. We therefore recommend the following clarifications to the regulatory text In § 92.206 (c) Nothing in this section requires the provision of any health service where the covered entity has a legitimate nondiscriminatory reason for denying or limiting that service to an individual including where the covered entity typically declines to provide the any comparable health care services to any individual |Strikethrough: or where the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual.| However a provider's belief that gender transition |Strikethrough: or| other gender affirming care |Underline: or reproductive health care | including but not limited to termination of pregnancy| can never be beneficial for such individuals for its compliance with a state or local law that reflects a similar judgment] is not a |Strikethrough: sufficient basis for a judgment that a health service is not clinically appropriate] |Underline: legitimate nondiscriminatory reason for denying or limiting the health service.|In § 92.207 (c) Nothing in this section requires coverage of any health service where the covered entity has a legitimate nondiscriminatory reason for determining that such health service fails to meet applicable coverage requirements |Strikethrough: such as medical necessity requirements| in an individual case |Underline: provided that the coverage requirements or medical necessity standards are not discriminatory themselves or applied in a discriminatory manner.| We further encourage HHS state clearly in the final rule that the familiar but-for causation test applies to establishing a violation of Section 1557.

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InterACT Advocates for Intersex Youth

The scope of the final rule Rationale The Final Rule should recognize that Congress has historically treated excepted benefits (such as stand-alone dental and vision products and Medicare supplemental insurance) differently than traditional health insurance coverage. Most provisions of Title XXVII of the Public Health Service Act (PHSA) Part 7 of the Employee Retirement Income Security Act (ERISA) and Chapter 100 of the Internal Revenue Service Code (the Code) do not apply to excepted benefits as defined in Section 2791 of the PHS Act Section 733 of ERISA and Section 9832 of the Code. Applying these provisions to excepted benefits could lead to significant disruption of these products.As with HRAs sweeping in excepted benefits would also create an unlevel playing field with carriers specializing in excepted benefits which do not receive federal funds from HHS. This would not just affect excepted benefits but would also have serious unanticipated consequences for the exchange market. The market for such excepted benefits as dental vision and Medicare supplemental insurance is mature and stable and not subject to the wide swings in profitability that individual health insurance exchanges have historically experienced. If offering health benefits in an exchange means that issuers' excepted benefits are subject to the significant administrative requirements of Section 1557 it will place those products at a competitive disadvantage to competitors in the excepted benefits market that are not covered entities ultimately discouraging them from participating in the exchange market and thus reducing the options available to consumers

Blue Cross Blue Shield Association

Scope of Applicability and Applicability to Excepted Benefits and Short-Term Limited Duration Insurance § 92.207 applies to all of a health insurer's programs and activities when providing health insurance including excepted dental benefits. The ADA agrees with the Department that the issuers of excepted dental benefits should be held to the same standards as dental offices.

American Dental Association

Covered Health Programs and Activities We applaud HHS for clarifying that the scope of Section 1557 covers an expansive range of programs and activities consistent with Congressional intent. We support the Department's proposal to return to the 2016 interpretation that applies Section 1557 to all health programs and activities receiving funding from the Department or administered by the Department such as state or federally-facilitated Exchanges health insurance issuers that receive federal financial assistance and third-party administrators (or Pharmacy Benefits Managers) [Footnote 1: Nondiscrimination in Health Programs and Activities 87 Fed. Reg. 47824 47858 (proposed Aug. 4 2022) (to be codified at 42 CFR Parts 438 440 457 and 460)] We also support the proposed rule's expanded enforcement of nondiscrimination in health insurance coverage to include discriminatory health plan designs adopted by group health plans as well as marketing practices [Footnote 2: 87 Fed. Reg. at 47876 47912 (Proposed § 92.4)].

Senate Democrats

• Application to Markets BCBSA supports a broad application of Section 1557 but recommends that it not be extended to markets where it would create an unlevel playing field and steer consumers away from covered entities. This includes operations related to acting as a third-party administrator (TPA) for self-funded group health plans and excepted benefits such as dental vision and Medicare supplemental insurance where many entities are not subject to the rule. The scope of the final rule should not extend to or Administrative Services Only (ASO) or State Drug Assistance Program (SDAP) contracts administered by a covered entity as it would create an incentive for plan purchasers to cease doing business with a covered entity.

Blue Cross Blue Shield Association

We similarly support the clarification that issuers that receive federal financial assistance are covered entities. In instances in which they are acting as a third-party administrator for a self-funded group health plan even if the group health plan itself does not receive federal financial assistance. These proposed policies will reverse the Trump Administration's harmful actions that narrowed the scope and application of Section 1557 and left many consumers without fundamental civil rights protections. The proposals will also help achieve health equity improve health outcomes and ensure that individuals can access health care without unnecessary barriers

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U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

2. Scope – Applicability: In addition to applying to covered health insurance issuers inside and outside of exchanges in the individual and group markets Medicare Advantage organizations Medicare Part D plan sponsors and Medicaid managed care organizations the Proposed Rule also would apply to a covered issuer's excepted benefits and its operations related to acting as a third-party administrator (TPA) for self-funded group health plans.Recommendation 1:BCBSA recommends that TPA operations be excluded from the scope of the final rule whether the TPA is connected to a covered entity or not. Rationale BCBSA supports a broad application of Section 1557 but recommends that it not be extended to markets where it would create an unlevel playing field and steer consumers away from covered entities. Numerous entities providing insurance or ASO services to employers fall completely outside the scope of Section 1557 creating an unlevel playing field for those TPAs that would be considered in-scope by connection to a covered entity. This would place issuers that participate in programs that receive federal funds at a competitive disadvantage to TPAs and issuers who do not participate in programs that receive federal funds from HHS. This may lead to some employers that are not subject to the rule (i.e. those employers not receiving federal funds from HHS) purchasing insurance or ASO services from insurers and TPAs that do not receive federal funds from HHS to avoid the administrative burden of the new requirements. This might have unintended consequences in markets that trigger being subject to the rule such as participating or exchanges as some entities might not participate in those markets as they view the requirements this triggers as burdensome and adding cost to their TPA business

Blue Cross Blue Shield Association

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[Bold: Applicability] NAHU members would appreciate it if in any final rule HHS were to provide greater clarification about the applicability of the proposed rule. What constitutes a covered entity and applicable health programs and activities are in some cases very clear and in other cases not at all. The proposed rule explicitly does not include all group health plans on the lengthy list of health programs. The proposed rule affects directly based exclusively on rates that a covered entity's employee benefit plan is not necessarily affected. However it does note that certain group health plans will be required to directly comply with the regulation. Further many more will be affected by its requirements due to the applicability of regulation to either the health insurance carrier that bears the risk for their plan or to a carrier or other covered entity that provides administrative services to the plan or serves as a third party claims administrator. NAHU members believe to increase regulatory compliance and mitigate compliance costs for employer group plan sponsors any final rule should provide clearer delineation and direct examples of instances when and how this regulation will apply to different types of group health benefit plans.

As part of this clarification our associate urges HHS to provide more detailed information including numerous clear examples about HHS based funding streams that may directly or indirectly flow to a group health plan. There by requiring the employer group health plan to comply with all provisions of the proposed rule. For example if an applicable large employer has employees eligible for coverage who obtain federally subsidized health insurance coverage through a health insurance exchange marketplace would this constitute an indirect source of funding? What about Medicare employer group waiver plan [EGWP] participants? Suppose the federal government implements new subsidies for employer-based health insurance coverage such as the funding made available to both employer groups and individuals during the height of the COVID 19 pandemic (PPP loan funds recent or tax credits paid leave credits COBRA subsidies etc.) Would these tax credits and subsidies qualify as indirect funding? No comments are associated with this issue.

[Bold: Network Adequacy] We appreciate the Department's attention to network adequacy and how plan choices regarding provider networks may violate Section 1557. People with disabilities rely on specialists for many aspects of their medical care and many managed care systems are based on the premise of funneling the most commonly accessed medical services which frequently includes specialists. That states need to strengthen their network adequacy provisions to ensure they are also covering the medical services of a wide spectrum of specialists.

Rule notes that certain health insurance plans may violate Section 1557 by creating "narrow networks" that exclude physicians and other health care providers who may treat conditions associated with higher medical costs. The purpose of such a network design is to allow insurers to offer lower premiums by limiting the group of providers available to those enrolled in the plan. However narrow networks erect insurmountable barriers to health care access especially for the very sick and those living with complex medical conditions who may not be able to receive treatment from a certain specialist because of the exclusion from a narrow network. For example the Proposed Rule properly notes that narrow health care networks may exclude care for people living with disabilities and transgender people seeking gender-affirming care. The design of narrow networks also disparately impacts people of color and raises discrimination concerns. Studies have shown that people living with low incomes without employer sponsored health insurance and the uninsured are more likely to select health insurance plans with narrow networks. Another study of insurance plans across 37 states showed that Hispanic people were "significantly more likely to be in a narrow-network plan than in a plan with a broad network while the opposite was true for non-Hispanic white people" and that enrollment disparities also exist for Black people. Consequently narrow networks regularly exclude acute care and academic hospitals which may disparately impact people of color. In exchange for higher rates these hospitals are more likely to be "engaged in medical education, offer specialized expensive services typically associated with tertiary care hospitals; and serve a higher percentage of low income (and poorly reimbursed) patients." Notably analysis of data on inpatient hospitalizations in the period 2012 14 for Medicare beneficiaries ages 65 and older revealed that academic hospitals serve larger proportions of Black beneficiaries compared to non-teaching hospitals. A related study also found that people treated at

1.2. Network Adequacy [Preamble] The Preamble recognizes that network adequacy is regulated by other HHS regulations and that this limits the scope of Section 1557 to establish uniform or minimum network adequacy standards. However the Preamble does note concerns with the prevalence of narrow networks that could limit or deny access to care for individuals with certain disabilities. HHS solicited comments on a range of issues including how Section 1557 might apply to provider networks and the ways in which provider networks limit or deny access to care for individuals on the basis of race color national origin sex age or disability. Recommendation: BCBSA agrees with HHS that network adequacy is governed by other federal and state requirements and is generally outside the scope of Section 1557. Rationale: BLBS companies are historically known for offering broad networks and when they offer high value networks they are not developed in a way that is discriminatory. HHS has sufficient authority outside of Section 1557 to address issues of network adequacy in specific health programs– as the Preamble recognizes. Shoehorning another duplicative layer of network adequacy requirements into Section 1557 would add unnecessary regulatory uncertainty in an area where other regulatory requirements continue to evolve (e.g. the new network adequacy requirements in the 2023 Notice of Benefit and Payment Parameters). This would not be helpful for either consumers or the federal government. Health plans would be disincentivized from developing cost effective networks. If they could not rely on compliance with the regulations directly governing those networks to protect them from regulatory censure. The result would be fewer choices and higher costs for members the federal government and ultimately taxpayers.

Network Adequacy We encourage OCR to state that issues may be in violation of nondiscrimination requirements through provider networks if individuals are unable to access providers who meet their unique needs. We believe that provider networks cannot ensure meaningful access for individuals with LEP if they exclude qualified and willing providers who are fluent in languages commonly spoken in a community. We continue to hear a strong preference for such providers from partner community groups and we know increasing workforce diversity continues to be a priority for this administration. For example if there is a large and growing community of speakers of a language in a metropolitan area including health providers from that community but an insurance carrier operating in the area does not contract with any of them that may indicate a failure to provide meaningful access to individuals with LEP.

- Network Adequacy Requirements. BCBSA agrees with HHS that network adequacy is governed by other federal and state requirements and is outside the scope of Section 1557. To the extent that HHS has concerns regarding network adequacy we strongly recommend that they be addressed through those regulations that directly govern provider networks to avoid dual regulation that both initially and increasingly overtime may not have the same requirements.

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National Immigration Law Center

Blue Cross Blue Shield Association

are a growing problem and that Sec. 1557 can and should be used to help stop discriminatory network designs. HHS asks for comment on how Sec. 1557 might apply to provider network development. One factor we recommend to be considered is whether the plan's contracting with existing providers reflects the populations with LEP in their service area. As discussed above, language is more than interpretation and translation, but involves cultural competency as well. For immigrant older adults it is important that the providers have familiarity with cultural understandings of health and wellbeing in order to provide effective healthcare. For example, a Vietnamese American doctor who speaks Vietnamese and has some familiarity with Vietnamese culture is likely to be better positioned to provide culturally appropriate care to other Vietnamese Americans than is a white doctor. Plans should also be required to analyze their service area and contract with providers especially essential community providers and providers of color. [Footnote 46: According to a Black older adult focus group participant commenting on the importance of being served by health professionals who relate to their lived experiences or share their identity, "I feel more comfortable with someone who does see me who can relate to me who knows what it's like to be me. There are certain things that you can't relate to without being in that community." Commonwealth Fund, What an Ideal Health Care System Might Look Like: Perspectives from Older Black and Latina Adults, [Jul. 21 2022], www.commonwealthfund.org/publications/2022/jul/what-ideal-health-care-system-might-look-like.] to ensure they are not perpetuating redlining or provider shortage areas where people of color live. [Footnote 47: Jamille Fields Allsbrook & Katie Keith, ACA Section 1557 As A Tool For Anti-Racist Health Care, Health Affairs (Dec. 8 2021)]

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https://www.healthaffairs.org/do/10.1377/forefront.20211207.962085/full/.]

Another factor should be adequate access to specialists who treat conditions that [illegible] also requests comment on the impact that the lack of accessible medical and diagnostic equipment (MDE) has in limiting or denying access to care. In addition to not being able to find providers especially specialists who have this equipment another way lack of accessible MDE limits access to care is that a person with a disability may be limited to seeing the one provider in network who has accessible MDE or required to travel farther or wait longer for an appointment. This is discriminatory when people without disabilities do not face these same barriers.

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Justice in Aging

No comments are associated with this issue.

Justice in Aging

Rule notes that certain health insurance plans may violate Sec. 1557 by creating "narrow networks" that exclude physicians and other health care providers who may treat conditions associated with higher medical costs. The purpose of such a network design is to allow insurers to offer lower premiums by limiting the group of providers available to those enrolled in the plan. However, narrow networks erect insurmountable barriers to health care access, especially for the very sick and those living with complex medical conditions who may not be able to receive treatment from a certain specialist because of the plan's exclusion from a narrow network. For example, the Proposed Rule properly notes that narrow health care networks may exclude care for people living with disabilities and transgender people seeking gender-affirming care. The design of narrow networks also disparately impacts people of color and raises discrimination concerns. Studies have shown that people living with low incomes without employer-sponsored health insurance and the uninsured are more likely to select health insurance plans with narrow networks. Another study of insurance plans across 37 states showed that Hispanic people were "significantly more likely to be in a narrow network plan than in a plan with a broad network while the opposite was true for non-Hispanic white people" and that enrollment disparities also existed for Black people. Consequently, narrow networks regularly exclude acute care and academic hospitals which may disparately impact people of color. In exchange for higher rates, these hospitals are more likely to be "engaged in medical education, offer specialized expensive services typically associated with tertiary care hospitals, and serve a higher percentage of low-income [and poorly reimbursed] patients." Notably, analyses of data on inpatient hospitalizations in the period 2012–14 for Medicare beneficiaries ages 65 and older revealed that academic hospitals serve larger proportions of Black beneficiaries compared to non-teaching hospitals. A national study also found that people treated at

Alliance of Multicultural Physicians

Insurance Plan Benefit DesignDespite protections in the ACA, insurers still seek to avoid high-cost populations such as people with disabilities or chronic conditions as well as others with high health needs. We support strong regulatory protections prohibiting discriminatory plan benefit design and marketing practices. Without these provisions, health plans could for example cover inpatient treatment for mental health conditions for men but not women or cover certain categories for adults except those with developmental disabilities or place all or most prescription drugs used to treat a certain condition on a health plan's highest cost formulary tier. As just one example, private insurers often place stringent utilization management controls on medications that are primarily used by people with specific chronic conditions such as AIDS/HIV. Nationally and in the Commonwealth, People of Color face higher rates of chronic disease such as diabetes, obesity, stroke, heart disease, and cancer. [Footnote 10: Kenneth E. Thorpe et al., The United States Can Reduce Socioeconomic Disparities By Focusing On Chronic Diseases, Health Affairs (August 17 2017), https://www.healthaffairs.org/do/10.1377/forefront.20170817.061661/full/.] Regardless of benefit design, more Black and Latina families in Massachusetts report challenges paying medical bills and are more likely to report having unmet needs for medical care. [Footnote 11: 2021 Cost Trends Report, Massachusetts Health Policy Commission, (September 2021), https://www.mass.gov/doc/2021-health-care-cost-trends-report/download.] Ensuring access to services and medications for people who already face affordability barriers is critical to realizing the goals of the ACA and § 1557.

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Health Care For All

related coverage have long criminalized against applicants and enrollees on the basis of sex and intersecting identities. For example, some insurance companies refuse to cover [embedded hyperlink text (https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/)] certain types of care that are traditionally used by women such as in vitro fertilization (IVF). Private and public insurers often discriminate based on relationship status and sexual orientation with policies that require single people or those in non-heterosexual relationships to pay out of pocket for a predetermined number of failed intrauterine insemination cycles before providing them coverage when different-sex couples do not have to meet the same standard. The high cost and lack of coverage for fertility treatment including IVF are large barriers for people who experience infertility and intersect with forms of bias and discrimination including provider bias and harmful preconceptions about their desire and need for fertility treatment. Women of color have a long history of forced sterilization and reproductive coercion in this country and continue to report [embedded hyperlink text (https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/disparities_in_access_to_effective_treatment_for_infertility_in_the_u.pdf#members.pdf)] that providers do not take their fertility concerns seriously instead "emphasizing] birth control over procreation." As the [Italics, Nobis] eliminated the constitutional right to abortion, it also undermined the right to privacy and cunsurring doctrines attacked related rights to contraception or consensual sexual contact and same-sex marriage. Many individuals already struggled to get full coverage or services for contraception, and especially emergency contraception. Some state legislatures have banned emergency contraception [embedded hyperlink text (https://www.guttmacher.org/state-policy/explore/emergency-contraception)] from their state family planning

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Physicians for Reproductive Health

over discriminatory value assessment methodologies. The disability community has long been concerned with a particular tool used in value assessment known as the Quality-Adjusted Life Year (QALY). Similar metrics may be known as Disability Adjusted Life Year (DALY) or related terms. In this comment we will refer to QALYs but intend this to apply to DALYs or other similar metrics. All of these metrics seek to measure how much less value (to society and to the individual) a year of life lived with a disability is compared to a year of life in "perfect health." We are concerned about the use of QALYs in any health-related context. We are most concerned about the use of QALYs in making coverage and access determinations such as benefit design formulary design and utilization management. The concept of the QALY is concerning on its face. It is based on the assumption that a year of life with a disability is inherently of lower quality and lower value to the individual and to society than life without a disability. The methodologies used to create the QALY pose greater concerns. These methodologies are based on surveys of the general public on their preferences for different health states. There is significant evidence that the general public has negative attitudes toward disability and people with disabilities. Congress recognized that people with disabilities face discrimination from the general public when it passed disability civil rights statutes, including the Rehabilitation Act Individuals with Disabilities Education Act and the ADA. The National Council on Disability (NCD) undertook a series of reports in 2018 regarding biases and the ways in which the lives of people with disabilities are undervalued in the health care system. NCD recommended that CCIIO, in conjunction with other applicable agencies, issue guidance that "payment decisions should not rely on cost-effectiveness research or reports that are developed using QALYs," and that "covered health insurance programs should not rely on cost effectiveness research or reports that gather input from the public on health preferences that [QALY Value Assessment Methodologies]. The NHC applaud[s] the CMS is using

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The proposed rule to explore the civil rights implications of value assessment methodologies and value-based purchasing arrangements. The NHC is committed to the promotion of high value care and works to ensure that the cost of health care products and services align with value to the patient. The NHC recognizes patients as the source of authority on defining "value" in the context of the health care system and therefore urges CMS to incorporate a patient-centric perspective in any efforts to eliminate discriminatory implications of value assessment. If value is defined from an appropriate patient perspective it will better meet the needs of all patients. It is also important that evidence about value should not come from comparative clinical effectiveness research that treats extending the life of an elderly disabled person terminally ill individual as of lower value than extending the life of an individual who is younger non disabled or not terminally ill

Nationa Health Council

No comments are associated with this issue

remains a common concern in the health care context. [We support the Department's proposed new §92.208 prohibition on sex discrimination related to marital parental or family status. Sex discrimination in the context of marital parental or family status remains a common concern particularly in the area of reproductive health care. We note that the proposed rule limits the application of this nondiscrimination provision to prohibiting the consideration of an individual's sex in the application of "[Italics: any rule] concerning an individual's current perceived potential or past marital parental or family status." [Footnote 27: 87 Fed. Reg. 149 n.47318. [Aug. 4 2022].] [Emphasis added.] This construction importantly would address some types of discrimination experienced by same-sex couples in the health care context. For example the provision would prohibit insurance plans from denying access to IVF for same sex married couples where the plan requires beneficiaries to be both married and in a different sex relationship to access the coverage benefit. [See e.g. the example of DSF HealthCare a self-insured Catholic hospital system with facilities in Illinois and Michigan which recently adopted an insurance policy for its employees that limits IVF coverage to "married couples" of opposite sex spouses." [Footnote 28: Shira Stein Hospital Chain Blanks Formerly Coverage for its LGBTQ Employees BLOOMBERG LAW [July 18 2022] https://www.bgov.com/core/news_articles/RF7N1HTDG1LR.] However the proposed rule fails to address marital status discrimination that occurs outside of the application of a rule. Individual bias by health care providers against the use of birth control and sterilization for single unmarried and/or childless patients that results in denial of the care may also be prohibited discrimination under Section 1557. For example it is common for some health care providers to deny hormonal birth control to single and unmarried patients or to deny UD placement or hysterectomies to patients who are unmarried childless or are not

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previsions relating to discrimination on the basis of sex HHS is proposing to ensure equal access to health care programs or the basis of sex and prohibit discrimination based on marital family and parental [including termination of pregnancy] status along with gender identity and sexual orientation. ANA notes that these protections are vital and urges the agency to finalize these provisions. At the same time ANA encourages HHS to utilize nurses and their expertise to ensure compliance with these important protections. ANA and its members strongly believe that discrimination has no place in nursing practice education or research. It has no place in health care and nurses strongly believe that all patients be treated equally respectfully and with civility. [Footnote 2: The Nurse's Role in Addressing Discrimination: Protecting and Promoting Inclusive Strategies in Practice Settings Policy and Advocacy. American Nurses Association. 2018 https://www.nursingworld.org/~4abb21/globalassets/practiceandpolicy/nursing-excellence/ana-position-statements/social-issues-and-health-care/the-nurses-role-in-addressing-discrimination.pdf. Accessed September 2022] This is especially important to safeguard access for people who often face multiple barriers to care including LGBTQ+ individuals. For these individuals sex discrimination may take specific form in health care such as coverage limitations and encounters with providers who deny them care based on their gender identity or sex-stereotyped characteristics. ANA is in the process of issuing a statement on gender affirming care which summarizes the association's strong position against policies that restrict or criminalize care to this vulnerable patient population. [Footnote 3: American Nurses Association. American Nurses Association Opposes Restrictions on Transgender Healthcare and Criminalizing Gender-Affirming Care. 2022. Unpublished Statement.] Without these protections providers and payers can deny care to transgender persons and to other LGBTQI+ patients based on sex stereotyping. This crucial work complements

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is essential to ensuring health coverage for women and other pregnant people.[While the majority of this regulation's beneficial the omission of an explicit protection for pregnancy related conditions must be addressed before this rule is finalized. The Department of Health and Human Services seemed to anticipate this seeking further input on these issues as well as the impact of the federal right to abortion being overturned in the recent Supreme Court decision Dobbs v. Jackson Women's Health Organization. The finalized rule should explicitly frame pregnancy termination in its definition of sex discrimination. Many criminalities could not access abortion care prior to the Dobbs decision and many criminalized communities will continue to bear the brunt of limited access to abortion bans are implemented [Footnote 22: Isaac Maddow-Zimet and Kathryn Kost "Even Before Roe Was Overturned Nearly One in 10 People Obtaining an Abortion Traveled Across State Lines for Care" Guttmacher Institute July 21 2022 https://www.guttmacher.org/article/2022/07/even-roe-was-overturned-nearly-one-10-people-obtaining-abortion-traveled-across] Protecting patients is even more important as criminalization of pregnancy outcomes increases and as some states seek to punish pregnant people for seeking abortions out of state [Footnote 23: "Criminalization and Civil Punishment of Pregnancy and Pregnancy Outcomes" National Advocates for Pregnant Women May 2020 https://www.nationaladvocatesforpregnantwomen.org/wp-content/uploads/2019/10/UPR-Crim-report.pdf. Caroline Kitchener and Devlin Barrett "Antiabortion Lawmakers Want to Block Patients From Crossing State Lines" The Washington Post June 30 2022 https://www.washingtonpost.com/politics/2022/06/29/abortion-state-lines/.] These attacks on abortion access are rooted in white supremacy and the states seeking to restrict abortion are those with the worst outcomes for Black women's maternal health [Footnote 24: Black Maternal Health Federal Policy Collective

The Century Foundation

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This exhibit protect or should be present at least two areas of the final rule regulation. First termination of a pregnancy should be explicitly named in the definition of sex discrimination at section 92.101(a)(2). This new definition could read: "discrimination on the basis of sex includes but is not limited to discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions [bold and italics "including termination of pregnancy] sexual orientation, and gender identity."

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The Century Foundation

Title VII Title IX's abortion neutrality and organizing definition of pregnancy is not an isolated ruling. Title VII's Pregnancy Discrimination Act addresses the limited short-term abortion exceptions and adds further insight into the original meaning of "pregnancy-related conditions." [Footnote 20: 42 U.S.C. 2000e(k)] Title IX relies on guidance from the Pregnancy Discrimination Act an amendment of Title VII for their definition of "sex". The Act bars employers from "discriminating against employees on the basis of pregnancy childbirth or related medical conditions." [Footnote 50: Ibid.] As the Department of Education clarifies in the proposed rule "The fact that Congress did not amend Title IX's definition of 'sex' to explicitly include pregnancy as it did for Title VII in 1978 does not signal Congress's intent to exclude pregnancy coverage under Title IX." [Footnote 51: Ibid.] Title VII's definition of sex then is the basis of Title IX's own interpretation. Under Title IX Title VII does not have an explicit abortion neutrality clause. It states that a company is not required to cover the cost of an abortion or their health insurance as a benefit or otherwise. They are however expected to cover medical issues that may arise from an abortion complication like excessive hemorrhaging. As it may result in subsequent surgeries or medical care beyond the scope of the abortion. Additionally employers are required to provide medical insurance coverage when the life of the mother is at risk. Title VII does not provide a clear definition as to what falls under the "or related medical conditions." clause though subsequent district court rulings and guidance announcements have clarified that it includes breastfeeding and complications arising from abortion. By following the Department of Education's own reasoning as it relates to Title VII and Title IX definitions and protections Title IX's proposed definition of "or related conditions" is derived from Title VII's "related medical conditions." The department defines Title IX's "pregnancy or related conditions" as "(1) Pregnancy childbirth termination of pregnancy or lactation.

The Heritage Foundation

Bold: Expanding patient protections will improve health equity]Discrimination in health care undermines the quality of that care and the burden of discrimination falls on already marginalized groups. The proposed regulations for section 1557 would make significant strides in preventing this discrimination especially for LGBTQ people and people who need language assistance. For patients who face discrimination these regulations would allow them some recourse to help make up for that harm. Unfortunately these regulations do not provide any protection for discrimination based on pregnancy status including pregnancy termination. These protections are essential in ensuring that patients are able to access the health care they need and are only more important to include given the devastating Supreme Court ruling in Dobbs v. Jackson Women's Health Organization. Before finalizing these rules the Biden administration should include the protections for abortion care described above in this comment. Doing so will ensure that the goal of section 1557 is better achieved.

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We support the explicit prohibition of discrimination on the basis of pregnancy or related conditions as a form of sex-based discrimination in the final rule. The proposed rule notes that HHS believes it could be "beneficial" to include a provision specifically prohibiting discrimination on the basis of pregnancy or related conditions as a form of sex based discrimination. We wholeheartedly agree. Following the devastating decision in Dobbs v. Jackson Women's Health Organization it is critical more than ever before that HHS clarify in the final rule that discrimination on the basis of pregnancy or related conditions— including termination of pregnancy— is explicitly considered a form of sex based discrimination throughout the regulation. [Footnote 18: Dobbs v. Jackson Women's Health Organization 597 U.S. __ 142 S. Ct. 2228 (2022).] The Dobbs decision has upended abortion access for millions of people throughout the United States and the impacts of this decision are most acutely felt by those who already face barriers to health care services including low income individuals women of color young women those with disabilities and LGBTQ+ individuals. [Footnote 14: See e.g. 1 in 3 American Women Have Already Lost Abortion Access. More Restrictive Laws are Coming. Washington Post (Aug. 22 2022).]

U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Additionally we recommend that the prohibition on discrimination of pregnancy or related conditions including termination of pregnancy should not be listed under Section 92.208. Including "pregnancy or related conditions including termination of pregnancy" discrimination could result in policies that are biased against single people who experience discrimination based on obtaining or having obtained an abortion. While this action is welcome for ensuring robust enforcement against sex being used to determine eligibility for a health program in specific instances including discrimination on the basis of abortion in this context could cause confusion that discrimination because of having had an abortion only occurs in a marital parental or family context. Enacting the following clarifying language or similar guidance if the department includes discrimination based on obtaining an abortion outside of Section 92.208

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The Leadership Conference on Civil and Human Rights

protections against sex discrimination related to pregnancy or related conditions. This approach is critically important in the wake of the Dobbs v. Jackson Women's Health Organizations decision. [Footnote 7: https://www.supremecourt.gov/opinions/21pdf/19-1392_6j37.pdf. The 2020 rule removed prior regulations that prohibited covered entities from discrimination based on pregnancy false pregnancy termination of pregnancy and recovery from childbirth or related medical conditions thereby opening women childbearing age to high-risk medical and emotional situations. Thus we encourage HHS to strengthen its approach to defining sex discrimination related to pregnancy or related conditions at § 92.101(a)(2) and throughout the regulatory text.Reproductive justice or advancing abortion rights can be understood as a human rights issue for section to racial structural and multiracial inequalities relying on psychological science. APA in 2022 again formally denounced abortion restrictions and reaffirmed its advancing reproductive justice for childbearing individuals especially for those from socially and economically marginalized communities. [Footnote 8: APA. (2022 February 1). APA Resolution Affirming and Building on APA's History of Support for Reproductive Rights. Washington DC https://www.apa.org/about/policy/resolution-reproductive-rights.pdf.] APA compiled and based decades of psychological research in policy statements amicus briefs and practice guidelines to demonstrate that people denied abortions are more likely to experience higher levels of anxiety lower life satisfaction and lower self-esteem compared with those who can obtain abortions [Footnote 9: https://www.apa.org/topics/abortion/]. Further research suggests that the inability to obtain an abortion increases the risk for domestic abuse among those who are forced to stay in contact with violent partners putting them and their children at risk. [Footnote 10: Roberts SCM Biggs MA Chibber KS Gist JI Rocca CH Foster DG. Risk of violence from the man involved in the pregnancy after

American Psychological Association

against patients in the treatment of pregnancy emergencies and complications including termination of pregnancy miscarriage management and other pregnancy outcomes.[/Italics] The final rule should clarify that EMTALA and 1557 apply to all emergency hospitals. We urge the Department to go further in explaining how Section 1557 and the Emergency Medical Treatment & Labor Act (EMTALA) each protect pregnant patients in emergency situations. The Rule should explain that EMTALA and Section 1557 each prohibit the denial of care including denying termination of pregnancy. EMTALA requires that participating entities provide stabilizing treatment to pregnant patients. [Footnote 36: U.S. DEPT. OF HEALTH & HUM. SERVS., HHS SECRETARY LETTER TO HEALTH CARE PROVIDERS ABOUT EMERGENCY MEDICAL CARE (July 11, 2022), https://www.hhs.gov/sites/default/files/emergency-med-cal-care-letter-to-health-care-providers.pdf.] Under Section 1557 refuses to provide pregnant patients with emergency care that may include termination of pregnancy is patently sex discrimination. EMTALA explicitly protects patients in situations that threaten their health and life and Section 1557 provides additional protections against discrimination on the basis of sex including abortion. We agree with the proposed rule's clarification that EMTALA protects emergency care for pregnancy or related conditions including termination of pregnancy. In the preamble to the proposed rule the Department explains that EMTALA protects the care a person needs when presenting with an "emergency medical condition." [Footnote 37: Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824 (proposed August 4, 2022) (to be codified at 42 CFR 438; 42 CFR 440.42; 42 CFR 457.42; 42 CFR 460.45; 42 CFR 80.45; 42 CFR 84.45; 42 CFR 86.45; 42 CFR 91.45; 42 CFR 92.45; 42 CFR 147.45; 45 CFR 155; and 45 CFR 156).] Both the proposed rule's preamble and the guidance provided by the Department on July 13, 2022 ("July guidance") make clear that the EMTALA statute preempts any state laws or mandates that employ a more

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[Bold and Italics: Prohibition on Sex Discrimination Related to Marital, Parental or Family Status.][§ 92.208(b)][Bold] The AAMC supports the proposal to expressly prohibit discrimination on the basis of sex with respect to an individual's marital, parental or family status similar to the Department's Title IX regulations.] The proposed provision would prohibit a covered entity from considering an individual's sex when applying any rule concerning an individual's current, perceived potential or past marital, parental or family status and is based on OCR experience with Section 1557 enforcement. [Footnote 11: 87 Fed. Reg. 47824 at 47878.] HHS asks whether to also include a provision to specifically address discrimination on the basis of pregnancy-related conditions. HHS believes it could be beneficial to expressly address pregnancy-related sex-based discrimination in order to ensure nondiscriminatory access to care. The AAMC believes that everyone should be able to access comprehensive health care including reproductive health care and we are concerned about the impact that the Supreme Court's decision in [Italics: Dobbs v. Jackson Women's Health Organization], may have on coverage and care. [Footnote 12: AAMC Statement on Supreme Court Decision in Dobbs v. Jackson Women's Health Organization (June 2022).] Considering the impacts of the changing landscape for access to reproductive health care we agree with the Department that a provision expressly prohibiting discrimination on the basis of pregnancy-related conditions as a form of sex-based discrimination is prudent.

Association of American Medical Colleges [AAMC]

[Underlined: Sex discrimination on the basis of marital, parental or familial status.] CalHHS welcomes the addition of an express prohibition against discrimination based on current, perceived potential or past marital, parental or family status. We also strongly support extending the proposed section 92.208 to prohibit discrimination on the basis of pregnancy-related conditions, including with respect to a person's decision to terminate a pregnancy. As highlighted above these bases are already codified in our state nondiscrimination law and is of heightened national importance due to the recent troubling setbacks in reproductive health freedoms and access notably the U.S. Supreme Court's decision in Dobbs v. Jackson Women's Health Organization, 142 S. Ct. 2228 (2022). CalHHS agrees with the preamble's reasoning to not impact the current abortion neutrality provision in Title IX given the absence of any such comparable test of Section 1557 and the referenced availability of existing federal statutory protections for health care entities and other individuals in the provision, payment or referral of abortion services.

California Department of Health Care Services

[Bold: 7. HHS cannot use Section 1557 to promote abortion and preempt state abortion laws.][Bold: A. Section 1557 does not prohibit discrimination based on pregnancy-related conditions.]HHS proposes that § 92.208 include a provision "to specifically address discrimination on the basis of pregnancy-related conditions." [Footnote 230: 87 Fed. Reg. 47878.] Under the Title IX proposed regulations "Discrimination on the basis of sex" would include discrimination on the basis of "pregnancy or related conditions" which is defined in regulations as "(1) Pregnancy, childbirth, termination of pregnancy or lactation, (2) Medical conditions related to pregnancy, childbirth, termination of pregnancy or lactation, or (3) Recovery from pregnancy, childbirth, termination of pregnancy, lactation or their related medical conditions." [Footnote 231: 87 Fed. Reg. 41568.] "Termination of pregnancy" is not defined in the proposed Title IX regulations. This definition of "pregnancy-related conditions" should not be adopted.

Ethics & Public Policy Center

The Proposed Rule arbitrarily and capriciously fails to recognize the biological reality that only females can get pregnant and give birth—a reality that is recognized in the ACA itself. [Footnote 235: See, e.g., ACA Section 4503 ("pregnant woman"); Section 2951 ("a woman who is pregnant"), Section 1945 ("pregnant women"); Section 2303 ("pregnant women"), Section 2801 ("pregnant women"); Section 511 ("pregnant women"); Section 2952 (relative inherent health consequences for "women of reproductive age [pregnancy], Section 10213 ("pregnant and parenting women"), see also Section 3021 ("women's unique health care needs").] The Proposed Rule states that "transgender man or nonbinary person assigned female at birth" can give birth. [Footnote 236: 87 Fed. Reg. 47865.] No one is "assigned female at birth", a person is (or is not) a female and that biological reality is recognized at birth. Saying men cannot get pregnant or give birth and to imply otherwise is insulting and degrading to women. HHS as a federal health organization should not continue perpetuating unscientific forces and misinformation when it comes to human reproduction. Proposed § 92.206(b) should not use the nonsense and unclear phrase "sex assigned at birth." There is a more precise word that should be used: sex

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Ethics & Public Policy Center

[Bold: C. HHS should clarify that Section 1557 does not prohibit discrimination based on termination of pregnancy or abortion.] The Department should consider the alternative of not including "termination of pregnancy" as a pregnancy related condition or clarifying that "termination of pregnancy" does not cover abortion under 1557. Abortion is not the moral equivalent to pregnancy and childbirth and should not be treated as such. Further, if HHS finalizes a rule that promotes abortion it must consider the irreparable loss of life to unborn who are killed via abortion as a result of abortion required or promoted by Proposed Rule.

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assuring Americans access to emergency services irrespective of their financial or insurance status with the provision of stabilization and transfer to another facility if necessary. Since its inception EMTALA guidelines have not generated significant controversy or confusion. Unfortunately this is no longer the case. The Biden Administration is reinterpreting EMTALA in response to the US Supreme Court's overturning of Roe v. Wade. On July 11 2022 the Centers for Medicare and Medicaid Services (CMS) placed the health care industry "on notice" with regard to EMTALA. If a "pregnant patient" in the "emergency department is experiencing an emergency medical condition as defined by EMTALA and that abortion is the stabilizing treatment necessary to resolve that condition the physician must provide that treatment." Further CMS makes abundantly clear that regardless of a state's restrictions or prohibitions regarding abortion "state law is preempted". This unprecedented action by the Biden administration through CMS raises profound concerns particularly its inference that direct abortion is the medically indicated intervention in cases of pregnancy complication. Physicians and hospitals opposed to abortion provided high quality care to mothers and babies before and after the Roe decision in 1973 and in the post-Roe world their practices and high standards of care will not change. They will continue to focus on both lives: mother and child. They will not be deterred by the novel and highly problematic EMTALA guidelines emanating from the Biden administration that misleadingly seek to equate management of both ectopic pregnancy and miscarriage with abortion and that predict widespread injuries and deaths among women if state abortion restrictions are followed. We are dismayed by the Biden administration's new guidance regarding EMTALA and we ask the administration to rescind it immediately. Regardless of whether a woman experiences an ectopic pregnancy a miscarriage or another complication related to pregnancy pro life physicians and hospitals will continue to do what they have always done: respect protections for the full spectrum of reproductive health care including abortion care contraceptive care fertility care and prenatal birthing and postpartum care. [Bold: A. The final rule should clearly affirm that denial of abortion care is prohibited sex discrimination under Section 1557 [[Italics: i. Abortion is essential health care and we are experiencing a public health crisis with regard to abortion access in the United States. [Abortion is a normal and common part of health care. Everybody deserves to have access to abortion regardless of where they live and whether or how they are insured. And yet discrimination against people who have ended or are seeking to end a pregnancy is a common occurrence. Discriminatory health care can manifest as a denial of care incorrect or delayed diagnosis delayed treatment resulting in the deterioration of patient health or a dismissal of serious medical symptoms. [Footnote 1: See Zaven Vilines Effects of Gender Discrimination on Health MED CAL NEWS TODAY [Nov 23 2021] https://www.medicalnewstoday.com/articles/effects-of-gender-discrimination#examples [providing that "doctors are more likely to view women's chronic pain as psychological exaggerated or even made up in comparison with men's pain"] | Because "[p]atients rely on their health care providers to give them accurate information based on medical evidence and their health needs" [Footnote 2: NAT'L PSH P FOR WOMEN & FAMS BAD MEDICINE: HOW POLITICAL AGENDA IS UNDERMINING ABORTION CARE AND ACCESS IN OKLAHOMA (2019) https://www.nationalpartnership.org/our-work/resources/bad-medicine-in-oklahoma.pdf [doctors with a personal bias against abortion can cause substantial harm to patients seeking care particularly to those who seek care in emergency circumstances. [In addition abortion stigma [Footnote 3: Abortion stigma is rooted in sex based tropes that women and people capable of pregnancy are inherently nurturing and maternal expected by society to be chaste (which an unwanted pregnancy is seen as diametrically

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neutrality provision which states that "nothing in this chapter shall be construed to require or prohibit any person or entity or private entity to provide or pay for any benefit or service including the use of facilities related to an abortion. Nothing in this section shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion." [Footnote 28: 20 U.S.C. § 1681(a)] Additionally Title IX requires that institutions and individuals have access to strong religious liberty protections in the form of exemptions. Relying on HHS "applies by extension" the department fails to provide an explanation for why Section 1557's purported rule [Indicy/Bodd does not include an abortion neutrality clause nor does it import key religious exemption protections. If the department is supposedly relying upon Title IX's interpretation of sex which includes a poorly defined use of "termination of pregnancy" then it does not follow for HHS to abandon the longstanding abortion neutrality clause.

The Heritage Foundation

Title VII Title IX's abortion neutrality and longstanding definition of pregnancy is not abrogated by Title VII's Pregnancy Discrimination Act addresses the limited circumscribed abortion provisions and adds further insight into the original meaning of "or related conditions." [Footnote 29: 42 U.S.C. 2000e(k)] Title IX relies on guidance from the Pregnancy Discrimination Act an amendment of Title VII for their definition of "sex". The Act bars employers from "discriminating against employees on the basis of pregnancy childbirth or related medical conditions" [Footnote 30: Ibid.] As the Department of Education clarifies in the proposed rule "the fact that Congress did not amend Title IX's definition of 'sex' to explicitly include pregnancy as it did for Title VII in 1978 does not signal Congress's intent to exclude pregnancy coverage under Title IX." [Footnote 31: Ibid.] Title VII's definition of sex then is the basis of Title IX's own interpretation. Under Title IX Title VII does not have an explicit abortion neutrality clause. It states that a company is not required to cover the cost of an abortion or their health insurance as a benefit or otherwise. They are however expected to cover medical issues that may arise from an abortion complications like excessive hemorrhaging as it may result in subsequent surgeries or medical care beyond the scope of the abortion. Additionally employers are required to provide medical insurance coverage when the life of the mother is at risk. Title VII does not provide a clear definition as to what falls under the "or related medical conditions" clause though subsequent district court rulings and guidance announcements have clarified that it includes breastfeeding and complications arising from abortion. By following the Department of Education's own reasoning as it relates to Title VII and Title IX definitions and protections Title IX's proposed definition of "or related conditions" is derived from Title VII's "related medical conditions." The Department defines Title IX's "pregnancy or related conditions" as: "(1) Pregnancy childbirth termination of pregnancy or lactation, We further oppose the interpretation of Section 1557's incorporation of Title IX to exclude that law's longstanding religious exemption [See 20 U.S.C. § 1681(a)(3)] and its abortion neutrality provision [See 20 U.S.C. § 1688] which protects the rights of healthcare providers and entities like doctors nurses and hospitals to refrain from involvement in abortion. [See Doerflinger R. (2021) "The 'Equality Act': Threatening Life and Equality" available at https://ozinstitute.org/the-equality-act-threatening-life-and-equality/ detailing the history and purpose of Title IX's religious exception and abortion neutrality provision.]

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The Heritage Foundation

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Charlotte Lozier Institute

[halics Dobbs]. We expect a stark increase in prosecution for self managed abortion, as any other pregnancy outcomes such as miscarriage will also be the subject of prosecution. [Footnote 25: There have been over 60 documented cases of people being criminally arrested or investigated for self-managing abortion or assisting someone else obtain an abortion. Laura Huss Self Managed Abortion is Not Legal in Most of the Country but Criminalized Can Happens Anyway IF/WHEN/HOW (Aug 9 2022) https://www.ifwhenhow.org/ abortion-criminalization-new-research/; Robert Baldwin Losing a Pregnancy Could Land You in Jail in Post-Roe America NPR (Ju 3 2022) https://www.npr.org/2022/07/03/1109015404/abortion prosecuting pregnancy loss (interviewing legal experts from If/When/How and the National Advocates for Pregnant Women). IF/WHEN/HOW FULFILLING ROE'S PROMISE 2019 UPDATE 1 (2019) https://www.ifwhenhow.org/resources/roes-unfinished promise-2019-update/; Ieting Paltrow & Flavin Arrests of and forced interventions on Pregnant Women in the United States 1973–2005 Implications for Women's Legal Status and Public Health 38 J Health Politics Policy & Law 299 (2013)]. Sandhya Dates Criminalization of Pregnancy has Already Been Happening to the Poor and Women of Color NPR (Aug. 3 2022) https://www.npr.org/2022/08/03/1114381472/criminalization of pregnancy has already been happening to the poor and women of [including expert accounts of the intersection of incarceration and pregnancy outcomes for people of color.] With at least thirteen states where abortion is already illegal or criminalized pregnant people are [under] increased surveillance and treated with heightened suspicion. [Footnote 26: It's has already occurred while the protections of Roe were intact. Pregnant people have been investigated penalized and even incarcerated where there's suspicion that a person was responsible for the [criminalization of their pregnancy. See Brief for If/When/How: Lawyering for [illegible] view is that Section 1557 does not require the Department to incorporate the language of Title IX's abortion neutrality provision [Footnote 1 20 U.S.C. 1688. "Nothing in this chapter shall be construed to require or prohibit any person or public or private entity to provide or pay for any benefit or service including the use of facilities related to an abortion. Nothing in this section shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion." "[I]n its Section 1557 regulation HHS OCR further notes that there are several other statutory and regulatory provisions related to the provision of abortions that may apply to an entity covered by Section 1557 and OCR will apply such provisions consistent with the law. While HHS OCR acknowledges that though Congress did not require the Department to incorporate the language of Title IX abortion- neutrality provision in its Section 1557 regulations it is seeking comment on this approach and on other possible readings of the Title IX abortion neutrality provision as well as whether the Department should align its Title IX regulation regarding the abortion neutrality provision of Title IX with the 2000 'Common Rule' version of that regulatory provision that more than 20 agencies have long adopted.NCPA is concerned about state laws that limit patients' access to medically necessary medications and impede physicians and pharmacists from using their professional judgment. Following the U.S. Supreme Court [in] Dobbs v. Jackson Women's Health Organization doctors physicians pharmacists and other health care professionals face a confusing legal landscape due to state laws' significant criminal and civil penalties lack of clarity confusing language and unknown implementation regulatory and enforcement bodies. This raises many questions about how broadly state laws will be interpreted and the impact of these actions on pharmacists' ability to serve the needs of the patients. Pharmacists need clear guidance from HHS OCR to support the [illegible] access to FDA approved medications we request additional and immediate clarification that health care providers must continue to be able to implement life-saving measures to people especially those with disabilities and urge the Department to prioritize its issuance. People with disabilities experience discrimination in the provision of health care services and as such we also encourage HHS under your stewardship to pursue interim steps to clarify emphasize and enforce existing disability anti-discrimination requirements in health care especially after the recent Supreme Court decision to overturn Roe v. Wade [Footnote 33: DOBBS STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH ET AL. v. JACKSON WOMEN'S HEALTH ORGANIZATION ET AL. [2022] 597 U.S. 19 1 142 S. Ct. 1397 [Supreme Court Of The United States] 19-1392 Dobbs v. Jackson Women's Health Organization [08/24/2022] [supremecourt.gov] which overturned Roe v. Wade removing the constitutional right to abortion services]. Accessibility of health care settings will become increasingly important as people with disabilities will be traveling to unfamiliar locations to access medications and procedures and will depend on facilities being accessible upon arrival [Footnote 34: Rosman K. (2022). For a Woman in a Wheelchair Abortion Access Was One More Climb. Retrieved 25 July 2022 from: https://www.nytimes.com/2022/07/14/style/abortion-access-disability-planned-parenthood.html.] HHS is poised to address the ongoing discrimination against those with disabilities in the delivery of health care services as outlined in the Section 504 RFI through the Office of Civil Rights (OCR) [Footnote 15: HHS has the jurisdiction to treat discrimination cases as outlined through the Office for Civil Rights (OCR) through this department. DEPARTMENT OF HEALTH AND HUMAN SERVICES n.d. Discrimination on the Basis of Disability in Critical Health and Human Service Programs or Activities. Office for Civil Rights (OCR) Office of the Secretary HHS pp. 1-2.] We strongly support HHS Secretary Becerra's issuing [Bold. Background Longstanding Abortion Neutrality Provision]When Title IX was enacted in 1972 it ensured that "no person in the United States shall on the basis of sex be excluded from participation in be denied the benefits of or be subjected to discrimination under any educational program or activity receiving Federal financial assistance[]" 20 U.S.C. § 1681(a). Title IX has played a significant role in including women in athletic academic and extracurricular pursuits in K-12 schools and institutions of higher education.In 1988 Congress enacted an abortion "neutrality" provision which clarifies Title IX funding may neither require nor prohibit abortion. It reads: "Nothing in this chapter shall be construed to require or prohibit any person or public or private entity to provide or pay for any benefit or service including the use of facilities related to an abortion. Nothing in this section shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion." Title IX's commitment to neutrality in the case of legal abortion has long protected individuals and entities' rights of conscience when they hold sincere moral religious or ethical reasons for declining to participate in abortion. Similar 'abortion neutrality' provisions have long appeared elsewhere in federal law as well including the Church amendments the Coats Snowe amendment and the Pregnancy Discrimination Act Because of the abortion neutrality provision women and girls do not face an implicit expectation that they should choose abortion to maintain their rights or opportunities as athletes and students. Title IX considered the demands joys and alternative opportunities that arise when people face the prospect of pregnancy and parenting and sought to provide accommodations and flexibility for mothers and fathers.

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Senator Kristen Gillibrand

The Heritage Foundation

Finally health practitioners providing abortion services now face increased risk of criminal prosecution civil prosecution or adverse licensing enforcement in states that prohibit abortion services. Fear of potential civil or criminal or licensing consequences may lead some providers to refuse to provide abortion care or information about abortion care altogether. Further although telehealth providers might provide telehealth or services to out-of-state patients where allowed this raises concerns about the privacy of reproductive health information tracked through telehealth applications including whether or not patients seek abortions across state lines. [Footnote 76: See Center For Connected Health Policy Abortion Declaration on Telemedicine & Privacy (July 2022) https://www.cchpca.org/telehealth-policy-heads-up-with-abortion-decision-plus-telehealth-and-recommendations-from-white-house-memo (noting concerns about increased surveillance).] To encourage and improve access to abortion services the Proposed Rule might explicitly reference the security and privacy requirements under HIPAA pertaining to maintaining the security and privacy of protected reproductive health or abortion health services information created and stored for telehealth services or mobile health applications. The Proposed Rule could further clearly note that these privacy requirements preempt any conflicting state laws that would seek to expose or remove the security protections of this information.

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Attorneys General of California, New York, Massachusetts, and nineteen other States

related conditions to include the termination of pregnancy i.e. abortion. HHS endorses the view that abortion and other pregnancy-related conditions are already included in Section 1557 because it prohibits discrimination in health programs on the basis of any ground listed under Title IX. 42 U.S. Code § 18116. It therefore incorporates Title IX's regulation prohibiting discrimination on the basis of "pregnancy childbirth false pregnancy termination or pregnancy or recovery therefrom." 45 CFR § 86.40(a). As HHS previously recognized this long-standing interpretation is consistent with other Federal agencies and courts' interpretations of the scope of sex discrimination. 81 Fed. Reg. at 31387-88. The Proposed Rule should expressly incorporate this long-standing interpretation by including a standalone provision mirroring the specific prohibitions found in the Title IX regulations. The inclusion of a standalone provision would ensure effectively implement Section 1557's sex discrimination protections by expressly including all pregnancy-related conditions including pregnancy termination and by making clear that covered entities are prohibited from discriminating against a person on the basis of those conditions. Such a provision is particularly important in the wake of [Italics: Dobbs v. Jackson Women's Health Organization] 597 U.S. (2022) which has caused widespread confusion among covered entities about their legal obligations related to abortion in the changed national landscape. A standalone provision would also provide an opportunity for HHS to clarify the interplay between Section 1557 and other federal statutes or regulations related to abortion that may apply to covered entities. Thus we support HHS in including express language regarding the termination of pregnancy in defining sex discrimination. By providing much needed clarity to covered entities on the scope of sex discrimination protections a strengthened definition of sex discrimination that enumerates specific forms of discrimination concerning pregnancy and its related conditions would also benefit patients. In the fallout of the [Italics: Dobbs

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Religious Exemption And Abortion Neutrality Provision Section: The NPRM proposes to exclude Title IX's religious exemption and abortion neutrality provisions from incorporation into the Section 1557 regulation. The Department narrowly considers Section 1557's incorporation by reference of Title IX to include only what it claims is the prohibited basis for discrimination (i.e. sex) [Italics: but not] the exceptions set forth in Title IX. A district court considering a previous version of the Section 1557 regulations which interpreted Section 1557's scope of incorporation of Title IX similarly to the present NPRM issued a nationwide injunction against it. In Franciscan Alliance v. Burwell 227 F. Supp. 3d 660 (2016) the court stated Congress specifically included in the text of Section 1557 "20 U.S.C. 1681 et seq." That Congress included the signal "et seq." which means "and the following" after the citation to Title IX can only mean Congress intended to incorporate the entire statutory structure including the abortion and religious exemptions. Title IX prohibits discrimination on the basis of sex but exempts from this prohibition entities controlled by a religious organization where the proscription would be inconsistent with its religious tenets. Title X also categorically exempts any application that would require a covered entity to provide abortion or abortion related services. Therefore a religious organization refusing to act in conformity with its religious tenets on the basis of sex does not discriminate on the grounds prohibited by Title IX. Failure to incorporate Title IX's religious and abortion exemptions nullifies Congress's specific direction to prohibit only the ground proscribed by title IX. That is not permitted. Franciscan Alliance at 690-91 (internal citations and footnotes omitted) [The Department disagrees with the conclusion of Franciscan Alliance and says that it is not bound by the decision. The NPRM does not explain why the reasoning of Franciscan Alliance is wrong; however despite the NPRM's omitted explanation a final rule should contemplate the Department's divergence from established

Charlotte Lozier Institute

As outrageous as the flagrant attempt to impose abortion on health care just after the Supreme Court's repudiation of Roe v. Wade in the Dobbs decision. The Biden administration wants the federal government to declare the refusal to perform an abortion a form of unlawful discrimination! Medical professionals and Catholic hospitals would not be allowed the right to reject abortion. Religious liberty and conscience rights that are guaranteed by law in the US would be subject to "review" and rejection by the Office of Civil Rights of HHS. It is would be laughable if it were not seriously proposed by bureaucrats in positions of power!

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In the preamble HHS notes that although it does not propose retaining the 2016 Final Rule language the protections still apply because of the underlying Title IX regulations. We agree that the Title IX definition applies but given the pervasive nature of discrimination related to termination of pregnancy particularly post-Dobbs we urge HHS to specifically include termination of pregnancy in this definition. Additionally HHS does not define sex discrimination consistently in the proposed rule. It notes that sex discrimination includes "pregnancy or related conditions" at § 92.101(a)(2) but only "pregnancy" under § 92.101 and § 92.10. We urge HHS to be consistent throughout the final rule.

American Psychological Association

against patients. In the treatment of pregnancy emergencies and complications including termination of pregnancy miscarriage management and other pregnancy outcomes.' [Italics:] The final rule should clarify that EMTALA and Section 1557 apply in all emergency situations. We urge the Department to go further in explaining how Section 1557 and the Emergency Medical Treatment & Labor Act (EMTALA) each protect pregnant patients in emergency situations. The Rule should explain that EMTALA and Section 1557 each prohibit the denial of care including denying termination of pregnancy. EMTALA requires that participating entities provide stabilizing treatment to pregnant patients. [Footnote 56: U.S. DEPT. OF HEALTH & HUM. SERVS. HHS SECRETARY LETTER TO HEALTH CARE PROVIDERS ABOUT EMERGENCY MEDICAL CARE (Jul. 11 2022) https://www.hhs.gov/sites/default/files/emergency-med cal-care-letter-to-health-care-providers.pdf.] Under Section 1557 refusals to provide pregnant patients with emergency care that may include termination of pregnancy is patently sex discrimination. EMTALA explicitly protects patients in situations that threaten their health and life and Section 1557 provides additional protections against discrimination on the basis of sex including abortion. We agree with the proposed rule's clarification that EMTALA protects emergency care for pregnancy or related conditions including termination of pregnancy. In the preamble to the proposed rule the Department explains that EMTALA protects the care a person needs when presenting with an "emergency medical condition". [Footnote 57: Nondiscrimination in Health Programs and Activities 87 Fed. Reg. 47824 (proposed August 4 2022) (to be codified at 42 CFR 438.42 LFR 440.42 CFR 457.42 LFR 460.45 CFR 80.45 CFR 84.45 CFR 86.45 CFR 91.45 CFR 92.45 CFR 147.45 LFR 155 and 45 CFR 156).] Both the proposed rule's preamble and the guidance provided by the Department on July 11 2022 ["July guidance"] make clear that the EMTALA statute preempts any state laws or mandates that emulate a more

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Center for Reproductive Rights

the ability to select a particular provider in order to avoid a provider or institution that withholds care based on religious doctrine even if the patient is aware of such restrictions which is typically not the case as many institutions lack transparency on how its religious tenets may impact its policies in ways that have repercussions on patients ability to access necessary health services [Footnote 5: See Emily Cahoon & Maggie Siddiqui Religious Liberty Should Do No Harm Center for American Progress (Apr. 2019) https://www.americanprogress.org/wp-content/uploads/2019/03/ReligiousLiberty-report-6.pdf.] Accordingly we strongly urge that the Final Rule include the Proposed Rule's clarification that the Emergency Medical Treatment and Labor Act [EMTALA] protects emergency care for pregnancy-related conditions including termination of pregnancy. In the preamble to the Proposed Rule the Department explained that EMTALA protects the care a person needs when presenting with an "emergency medical condition." Both the Proposed Rule's preamble and guidance the Department provided on July 11 2022 ["July 11 guidance"] makes clear that the EMTALA statute preempts any state law or mandates that employ a more restrictive definition of an emergency medical condition [Footnote 6: U.S. Dept. of Health & Human Servs. HHS Secretary Letter to Health Care Providers About Emergency Medical Care (July 11 2022) https://www.hhs.gov/sites/default/files/emergency-medical-care-letter-to-health-care-providers.pdf]. The Department's July guidance clarifying that "emergency medical conditions involving pregnant patients may include but are not limited to ectopic pregnancy complications of pregnancy loss or emergent hypertensive disorders such as preeclampsia with severe features" should also be incorporated into the Final Rule's discussion of EMTALA [Footnote 7: U.S. Dept. of Health & Human Servs. HHS Secretary Letter to Health Care Providers About Emergency Medical Care (July 11 2022) https://www.hhs.gov/sites/default/files/emergency-medical-care-letter-to-health-care-providers.pdf].

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Center for American Progress

Amendment." We support the Department's decision not to incorporate Title IX's abortion neutrality provision also known as the Danforth Amendment and urge the Department to issue a final rule without it. We strongly agree with the Department's recognition that Section 1557 does not require the incorporation of the Danforth Amendment. [footnote 43: 20 U.S.C. 1688 ("Nothing in this chapter shall be construed to require or prohibit any person or public or private entity to provide or pay for any benefit or service including the use of facilities related to an abortion. Nothing in this section shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion.")] Inclusion of the Danforth Amendment runs counter to the congress onal intent of Section 1557 and would contribute to provider confusion and health care denials related to pregnancy and pregnancy-related care. Section 1557 was included in the Affordable Care Act "to expand access to care and coverage and eliminate barriers to access" [footnote 44: 81 Fed. Reg. 31375 31377 (2016).] based on the government's "compelling interest in ensuring that individuals have nondiscriminatory access to health care." Congress' silence on incorporation of the Danforth Amendment is not an oversight on the part of Congress but rather an intentional omission. As the Department pointed out in the 2016 rule and the preamble to the 2022 proposed rule Congress clearly chose which parts of the four statutes to incorporate by referencing the enforcement mechanisms and the grounds for discrimination from the referenced statutes. [Footnote 45: Nondiscrimination in Health Programs and Activities 87 Fed. Reg. 47824 47839 (proposed Aug. 4 2022); Nondiscrimination in Health Programs and Activities 81 Fed. Reg. 31376 31378 80 (May 18 2016).] Section 1557 incorporates the bases of discrimination prohibited by Title IX, it does not incorporate the Title IX exemptions. Any contrary interpretation runs contrary to congressional intent.

Center for Reproductive Rights

Underlined: Sex discrimination on the basis of marital parental or familial status: CalHHS welcomes the addition of an express prohibition against discrimination based on current perceived parental or past marital parental or family status. We also strongly support extending the proposed Section 92.208 to prohibit discrimination on the basis of pregnancy-related conditions including with respect to a person's decision to terminate a pregnancy. As highlighted above these bases are already codified into our state nondiscrimination laws and in view of heightened national importance due to the recent troubling setbacks in reproductive health freedom's and access notably the U.S. Supreme Court's decision in Dobbs v. Jackson Women's Health Organization (142 S. Ct. 2228 (2022)). CalHHS agrees with the preamble's reasoning to not import the current abortion neutrality provision in Title IX given the absence of any such command in the text of Section 1557 and the referenced available tried existing federal statutory protections for health care entities and other individuals in the provision payment or receipt of abortion services.

California Department of Health Care Services

Excluding Title IX's Abortion Neutrality Provision From Section 1557 The Department's claim that the abortion-neutrality amendment is not part of the "basis" for interpreting the meaning of "discrimination on the basis of sex" is arbitrary and unconvincing. That amendment reads: "[Bold italic: Nothing in this chapter shall be construed to] require or prohibit any person or public or private entity to provide or pay for any benefit or service, including the use of facilities related to an abortion" (emphasis added). The statute could not be clearer. Nothing whether in definitions or operative provisions can be construed to require involvement in abortion. This amendment straightforwardly clarified and effectively narrowed [that] on what basis a legal action can be brought. The Department further signals that it believes individuals have a right to abortion regardless of a healthcare provider's objection because "explaining why Section 1557 should not be interpreted to incorporate the abortion neutrality provision the Department invokes the Emergency Medical Treatment and Active Labor Act [EMTALA] to require hospitals to provide abortions. The Department states that if a person has an "emergency medical condition" the hospital "must provide available stabilizing treatment [italic: including abortion] or an appropriate transfer to another hospital that has the capabilities to provide available stabilizing treatment notwithstanding any directly conflicting state laws or mandates that might otherwise prohibit or prevent such treatment." [See NPRM at p. 47879 emphasis added.] There is a significant legal question as to whether this is a correct interpretation of EMTALA. It is the position of CU that this is a grievously erroneous interpretation of EMTALA and contrary to the statute's plain language which requires healthcare providers to protect [italic: both] the mother and the unborn child. [See 42 U.S.C. § 1395dd(e)(1)(A)(i), see also "Pro-Life Laws Protect Mom and Baby. Pregnant Women's Lives are Protected in All States" available at https://law.ernstinstitute.org/pro-life-laws-protect-mom-and-baby-

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Charlotte Lozier Institute

In [italics: General Electric Co. v. Gilbert,] the Supreme Court held that Title VII's sex discrimination prohibition did not extend to classifications based on pregnancy. [footnote 252: 429 U.S. 125 (1976).] In response Congress passed the Pregnancy Discrimination Act in 1978 to explicitly state that discrimination because of sex includes "because of or on the basis of pregnancy childbirth or related medical conditions." [Footnote 253: 42 U.S.C. § 2000e(k).] Congress also included an explicit exemption for health insurance benefits for abortion. [Footnote 254: Id.] Once again demonstrating Congress chooses neutrality when it comes to abortion. Unless or until [italics: Gilbert] is overturned it is contrary to law for HHS to interpret discrimination based on sex to cover pregnancy and related conditions where the Supreme Court has already ruled that it does not

Ethics & Public Policy Center

|Bod: Abortion|HHS's redefinition of "sex" is drawn from Title IX. The department uses Title IX's redefinition of pregnancy to include "or related conditions" which is defined as "(1) Pregnancy or childbirth termination of pregnancy or lactation; (2) Medical conditions related to pregnancy childbirth termination of pregnancy or lactation; or (3) Recovery from pregnancy childbirth termination of pregnancy lactation or their related medical conditions." |Footnote 20: 87 FR 41390|This proposed redefinition of pregnancy was introduced a mere three weeks after the Supreme Court's decision in Dobbs v. Jackson Women's Health Organization on June 24 2022. This decision corrected the grave errors of [Italics] Roe v. Wade and Planned Parenthood v. Casey. | Nonetheless Title IX did not mention the Dobbs ruling nor its impact upon the way pregnancy and abortion rulings will necessarily be interpreted in the United States. Not only does Section 1557 define sex discrimination to include "termination of pregnancy" the department goes so far as to question on "what impact if any the Supreme Court decision in [Italics] Dobbs v. Jackson Women's Health Organization[has on the implementation of Section 1557 and these regulations." The department fails to explain why they are picking and choosing only certain parts of Title IX's definition of sex pregnancy and abortion to implement. |Footnote 21: HHS Announces Proposed Rule to Strengthen Nondiscrimination in Health Care July 25 2022 https://www.hhs.gov/about/news/2022/07/25/hhs-announces-proposed-rule-to-strengthen-nondiscrimination-in-health-care.html|

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The Heritage Foundation

|Bod: B. Section 1557 Incorporates Title IX's abortion neutrality provision.]The Proposed Rule states that it is "[t]he Department's view is that Section 1557 does not require the Department to incorporate the language of Title IX's abortion neutrality provision into its Section 1557 regulation." |Footnote 238: 87 Fed. Reg. 47879.| This is incorrect Title IX contains an explicit abortion neutrality provision: Nothing in Title IX "shall be construed to require or prohibit any person or public or private entity to provide or pay for any benefit or service including the use of facilities related to an abortion." |Footnote 238: 20 U.S.C. § 1688.| This "the ground prohibited under" Title IX does not include "provid[ing] or pay[ing] for any benefit or service including the use of facilities related to an abortion." Moreover Section 1557 cites Title IX's statutes as "20 U.S.C. 1681 [the statutes]." |Footnote 239: 42 U.S.C. § 18116 (emphasis added)| demonstrating that the entire Title IX scheme is supposed to be incorporated. To say otherwise would be arbitrary and capricious and contrary to law.

Ethics & Public Policy Center

It is arbitrary and capricious for HHS to rely on Title IX regulations to prohibit discrimination based on pregnancy related conditions [and marital parental and family status] while ignoring and refusing to rely on Title IX's statutory abortion neutrality provision and religious exemption. 45 CFR 92.6(b) should not be repealed.

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state abortion laws.|The Proposed Rule cites EMTALA obligations and a July 11 2022 letter from CMS. |Footnote 249: 87 Fed. Reg. 47879.| EMTALA requires hospitals to medically screen stabilize and appropriately transfer any individual with an "emergency medical condition" defined as "a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in [1] placing the health of the individual (or with respect to a pregnant woman the health of the woman [Italics] or her unborn child[in serious jeopardy (ii) serious impairment to bodily functions or (iii) serious dysfunction of any bodily organ or part." |Footnote 250: 42 U.S.C. § 1395dd(e)(1)(A) (emphasis added).| The EMTALA statute explicitly and repeatedly recognizes the unborn child. Indeed "appropriate transfer" is defined as a transfer "in which the transferring hospital provides the medical treatment within its capacity which minimizes the risks to the individual's health and in the case of a woman in labor [Italics] the health of the unborn child." |Footnote 251: 42 U.S.C. § 1395dd(c)(2)(A) (emphasis added).| By its own terms EMTALA imposes a duty to save both mother and child. CMS's July 11 letter which purportedly "does not contain 'new policy'" states (with emphasis): "[Italics: If a physician believes that a pregnant patient presenting at an emergency department is experiencing an emergency medical condition as defined by EMTALA and that abortion is the stabilizing treatment necessary to resolve that condition the physician must provide that treatment. When a state law prohibits abortion and does not include an exception for the life and health of the pregnant person—or draws the exception more narrowly than EMTALA's emergency medical condition definition [that is] that state law is preempted." |Footnote 252: Reinforcement of EMTALA Obligations specific to Patients who are Pregnant or are Experiencing Pregnancy Loss (UPDATED JULY 2022) https://www.cms.gov/medicareprudder-

Ethics & Public Policy Center

|Italics: Applies by extension or by convenience?|The Department of Health and Human Services per their own admits or is relying upon the redefinition of sex pregnancy and abortion from Title IX as the basis for their own rule. As HHS admits it is relying on an "applies by extension" argument from Bostock to Title IX to argue that the redefinition of sex pregnancy and abortion in Section 1557 has a reasonable basis |Footnote 22: 87 FR 47824| Nonetheless the department is willfully and unacknowledgably abandoning the longstanding abortion neutrality provision in Title IX. This opens the door for Section 1557's federal funds going towards promoting paying for and supporting abortion. The department fails to explain its pro-abortion agenda or why federal funds should go towards an abortion. Title VII does not require a provider to pay for an abortion Title IX remains neutral on funds going towards abortion and Title X bars the use of its funds going toward an abortion outright. What right or basis does Section 1557 have to promote abortion in the definition of sex without extending an abortion neutrality provision? The department fails to explain its failure to include an abortion neutrality clause. It must provide a clear explanation given this obvious and weighty departure from previous rules. In addition the department must provide an analysis of the expected cost and impact of allowing federal funds to go towards an abortion.

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The Heritage Foundation

Additionally many Americans prefer to receive care from a provider who shares their religious views or their life-affirming perspective on the dignity of unborn life. Although the proposed regulation seeks to assure faith-based or pro-life health care providers that the Department will follow existing laws those assurances ring hollow. The Department's proposal to explicitly exclude Title IX's religious exemption and abortion neutrality provisions from the scope of Section 1557 clearly communicates that its finger is on the scale of increased access to abortion – at the expense of those healthcare providers that have genuine religious or moral objections.

Charlotte Lozier Institute

access to FDA approved medications we request additional and immediate clarification that health care providers must continue to be able to implement life-saving measures to people especially those with disabilities and urge the Department to prioritize its issuance. People with disabilities experience discrimination in the provision of health care services and as such we also encourage HHS under your stewardship to pursue interim steps to clarify emphasize and enforce existing disability anti-discrimination requirements in health care especially after the recent Supreme Court decision to overturn Roe v. Wade |Footnote 15: DOBBS STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH ET AL. v. JACKSON WOMEN'S HEALTH ORGANIZATION ET AL. |2022| 597 U.S. 19 142 S. Ct. 1497 1997 |Supreme Court Of The United States| 19-1392 Dobbs v. Jackson Women's Health Organization |06/24/2022| Supremecourt.gov| which overturned Roe v. Wade removing the constitutional right to abortion services|. Accessibility of health care settings will become increasingly important as people with disabilities will be traveling to unfamiliar locations to access medications and procedures and will depend on facilities being accessible upon arrival |Footnote 16: Reisman R. (2022). For a Woman in a Wheelchair Abortion Access Was One More Challenge. Retrieved 25 July 2022 from https://www.nytimes.com/2022/07/14/style/abortion-access-ability-planned-parenthood.html.|HHS is poised to address the ongoing discrimination against those with disabilities in the delivery of health care services as outlined in the Section 504 RFI through the Office of Civil Rights (OCR) |Footnote 15: HHS has the jurisdiction to treat discrimination cases as outlined through the Office for Civil Rights (OCR) through this department. DEPARTMENT OF HEALTH AND HUMAN SERVICES Rin D Sex Discrimination on the Basis of Disability in Critical Health and Human Services Programs or Activities. Office for Civil Rights (OCR) Office of the Secretary (HHS pp.1-2|.We strongly support HHS Secretary Becerra issuing

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Senator Kirsten Gillibrand

changed significantly since 1972. Given the rules' ambiguity and the change in terminology of "termination of pregnancy," it is worth considering one method in particular which did not exist at Title IX's inception: chemical abortion. The Abortion pill — the new frontier.|The use of chemical abortion pills as opposed to surgical abortion procedures has risen to 54% of all abortion procedures and counting.In the chemical abortion process a woman typically takes two pills mifepristone and misoprostol. Mifepristone blocks the uterus from receiving a critical hormone progesterone which is required to sustain a pregnancy. As a result of the progesterone inhibitor the lining of the uterus deteriorates and cannot transfer adequate nutrients to the developing unborn child causing its death. Twenty four to 48 hours after taking mifepristone a woman takes the second part of the abortion pill regimen misoprostol which causes uterine contractions to complete the abortion process and empty the uterus.The FDA approved the use of chemical abortion pills up to ten weeks of pregnancy. They also suspended their in person dispensing requirement under the guise of Covid 19 safety protocols. The Biden administration made that change permanent in December 2021. The combination of widespread use paired with a greater risk for complications and adverse side effects makes chemical abortion pills an essential part of this abortion conversation.When Title IX was enacted in 1972 the "termination of pregnancy" clause reliably referred to surgical abortions. The widespread use of chemical abortion pills raises new concerns that were not present when Title IX was enacted. Nor were these concerns an issue when similar regulations like the Pregnancy Discrimination Act went into effect. Because of this it is important to ensure the proposed rule adequately considers chemical abortion pills under it's "termination of pregnancy" provision. Could a campus health center be accused of sex discrimination if it chooses to not dispense generally for abortion pills? If a campus health clinic dispenses abortion pill at student request, providing pregnancy related support to a student who [illegible] is essential to ensuring health coverage for women and other pregnant people|While the majority of this regulation is beneficial the omission of an explicit protection for pregnancy-related conditions must be addressed before this rule is finalized. The Department of Health and Human Services seemed to anticipate this asking for input on this omission as well as the impact of the federal right to abortion being overturned in the recent Supreme Court decision Dobbs v. Jackson Women's Health Organization. The finalized rule should explicitly define pregnancy termination and its definition of sex discrimination. Many communities could not access abortion care prior to the Dobbs decision and many racialized communities will continue to bear the brunt of limited access as abortion bans are implemented.|Footnote 22: Isaac Maddow-Zimet and Kathryn Kost "Even Before Roe Was Overturned Nearly One in 10 People Obtaining an Abortion Traveled Across State Lines for Care," Guttmacher Institute July 21 2022 https://www.guttmacher.org/article/2022/07/even-roe-was-overturned-nearly-one-10-people-obtaining-abortion-traveled-across]. Protecting patients is even more important as criminalization of pregnancy outcomes increases and as some states seek to punish pregnant people for seeking abortions out of state. |Footnote 23: "Criminalization and Civil Punishment of Pregnancy and Pregnancy Outcomes" National Advocates for Pregnant Women May 2020 https://www.nationaladvocatesforpregnantwomen.org/wp-content/uploads/2019/10/UPR-Criminal-report.pdf; Carolyne Kitchener and Alex Horton Barnett "Antiabortion lawmakers Want to Block Patients from Crossing State Lines" The Washington Post June 30 2022 https://www.washingtonpost.com/politics/2022/06/29/abortion-state-lines/ These attacks on abortion access are rooted in white supremacy and the states seeking to restrict abortion are those with the worst outcomes for Black women's maternal health.|Footnote 24: Black Maternal Health Federal Policy Collective

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The Heritage Foundation

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The Century Foundation

Additionally because of the Dobbs decision state efforts to restrict access to abortion have resulted in further challenges to accessing other sexual and reproductive health care including contraception fertility care and treatment and miscarriage management. We urge HHS to similarly consider that restrictions that deny access to sexual and reproductive health care should also be an enumerated form of sex discrimination.

U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

|Bold: Implications of the Dobbs Decision|Thank you for requesting comment on any potential implications of the recent Dobbs v. Jackson Women's Health Organization decision. This ruling has caused confusion about the role of the pharmacist in dispensing certain medications and threatened patient access to needed medications and care. Media reports.|Footnote 11: https://www.latimes.com/california/story/2022-07-11/post-roe-many-automimmune-patients-lose-access-to-gold-standard-drug |2| https://www.pharmacytimes.com/view/this-guidance-for-pharmacists-following-supreme-court-abortion-decision-creates-confusion |3| https://www.nola.com/news/healthcare_hospitals/article_238ad184-ff00-11ec-91ee-0f0660b21ce1.html |Data: The experiences of women who have been denied prescriptions and refills of methotrexate a medication that treats a variety of conditions such as rheumatoid arthritis inflammatory bowel disease psoriasis and cancer. Some pharmacists are refusing all prescriptions and refills because the medication can cause miscarriage and is an off-label treatment to end ectopic pregnancies. In some instances it has been reported that women are being questioned about the purpose and intended use of certain prescription medications. This is an uncomfortable interaction for any patient to experience at the pharmacy counter a location that is not completely private. We believe this is an example of gender-based discrimination. NHC is concerned that absent clarity about the role of the pharmacist and clarity on requirements to dispense medications these interactions and denials could continue despite implementation of the final Section 1557 implementing rule. In light of the Dobbs' decision we request HHS clearly delineate an example of these interactions in the final rule as potentially discriminatory action. We also request that HHS consider an expedited reporting and investigation process for complaints of this nature to facilitate timely access to prescription medications.

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National Health Council

|Italics: The Department continues to receive calls for clarification on both steps of the analysis|This confusion as to the extent and meaning of the department's proposed rule as it relates to abortion is not limited to one ideological viewpoint. On July 20 2022 a coalition of sixty Democrats wrote a letter to the Department of Education requesting that it clarify "specific protections for pregnancy students under Title IX." It appears that even pro-abortion Democrat elected leaders are unclear about key aspects of Title IX's ruling as it relates to abortion. In part of the letter the coalition asks the department to clarify how the Dobbs decision interacts with privacy laws affecting students. They recognize that the new post-Roe abortion landscape in which elected leaders can better advance policies that value and protects both the lives of women and the lives of preborn children requires a careful and specific consideration from the department as they issue sensitive rulings related to abortion and academic institutions. Similarly this commenter humbly requests similar explanations and definitions from the department related to abortion and Title IX.

The Heritage Foundation

|Bold: Pregnancy Discrimination|The proposed rule clarifies that the definition of discrimination "on the basis of sex" includes pregnancy and other related conditions. NAHU members would appreciate if HHS would provide clarification either in a final rule or via sub-regulatory guidance as to how these pregnancy-discrimination protections relate to and may be different from those guaranteed by the Pregnancy Discrimination Act of 1978. We would appreciate guidance on any expanded protections as well as the impact of this proposed regulatory change considering the recent Supreme Court of the United States decision in Dobbs v. Jackson Women's Health Organization.

National Association of Health Underwriters

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|Bold and Italics: Prohibition on Sex Discrimination Related to Marital, Parental or Family Status (§ 92.208)||Bold The AAMC supports the proposal to expressly prohibit discrimination on the basis of sex with respect to an individual's marital, parental or family status similar to the Department's Title IX regulations.| The proposed provision would prohibit a covered entity from considering an individual's sex when applying any rule concerning an individual's current, perceived potential or past marital, parental or family status and is based on OCR's experience with Section 1557 enforcement. |Footnote 11: 87 Fed. Reg. 47824 at 47878.| HHS asks whether to also include a provision to specifically address discrimination on the basis of pregnancy-related conditions. HHS believes it would be beneficial to expressly address pregnancy-related sex-based discrimination in order to ensure nondiscriminatory access to care. The AAMC believes that everyone should be able to access comprehensive health care including reproductive health care and we are concerned about the impact that the Supreme Court's decision in |Italics: Dobbs v. Jackson Women's Health Organization| may have on coverage and care. |Footnote 12: AAMC Statement on Supreme Court Decision in Dobbs v. Jackson Women's Health Organization (June 2022).| Considering the impacts of the changing landscape for access to reproductive health care we agree with the Department that a provision expressly prohibiting discrimination on the basis of pregnancy-related conditions as a form of sex-based discrimination is prudent.

|Underlined Sex discrimination on the basis of marital, parental, or familial status| CalHHS welcomes the addition of an express prohibition against discrimination based on current, perceived potential or past marital, parental or family status. We also strongly support extending the proposed Section 92.208 to prohibit discrimination on the basis of pregnancy-related conditions, including with respect to a person's decision to terminate a pregnancy. As highlighted above, these bases are already codified into our state nondiscrimination law, and is of heightened national importance due to the recent, troubling setbacks in reproductive health freedoms and access, notably the U.S. Supreme Court's decision in Dobbs v. Jackson Women's Health Organization (142 S. Ct. 2228 (2022)). CalHHS agrees with the preamble's reasoning to not import the current abortion neutrality provision in Title IX given the absence of any such command in the text of Section 1557 and the referenced availability of existing federal statutory protections for health care entities and other individuals in the provision, payment or referral of abortion services.

In |Italics: General Electric Co. v. Gilbert,| the Supreme Court held that Title VII's sex discrimination prohibition did not extend to classifications based on pregnancy. |Footnote 232: 429 U.S. 125 (1976).| In response, Congress passed the Pregnancy Discrimination Act in 1978 to explicitly state that discrimination because of sex includes "because of or on the basis of pregnancy, childbirth or related medical conditions." |Footnote 233: 42 U.S.C. § 2000e(k).| Congress also included an explicit exception for health insurance benefits for abortion. |Footnote 234: Id.| Once again demonstrating Congress chooses restraint when it comes to abortion. Unless or until |Italics: Gilbert| is overturned, it is unlawful for HHS to interpret discrimination based on sex to cover pregnancy and related conditions when the Supreme Court has already ruled that it does not.

|Bold: Abortion|HHS's redefinition of "sex" is a departure from Title IX. The department uses Title IX's redefinition of pregnancy to include "or related conditions" which is defined as: "(1) Pregnancy, childbirth, termination of pregnancy, or lactation, (2) Medical conditions related to pregnancy, childbirth, termination of pregnancy, or lactation, or (3) Recovery from pregnancy, childbirth, termination of pregnancy, lactation, or their related medical conditions." |Footnote 230: 87 FR 41390|This proposed redefinition of pregnancy was introduced a mere three weeks after the Supreme Court's decision in Dobbs v. Jackson Women's Health Organization on June 24, 2022. This decision corrected the grave errors of |Italics: Roe v. Wade| and |Italics: Planned Parenthood v. Casey.| Nonetheless, Title IX did not mention the Dobbs ruling, nor its impact upon the way pregnancy and abortion rulings will necessarily be interpreted in the United States. Not only does Section 1557 define sex discrimination to include "termination of pregnancy," the department goes so far as to question "what impact, if any, the Supreme Court decision in |Italics: Dobbs v. Jackson Women's Health Organization|, has on the implementation of Section 1557 and these regulations." The department fails to explain why they are picking and choosing only certain parts of Title IX's definition of sex (pregnancy and abortion) to implement. |Footnote 41: HHS Announces Proposed Rule to Strengthen Nondiscrimination in Health Care, July 25, 2022, https://www.hhs.gov/about/news/2022/07/25/hhs-announces-proposed-rule-to-strengthen-nondiscrimination-in-health-care.html|

|Bold: Dobbs|Italics: Dobbs|| HHS has no compelling interest in promoting abortion. |HHS also seeks comment on "what impact, if any, the Supreme Court's decision in |Italics: Dobbs v. Jackson Women's Health Organization| has on the implementation of Section 1557 and these regulations." |Footnote 240: 87 Fed. Reg. 47873.| In |Italics: Dobbs v. Jackson Women's Health Organization| overruling |Italics: Roe v. Wade| and holding that there is no constitutional right to abortion, |Footnote 241: No. 19-1392, (U.S. Jun. 24, 2022).| Past |Italics: Dobbs| the Biden administration is seeking ways for the federal government to pay for and promote abortion. |Footnote 242: Rachel N. Morrison, The Biden Administration's Post-Dobbs Post-Roe Response, FedSoc Blog, (July 13, 2022) https://fedsoc.org/commentary/fedsoc-blog/the-biden-administration-s-post-dobbs-post-roe-response.| But |Italics: Dobbs| made clear that there is no federal constitutional right to abortion and no compelling government interest in promoting abortion. Considering the Proposed Rule does not mention abortion would be considered a pregnancy-related condition it would be arbitrary and capricious and not a logical outgrowth for HHS to use 1557 regulations to promote abortion. And as the |Italics: Dobbs| Court stated "the 'goal of preventing abortion' does not constitute 'invidiously discriminatory animus' against women." |Footnote 243: Dobbs v. Jackson Women's Health Organization, No. 597 U.S. (2022) at 11 (quoting Bray v. Alexandria Women's Health Clinic, 506 U.S. 263, 273–274 (1993)) (internal quotation marks omitted).| The rule |Italics: Dobbs| explained "laws regulating or prohibiting abortion are not subject to heightened scrutiny. Rather, they are governed by the same standard of review as other health and safety measures." |Footnote 244: Id.|

|Bold: Section 1557 cannot preempt state abortion laws.| We ask that HHS clarify whether it is the Department's view that the proposed regulations could preempt a state abortion law. To the extent HHS would say its Section 1557 regulations would preempt certain state abortion laws it must explain as such in proposed rule and give states and the American public greater notice so that they can comment on the far-reaching implications of HHS's regulations. The lack of discussion in the Proposed Rule about the application to abortion would make any final rule requiring preemption of state abortion laws arbitrary and capricious and not a logical outgrowth of the proposed rule. Preempting state abortion laws would raise a major question under |Italics: West Virginia v. EPA.| It is ludicrous to infer that Section 1557 which promotes health care all of a sudden preempts state laws protecting life. Abortion is not health care and it is not discriminatory to not perform or provide an elective abortion.

Nondiscrimination on the Basis of Association (§ 92.209)|We are pleased that this NPRM restores clear and explicit protections against discrimination on the basis of association. This is consistent with long-standing interpretations of other non-discrimination laws which cover discrimination based on an individual's own characteristics or those of someone either with whom they are associated or with whom they have relationships. As noted in the NPRM preamble certain protected populations – including LGBTQI+ people – are particularly susceptible to discrimination based upon association. For instance an individual in a same-gender relationship and/or marriage could be subjected to discrimination based on their own and/or their spouse or partner's sex assigned at birth and/or gender identity whereas that same individual might not be similarly mistreated were they not in a same-gender relationship and/or marriage. Because of this it is important that the final rule make clear that this kind of associational discrimination is within the ambit of the rule's protections.

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Association of American Medical Colleges [AAMC]

California Department of Health Care Services

Ethics & Public Policy Center

The Heritage Foundation

(b)(5)

Ethics & Public Policy Center

Ethics & Public Policy Center

Equitas Health

(b)(5)

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[Bold: § 92.209 - Nondiscrimination on The Basis of Association][We strongly support the provision of the rule that prohibits discrimination on the basis of association. Consistent with longstanding civil rights law this provision makes it clear that Section 1557's protections extend to discrimination against associates partners or family members of protected class members based on that person's race color national origin sex age or disability. [Footnote 11: See e.g. Holcomb v. Iona College 521 F.3d 130 (2nd Cir. 2008) (Title VII); Larimer v. International Business Machines Corp. 370 F.3d 698 702 (7th Cir. 2004) (ADA).] The proposed language mirrors that of Title and Title I of the ADA which protect against discrimination based on association or relationship with a person with a disability as well as regulatory language implementing Title of the ADA. [Footnote 12: 42 U.S.C. 12112(b)(4)(Title I); 42 U.S.C. 12182(b)(1)(E)(Title II); 28 C.F.R. 35.130(g)(Title II) (2016).] [This language was included in the 2016 Final Regulations and then was removed from the 2020 Final Regulations over commenters' protest that the removal would cause confusion both for covered entities and for individuals. [Footnote 13: 85 Fed. Reg. 37198.]

We support the restoration of explicit protections against discrimination on the basis of association in Section 92.209. This is consistent with longstanding interpretations of other antidiscrimination laws which cover discrimination based on an individual's own characteristics or those of someone with whom they are associated or with whom they have a relationship. The proposed rule notes in the preamble that certain protected populations including LGBTQ people are particularly susceptible to discrimination based on association. An individual in a same-sex relationship or marriage could be subjected to discrimination based on their own and the spouse or partner's sex whereas that same individual might not be similarly mistreated were they not in a same-sex relationship. The final rule must make clear that this kind of associational discrimination is within the scope of the rule's protections.

[Bold: Nondiscrimination on the Basis of Association][§ 92.209]][We are pleased that this NPRM restores explicit protections against discrimination on the basis of association. This is consistent with longstanding interpretations of other antidiscrimination laws which cover discrimination based on an individual's own characteristics or those of someone with whom they are associated or with whom they have relationship. As noted in the NPRM preamble certain protected populations including LGBTQ people are particularly susceptible to discrimination based on association. An individual in a same-sex relationship or marriage could be subjected to discrimination based on their own and the spouse or partner's sex whereas that same individual might not be similarly mistreated were they not in a same-sex relationship. It is important that the final rule make clear that this kind of associational discrimination is within the ambit of the rule's protections.

[Bold: Italics: Support for NPRM's Replacement of Provisions from the 2016 Final Rule.] Given this existing state law framework and our shared values Call HHS strongly supports the NPRM's principal objective to restore nondiscrimination and equal access policies to those promulgated under the 2016 Final Rule. This includes: Expanding forms of sex discrimination to include discrimination on the basis of sex stereotypes sex characteristics including intersex traits pregnancy and related conditions sexual orientation and gender identity; Clarifying that nondiscrimination policies extend to associational bases.

WPHCA supports HHS extending additional protections to include discrimination based on an individual's relationship or association under §92.209. This is consistent with longstanding interpretations of other antidiscrimination laws which cover discrimination based on an individual's own characteristics or those of someone with whom they are associated or with whom they have relationship. As noted in the preamble certain protected populations including LGBTQ people are particularly susceptible to discrimination based on association. It is important that the final rule make clear that this kind of associational discrimination is within the scope of the rule's protections.

[Bold: Nondiscrimination on the Basis of Association][§ 92.209]][We are pleased that this NPRM restores explicit protections against discrimination on the basis of association. This is consistent with longstanding interpretations of other antidiscrimination laws which cover discrimination based on an individual's own characteristics or those of someone with whom they are associated or with whom they have relationship. As noted in the NPRM preamble certain protected populations including LGBTQ people are particularly susceptible to discrimination based on association. An individual in a same-sex relationship or marriage could be subjected to discrimination based on their own and the spouse or partner's sex whereas that same individual might not be similarly mistreated were they not in a same-sex relationship. It is important that the final rule make clear that this kind of associational discrimination is within the ambit of the rule's protections.

[Bold: TPCA supports HHS extending additional protections to include discrimination based on an individual's relationship or association per §92.209.] This is consistent with longstanding interpretations of other antidiscrimination laws which cover discrimination based on an individual's own characteristics or those of someone with whom they are associated or with whom they have relationship. As noted in the preamble certain protected populations including LGBTQ people are particularly susceptible to discrimination based on association. It is important that the final rule make clear that this kind of associational discrimination is within the ambit of the rule's protections. TPCA is immensely supportive of this expansive definition of discrimination under this rule as this will protect LGBTQ patients experiencing discrimination in health care settings especially in certain states where access to essential services is threatened. Many states lack embedded hyperlink text [https://www.americanprogress.org/article/a scenario on prevents lgbtq people accessing health care/][explicit LGBTQ discrimination protections in health care and TPCA appreciates the Administration's intention to return 1557 protections back to language in the 2016 rule and in many instances expand upon those protections.

MNACHC supports HHS extending additional protections to include discrimination based on an individual's relationship or association per §92.209. This is consistent with longstanding interpretations of other antidiscrimination laws which cover discrimination based on an individual's own characteristics or those of someone with whom they are associated or with whom they have relationship. As noted in the preamble certain protected populations including LGBTQ people are particularly susceptible to discrimination based on association. It is important that the final rule make clear that this kind of associational discrimination is within the ambit of the rule's protections. MNACHC is immensely supportive of this expansive definition of discrimination under this rule as this will protect LGBTQ patients experiencing discrimination in health care settings especially in certain states where access to essential services is threatened. Many states lack explicit LGBTQ discrimination in health care and MNACHC appreciates the Administration's intention to return 1557 protections back to language in the 2016 rule and in many instances expand upon those protections.

We are also encouraged by the Department's codification that Section 1557 prohibits discrimination on the basis of association. As is already established in other antidiscrimination laws discrimination by association includes discrimination against someone because of the characteristics of someone they have a relationship with or are associated with. This type of discrimination in a medical setting can include denial of care due to having a same-sex partner or for even having a parent in the LGBTQI+ community. It is important that protections against all forms of discrimination are explicitly prohibited in the final rule.

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National Disability Rights Network

The Leadership Conference on Civil and Human Rights

SIECUS: Sex Ed for Social Change

California Department of Health Care Services

Wisconsin Primary Health Care Association

Eating Disorders Coalition for Research, Policy & Action

(b)(5)

Tennessee Primary Care Association

Minnesota Association of Community Health Centers

38 Members of Congress

(b)(5)

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None st' mirat or on the bas s of assoc ation (§ 92 209IWe support restoring explic t protections against discrim' nation on the basis of association. As HHS notes in the preamble LGBTQI+ people are partic ularly susceptible to discrimination based on association. For example gay and lesbian older adults endure repeated questions from doctors about why their partner is with them and being told that only "family members" are allowed n appointments. This type of d scrimination has a negat ve effect on the health care being prov ded because it undermines comm' n cation and trust among the patient the partner or friend who provides care and the treatment providers. As one older woman reported about her experience when her partner was d agnosed with term nal cancer: "Through the 31 months of treatment before her death I had to dent fy myself in a var ety of medica settings and d fferent hospitals as: the roommate her s gnif cant other her sister. The stress of not being able to be safely out not be ng admitted to ICU'S as 'next of kin' thence the 'sister I added greatly to my pain sorrow and stress." Footnote 48 Study subm tted to SAGE and shared with permission of the storyte ler]

The Proposed Rule Strengthens Protect ons for LGBTQIA+ Individ uals We applaud HHS's proposed rule for mak ng explicit that Section 1557's protections against discrimination on the basis of sex nc udes gender identity which is consistent with the interpretation of the Supreme Court decision in Bostock and federal and discriminations laws. We support the proposed rule for clarifying that discrimination on the basis of sex n hea th care programs and activit es includes sex stereotypes sexual orientation gender or entation gender identity and sex character st c including intersex trait and mar tal parental or family status Footnote 22 Id. at 47936 (Proposed § 92 101)]. Sex stereotypes such as expectat on's about how people shou d present or com' municate have histor cally created bar' ers to equitable hea th care access and services. We also support the restor at on of enforcement of protect ons against discr' mination on the basis of ssoc ation which should protect LGBTQIA+ couples who may be turned away from care [Footnote 23 Id. at 47918 (Proposed § 92 209)]

No comments are associated with this issue

Section 1557 is an important too to address health ineq alities including disparities in access to abortion care. The Proposed Rule would clarify and strengthen ts anti-discrim' nation protections. LDF agrees with OCR's interpretat on that Section 1557 both provides an "independent basis for regulation of d scrimination in covered health programs and activ ties" and is applicable to an expans ve range of "health programs and activities" including programs admin stered by HHS Health insurance plans and Med care Part B. Footnote 50 Nond scrimination in Health Programs and Act vities 87 Fed. Reg 47824 47827 (Aug. 4 2022).] LDF also supports OCR's dec sion to make explic t that Sect on 1557 prohibits discr minat on in telehealth and by clinical algorithms

https://jamanetwork.com/journals/jama/article-abstract/2788483]

A m—promise to ach eve greater efficiency and effectiveness in the delivery of hea thcare by (1) improv ng population health (2) enhancing patient experiences (3) av oid ng unnecessary costs and driving cost efficiency (4) improving the experiences of c n c ans and healthcare staff and (5) advancing health equity It is for these reasons that we want to partner with the Agency and other stakeholders to develop and mplement policies that enable patient access to these technologies while also fostering trust in their accuracy and reliab ty.Bias de tection and Mitigat on vs E mination In this proposed rule HHS proposes to estab sh § 92.210 that states that a covered entity must not discriminate against any individua on the basis of race color nat onal origin sex age or disability through the use of clinical algor thms in its decision making. HHS is taking this action because it believes it is cr t cal to address this issue given recent research de monstrating the prevalence of c n cal algorithms that may result in discrimination. The HHS Office of Civil R ghts (OCR) be eves that proposed § 92.210 would put covered ent t es on not ce that they cannot use discr' natory clinical algor thms and may need to make reasonable modifications in their use o the algor thms unless do ng so would cause a fundamental alteration to the r health prog am or activity A fundamental assumption throughout this proposed rule is el mination of bias in clir cal algor thms is poss ble and prefe rable and that use of these products always results in harmful d scriminatory care MITA mem ber companies go to great lengths to mitigate b as inherent n clinical algorithms and provide transparency into how these technologies are deve oped. Medical imaging algorithm deve opers have extensive experience ba ancing the risks and benefits provided by a product to provide a safe effective dev ce Risk management processes qua ity management systems and intensive train ng programs all reflect a comm' tment to products which im prove patient care

1) HHS must fina ize provisions without delay that protect against discrimination in health care programs and activities n the above-captioned rule HHS is propos ng several provisions that would reinstate safeguards that protect against discriminat on covered health care programs and activ ties as outlined in Sect on 1557 of the ACA. These proposed provisions include reinstat ng the scope of Section 1557 clarifies application to health insurance issuers receiving federal financial assistance prohibits d scr' mination in clinical algor thms used to support decision mak ng and that nondiscr' mination provisions are applicable to services offered through telehealth tech no ogies HHS is right to propose these provisions and ANA urges the Agency to finalize th s proposed rule ANA s an informed and active stakeholder in the mplementation of health care policy ANA sees the proposed ru e rectifying what we saw as the 2020 rule-making t stituting a fundamental change in a rection that is a ntithetical to our principles of health system transformation namely un versal access to health care coverage for all citizens and residents We are pleased that HHS would return key def nitions and protection mechan sms that make Sect on 1557 mean ngfu to of especially to people who otherwise face disc' minatory barriers to care. Th s is ab olutely important as nurses and the health care delivery system focus on achieving health equity and identify approaches to overcome health disparit es.We be eve that existing regulations for Sect on 1557 and other HHS prog ams fulfill the intent of Congress to protect people from discrimination in health care that denies them access.Sect on 1557 should be implemented in a manner that promotes access for those who are subject to discrimination. [Bold As such HHS m ust f nalize proposed Section 1557 provisions that protect against discrimination in health care programs and activities We urge HHS to act expedit ously on this rule-making]

decision mak ng. The goal for each of these tools is to encourage appropriate clinical treatment while avoiding the harm of unnecessary treatment. Algorithms seldom dictate treatment; they more often nf uence clinical decisions and are only one n a variety of factors leading to a decision for treatment. The starting po nt for such decisions must always be the ind v dua patient. [Bold: Tools can he p inform how similar patients might fare with a particular course of treatment based on the best available science. However the clinician and patient must assess toget her how to manage that person's health.] Clinical algorithms are deve oped using the best informat on available in the medical l terature and shou d make every effort to guard aga nst b ases by us ng representat ve and inclus ve data sets. The inclusion of diverse patient samples relative to race and ethnicity has been a goa of clinical research for decades, however researcher have not always achieved this goal. Inaccurate or incomp ete data that might lea to flawed algorithms is the responsibility of the entire system of care not just covered entities including but not lim ted to federal fund ng agencies such as the Food and Drug Adm' nistration (FDA) the NIH National Heart Lung and Blood Inst tute (NHLBI) the Patient-Centered Outcomes Research Institute (PCORI) and the Agency for Health care Research and Quality (AHRQ). The ACC believes there shou d be continued support for coordinat or across all federa agencies to bette understand bias in our health systems how these biases may im pact clinical algorithm development and development of methods to create more accurate and inc usive algorithms that better serve pat ent needs and guard against adverse outcomes including d sc' mination Clinical algorithms vary in nature com plexity and utilization and it is important that a federal agencies not only appropr ately monitor and regulate against adverse outcomes such as incorrect clinical outputs or discr' minatory recommendations but also guard aga nst un ntended consequences that stifle innovat on and inadvertently hold clinicians

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Just ce in Ag ng

Senate Democrats

NAACP Legal Defense and Education Fund, Inc

Medical Imaging & Technology Alliance (MITA)

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American Nurses Association

American College of Card ology

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The direct attention to nondiscrimination on the basis of sex limited English proficient (LEP) individuals and people with disabilities and the clarification of the specific measures that are anticipated to comply with Section 1557 are welcome. Specifically we support the major clarifications in the rule: • The interpretation of Section 1557 to cover all health programs and activities administered by HHS• The interpretation that provision of Medicare Part B assistance is federal financial assistance and that entities receiving Medicare Part B funds must comply with the Rule• The application to health insurance issuers that receive federal financial assistance• The clarification that the protections against discrimination on the basis of sex including sexual orientation and gender identity and discrimination on the basis of sex stereotypes and the extension of these protections to CMS regulations• The expectation that compliance will require implementing programs to develop maintain and communicate clear policies and train on the provision of language assistance services for limited English proficient (LEP) individuals and effective communication and reasonable modifications to policies and procedures for people with disabilities • The requirement that implementing entities provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states.• The expectation of nondiscrimination based on clinical algorithms• The expectation that nondiscrimination extends to telehealth services and• The development of clear processes for requesting exceptions from the expectation of compliance

proposed rule OCR suggests providers should forgo the use of tools if the provider does not adequately understand how it works and should ask if the tool was properly validated and validated for the specific case and use whether it was tested in different populations to identify hidden bias and whether it allows barriers to access to be found and rectified among other things. While in this ideal a clinician must understand the tools they use when treating patients the College disagrees with this assessment due to broad complex and layered nature of algorithm development in the healthcare system. [Bold] It is unrealistic for every clinician to have complete understanding of the validation techniques utilized in the development and testing of every clinical algorithm or tool they use while caring for patients within the resources made available to[ay]. While it may be possible for organizations such as medical associations to publish this information for users to investigate it is incredibly difficult for clinicians to find underlying evidence used in the training and development of medical devices that utilize clinical algorithms because manufacturers often do not publish data that sufficiently identifies the information OCR suggests clinicians should review Before using the tool Device manufacturers closely guard how many of their devices and tools work and often invoke trade secret protections to prevent the publication and in depth discussion of their clinical algorithms making it impossible to truly understand how an algorithm works. Instead clinicians place great trust in the review and approval processes of regulatory agencies such as the FDA and rely on their clearance recommendations approval as well as the publication of data showing the efficacy of a tool to understand the appropriate clinical uses of tools and algorithms to make up for this lack of information access. [Bold] While the AEC would appreciate additional disclosures from device manufacturers during the FDA clearance and approval process the College does not believe the burden for understanding and transferring potential liability for

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Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard [MRCT Center] I

American College of Cardiology

The Proposed Rule Addresses Various Forms of Systemic Racism in Health Care The Department properly notes that racial health disparities in the United States are directly attributable to "persistent bias and racism" in the healthcare system. Both intentional and unintentional race discrimination serve as barriers to care lead to lower quality care and drive worse health outcomes for communities of color. Discrimination in health care is often systemic deeply embedded within the policies procedures and practices of covered entities to say nothing of the social determinants of health outside of healthcare systems. The Proposed Rule addresses several major drivers of systemic racism including both discrimination policies and procedures algorithmic discrimination and discriminatory health insurance networks. Each of these are a critical step toward addressing the ways in which racism manifests systemically in health care

Alliance of Multicultural Physicians

[Bold and Underline: Use of Clinical Algorithms in Decision-making]We appreciate the proposed rule's focus on nondiscrimination in the use of clinical algorithms in decision-making. We would recommend the rule language in the final rule that compels users of these algorithms to demonstrate benefit over the very least a lack of predictable harm. AAP strongly supports prohibitions on use of clinical algorithms that use race as a risk factor or those that because of existing structural racism ran amplify existing racial inequities. Race based medicine has been pervasively interwoven into the fabric of health care delivery in the United States for more than 400 years. Race is a historically derived social construct that has no place as a biologic proxy. In addition to valid measures of social determinants of health the effects of racism require consideration in clinical decision making tools in ways that are evidence informed and not inappropriately conflated with the limiting phenotype of race categorization [Footnote text omitted] L. Wright Wendy S. Davis Madeline M. Joseph Angelo M. Ellison Rob J. Heard Garris Tiffani L. Jonsaint the AAP Board Committee on Equity; Eliminating Race-Based Medicine. Pediatrics. July 2022; 150 (1): e2021056798. doi: 10.1542/peds.2021-056798]

American Academy of Pediatrics

[Bold and Underline: Use of Clinical Algorithms in Decision-making]We support the Department's proposal to address clinical algorithms such that covered entities would be on notice that they cannot base decisions in whole or in part on discriminatory clinical algorithms. Algorithms promise efficiency in health care but their potential for harm has been well documented in other fields such as criminal justice housing and employment the patient-provider relationship health care enrollment screening risk prediction diagnosis diagnosis treatment planning and the allocation of resources. [Footnote 14: Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (Jan. 25 2022) https://effectivehealthcare.ahrq.gov/products/racial-disparities-health-healthcare/protocol.]

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National Disability Rights Network

Use of Clinical Algorithms in Decision-Making:CCJ supports the addition of this new section and agrees with OCR that research shows that the use of automated decision-making systems (ADS) may result in discrimination. CCJ recommends that the proposed rule should include any form of ADS.

Genesee County Legal Aid Society dba Center for Civil Justice

Making Itself: HHS seeks comment on what types of clinical algorithms are being used in covered health programs and activities, how such algorithms are being used by covered entities; whether they are more prevalent in certain health settings; when clinical algorithms and variables based on protected grounds under Section 1557 are useful (or not), and what mechanisms are in place or should be in place to detect address and remediate possible discriminatory effects of the usage.[STS maintains the STS National Database which was established in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. The Database has four components each focusing on a different area of cardiothoracic surgery—Adult Cardiac Surgery Congenital Heart Surgery General Thoracic Surgery and Mechanical Circulatory Support. Currently the Adult Cardiac Surgery Database (ACSD) alone contains more than 7 million cardiac surgery procedure records and has more than 3800 participating physicians including surgeons and anesthesiologists representing more than 90% of all adult cardiac surgery hospitals across the United States and Canada. The STS National Database was developed specifically for cardiothoracic surgeons to measure relevant and necessary data for the purpose of quality improvement and provides tools such as the STS Short-Term Risk Calculator. The STS Short-Term Risk Calculator allows surgeons to calculate a patient's risk of mortality and morbidities for the most commonly performed cardiac surgeries. It incorporates STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity. Risk models developed by The Society of Thoracic Surgeons (STS) Quality Measurement Taskforce (QMTF) typically include demographic clinical and social risk variables. Their goal is to account for all factors not under the control of the provider that may be associated with differences in patient outcomes. In the development of risk models STS considers multiple published

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The Society of Thoracic Surgeons

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Specifically the Health Connector strongly supports the proposed rule's prohibition on the use of discriminatory clinical algorithms in health care decision making and extension of nondiscrimination protections to telehealth services and benefit design. The Health Connector has sought to enhance its focus on nondiscriminatory benefit and formulary design in recent years as part of its deepening health equity agenda and welcomes additional clarity and support in these endeavors from the federal regulatory framework governing nondiscrimination policy. Broadening the applicability of Section 1557 nondiscrimination protections will improve equitable access to health care and coverage for individuals and families across the Commonwealth.

(b)(5) Massachusetts Health Connector

Body: II. The Proposed Rule Addresses Various Forms of Systemic Discrimination in Health Care and Methods of Prevention. The Department properly notes that health disparities in the United States are directly attributable to persistent bias in the health care system. Both explicit and implicit discrimination serve as barriers to care and foster lower quality care and drive worse health outcomes for communities. Discrimination in health care is often systemic — deeply embedded within the policies, procedures and practices of covered entities. The proposed rule addresses several major drivers of systemic discrimination including onsite discrimination policies and procedures and algorithmic discrimination. The proposed rule takes a critical step toward addressing the ways in which discrimination manifests systemically in health care.

The Leadership Conference on Civil and Human Rights

Body: Prohibiting Discrimination in Automated Decision-Making. We agree with HHS that clinical algorithms can be discriminatory and particularly harmful to Black patients as they often indicate that Black patients must be more sick than white patients before they can receive treatment for life-threatening conditions such as kidney disease and heart failure. We support the proposed provision to prohibit discrimination through the use of clinical algorithms in decision-making. However, we request that HHS broaden the prohibition to include any form of automated decision-making system. For older adults and others there are numerous examples of discrimination in decision-making tools and systems that may fall outside the term "clinical algorithm." These include assessment tools for home and community-based services for both level of care determinations and services allocation that discriminate against groups or deny services needed to maintain community integration; Medicaid eligibility systems that wrongfully deny or terminate coverage; "gender conflicts" in health decisions that lead to misdiagnoses and discrimination in health care settings, and utilization review practices that are based on financial metrics rather than generally accepted standards of care. At a minimum, HHS should define the term "clinical algorithms" because it may otherwise be too narrowly construed. For example the Crisis Standards of Care which frequently lead to intersectional discrimination against older adults and disabled people of color may not be "clinical algorithms" under a narrow definition because they were often policies or ranking systems rather than automated decisions. [Footnote 16: Examining How Crisis Standards of Care May Lead to Intersectional Medical Discrimination Against COVID-19 Patients. Justice in Aging https://justiceinaging.org/wp-content/uploads/2021/12/JA-NAL Intersectional_Guide_Crisis_Care_2.10.21.pdf]

Center for Elder Law & Justice

[illegible] algorithms are crisis standards of care." The discriminatory use of clinical algorithms has no place in health care. Proposed Section 92.210 would make explicit that covered entities are prohibited from discriminating through the use of clinical algorithms on the basis of race, color, national origin, sex, age or disability under Section 1557. [Footnote 13: Id. at 176-187.] | Many clinical algorithms dictate that Black patients for example must be more sick than White patients before they can receive treatment for a range of life-threatening conditions including kidney disease, heart failure and pregnancy-related complications. Similarly, crisis standards of care which are also driven by clinical algorithms have often reflected bias against people with disabilities, people of color and older adults. They typically prioritize care toward patients who are younger and do not have disabilities excluding or de-prioritizing those who have certain health conditions, those who are perceived unlikely to survive in the intermediate or long term and those believed to require greater resources to survive an acute episode of illness. This provision in the proposed rule is critical in addressing one of the most prevalent forms of systemic discrimination in health care today.

The Leadership Conference on Civil and Human Rights

regulation notifying covered entities that they "must not discriminate on the basis of race, color, national origin, sex, age, or disability in [their] health programs and activities through the use of clinical algorithms in decision making." 87 Fed. Reg. at 47918. As the research cited in the NPRM demonstrates, this type of discrimination is increasingly prevalent, yet based on the States' investigatory experiences it is generally not transparent to consumers and can be poorly understood even by providers. [Footnote 61: Although the States appreciate the American Medical Association's framework which HHS describes on 87 Fed. Reg. at 47888, our experiences to date have not demonstrated robust or widespread implementation of this framework.] The proposed regulation appropriately puts covered entities on notice of the relevance of Section 1557 to clinical algorithms and is likely to increase the healthcare sector's attention and investment in review and auditing of these types of processes. To ensure the success of these efforts the States recommend the following clarifications described in more detail below: (1) that a decision may be made "in reliance" on an algorithm even in circumstances where human judgment is involved; (2) that this regulation is exemplary and does not limit other types of automated decision making that may violate Sec. 1557; (3) that a clinical algorithm may be facially discriminatory even if protected characteristics are not explicit variables and that disparate impact evidence is highly probative of discrimination; and (4) that HHS does not intend to limit other regulations or requirements that States may impose on covered entities to protect consumers against discrimination by clinical algorithms or other automated decision making. First we commend HHS for its focus on decision making since it is when algorithms and other automated systems are used to make decisions that impact care that they have the greatest potential to cause discrimination and harm. A decision may be made "in reliance" on an algorithm even if independent medical judgment is also an element of the [illegible] would prohibit a covered entity from discriminating against any individual on the basis of race, color, national origin, sex, age or disability by using clinical algorithms in its decision making. This provision is not intended to hinder the use of clinical algorithms but to prevent discrimination, with the effect of increasing reliance on clinical algorithms in health care decision-making. The Preamble notes that covered entities are responsible for ensuring that any action they take based on a clinical algorithm does not result in discrimination prohibited by this part irrespective of whether they played a role in designing the algorithm. The Proposed Rule does not define the term "clinical algorithm." Recommendation: BCBSA supports the goals of this provision, urges HHS to work with stakeholders first to clarify the meaning of clinical algorithms and to engage with private and public stakeholders on the development and adoption of national industry standards prior to mandating requirements to safeguard against adverse bias and outcomes. Rationale: The current application of technologies could be significantly improved by the establishment of national governmental clearly defined and supported standards that address algorithm documentation, testing and auditing as well as stakeholder education as none exist today. Such standards would provide guidance around the transparency, reliability, trustworthiness and risk mitigation. In lieu of standards best practices at a minimum are needed. The development of definitions, national standards and technical implementation guides is necessary to drive care management efficiency and leverage critical data to improve patient outcomes. To foster deployment of novel technologies to scale, BCBSA and BCBS Plans are actively engaged in industry-led efforts such as the HL7 Gravity Project while increasing safeguards and privacy protections to enhance the appropriate use of sensitive consumer information as we previously discussed. We encourage HHS to review the work of HL7's Gravity Project and its efforts around identification of SDOH data sets necessary for addressing the

(b)(5) Blue Cross Blue Shield Association

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(b)(5) Attorneys General of California, New York, Massachusetts, and nineteen other States

landscape are important to further health equity [118] Clinical algorithms have the potential to be transformative tools in health care but there is demonstrable concern about the ways in which algorithms are sensitive to the biases of their creators [Footnote 116: See e.g. AHRQ IMPACT OF HEALTHCARE ALGORITHMS ON RACIAL AND ETHNIC DISPARITIES IN HEALTH AND HEALTHCARE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (Jan. 25 2022) https://effectivehealthcare.ahrq.gov/products/racial-disparities-health-healthcare/protocol; Matthew Hutson Even Artificial Intelligence Can Acquire Biases Against Race and Gender SCIENCE (Apr. 13 2017) https://www.science.org/content/article/even-artificial-intelligence-can-acquire-biases-against-race-and-gender; Stephanie S. Gervasi et al. The Potential for Bias in Machine Learning and Opportunities for Insurers to Address HEALTH AFFAIRS (Feb. 2022) https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01287; Ziad Obermeyer et al. Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations SCIENCE (25 Oct. 2019) https://www.science.org/doi/full/10.1126/science.aax2342, Elizabeth Edwards Preventing Harm from Automated Decision-Making Systems in Medicaid NATIONAL HEALTH LAW PROGRAM (Jun. 14 2021) https://healthlaw.org/preventing-harm-from-automated-decision-making-systems-in-medicaid/.] Recently the WHO convened experts over the course of two years to inspect the ways that these technologies appear across the health care sector and govern various decision-making processes within health care systems. WHO's subsequent report and guiding principles urge governments and entities to center human dignity autonomy and principles of inclusivity equity and accountability in order to ensure that these systems are implemented in a way that benefits every person. [Footnote 117 WORLD HEALTH ORG. ETHICS AND GOVERNANCE OF ARTIFICIAL INTELLIGENCE FOR HEALTH GUIDANCE WHO (Jun. 28 2021)]

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A new provision proposed by the Department seeks to eliminate the potential discrimination that patients may face when providers overly rely on algorithms in decision making by replacing or substituting the clinical judgment [Footnote 7 87 Fed. Reg. at 47880 47916 (Proposed § 92.210)] Clinical algorithms automated or augmented decision-making tools and models including machine learning and artificial intelligence (AI) are useful tools to help diagnose and inform the health care services a person will receive. But clinical algorithms can contribute to discrimination and bias against people of color and people with disabilities from screening out certain populations for treatment or priorities to incorrectly focusing on health care costs as a proxy to care to decreasing the quality of care patients receive [Footnote 8 See e.g. Kara Manke "Widely used health care prediction algorithm biased against black people" BERKELEY NEWS (Oct. 24 2019) https://news.berkeley.edu/2019/10/24/widely-used-health-care-prediction-algorithm-biased-against-black-people/] We encourage and even encouraging we applaud the Administration for working to ensure entities' usage of algorithms do not perpetuate patterns of discrimination against marginalized and underserved communities and to encourage more transparency and accountability in the development and use of algorithmic technologies

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Use of Clinical Algorithms in Decision- Making (§ 92.210)We echo the comments of the National Health Law Program that there is particular risk for error in the use of clinical algorithms in the provision of care to individuals with LEP and support limiting the use of any automated decision-making systems without checks by humans trained on nondiscrimination. We support robust restrictions on any potential discriminatory or biased automatic decision-making tools and the implicit bias often built into such systems

FDA-regulated vs Non-FDA-regulated Clinical AlgorithmsThroughout this proposed rule it is not entirely clear whether HHS is intending to capture clinical algorithms that are regulated as medical devices by the FDA or a broader set of software products. As discussed above MITA member company technologies are subject to FDA regulation and oversight that ensures the safety and efficacy of these products. HHS should be clear as to the exact scope of this proposed rule. Fostering Trust in Clinical AlgorithmsFinally we are concerned that the overall tone of this proposed rule could diminish trust in the use of AI and ML products. For example we are concerned about the Agency's use of the term "discriminatory clinical algorithm" starting on page 177 of the proposed rule. This assumes as the default position that clinical algorithms are resulting in discriminatory patient harms. While elimination of bias in algorithms is not a tenable goal identification and mitigation of bias is always an ongoing objective. Further clinical algorithm developers seek to be transparent about identified biases in clinical algorithms and educate caregivers about the existence of these biases so as to minimize impact to patient care As discussed above AI and ML technologies carry great promise to improve patient care and the practice of medicine. Framing these devices as dangerously discriminatory in all cases or as a baseline could damage the public's trust of these innovative technologies and diminish adoption by healthcare providers. Product developers and FDA go to great lengths to identify and mitigate bias in these technologies. Product developers also undertake extensive efforts to educate users about the uses and limitations of these products.

Role of Algorithms and Bias Discrimination And Interplay of the proposed rule expands upon the existing Section 1557 regulations to prohibit discrimination in health decision-making algorithms While our association understands that HHS included this specification in the proposed rule due to research indicating that clinical algorithms increasingly have the potential to be discriminatory we caution HHS to take care that any technology-based regulations remain evergreen In addition our members note that while over-reliance on algorithms can be problematic there are situations in which algorithms can lead individuals and institutions to make decisions and offer health based programs to individuals that can very beneficial. It would be very unfortunate if the unintended consequences of algorithm limitations. HHS should prioritize appropriate balance when finalizing any algorithm requirements

Undue Skepticism in the use of Clinical Algorithms in decision-making [§ 92.210]We support the proposed provision to prohibit discrimination through the use of clinical algorithms in decision making and appreciate HHS's discussion of how some crisis standards of care (CSCs) used during the COVID-19 pandemic were discriminatory. [Footnote 49: Justice in Aging et al. Examining How Crisis Standards of Care May Lead to Intersectional Medical Discrimination Against COVID-19 Patients (Feb. 2021) https://justiceinaging.org/wp-content/uploads/2021/02/HINAL_Intersectional_Guide_Crisis_Care_2_10_21_pdf.] However we recommend that HHS broaden the prohibition to include any form of automated decision-making systems as well as CSCs which were often ranking systems or processes that may not be considered automated. It is also important to note that an algorithm or screening tool that is equitable in its development is incomplete without culturally competent administration especially considering racial and other traits that exist for many patients in health care settings [Footnote 50 For example SAGE USA's resource on Disrupting Disparities provides best practices for collecting LGBTQ-identity data in a manner that protects privacy and fosters comfort for older adult patients.]

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While we agree with the intent of the proposed rule we believe that automatically placing liability on the covered entity has unintended consequences that will negatively impact patient care To illustrate we focus on the impact of two statements from the preamble to the proposed rule at [Bold: "While covered entities are not liable for clinical algorithms that they did not develop they may be held liable under this provision for their actions made in reliance on clinical algorithms." (i) "The fact that a covered entity did not design the algorithm or does not have knowledge about how the tool works does not alleviate their responsibility to ensure that they do not take actions that result in discrimination."]

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Center for Reproductive Rights

Senate Democrats

National Immigration Law Center

Medical Imaging & Technology Alliance (MITA)

National Association of Health Underwriters

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Justice in Aging

Mayo Clinic

This disparate treatment by medical providers as well as systemic disparities in health care needs and access are often reproduced by the clinical algorithms providers increasingly rely on to help diagnose and treat patients. For example although Black Americans are four times more likely to have kidney failure the standard algorithm used around the country to determine transplant list placement explicitly uses race as a factor and puts Black patients lower on the list than white patients even when all other factors determine identical. [Footnote 21 Rachel Bitchell & Cara Anthony Kidney experts say it's time to Remove Race From Medical Algorithms, Going Solo Commissioned HEALTH AFFAIRS, June 8 2021, https://khn.org/news/article/black-kidney-patients-racial-health-disparities/?utm_campaign=KHN%3A%20Daily%20Health%20Policy%20Report&utm_medium=email&_hsmi=133945886&_hsenc=p2ANqtz-40DkaxKPHQSQeAfuOeyU-A2aGfNgUdPyX4KJJqtvaQUUyan7RycEujUe8kMR673a6PIVDKFuJZgBVacR1yNazQ_Tte4lvXmfHP2n4JLzwK0&utm_content=133945886&utm_source=hs_email. Many doctors now believe that the data that led the algorithm's developers to include the race coefficient is actually a reflection of both systemic health disparities and discriminatory by providers and that the continued use of the algorithm leads to worse outcomes for Black patients. [Footnote 22 Id.] A 2019 study similarly found that algorithms used to identify sicker patients who would benefit from additional care led to Black patients receiving less quality care than their non-Black counterparts. [Footnote 23 Ziad Kartar Race Bias Found in a Major Health Care Risk Algorithm SCI AM (Oct. 24 2019) https://www.scientificamerican.com/article/racial-bias-found-in-a-major-health-care-risk-algorithm/].

[Bold and Underline: Use of Clinical Algorithms in Decision-Making]§ 92.210) NAEDS wholly agrees with OCR that clinical algorithms and similar tools should not be used to discriminate against individuals. However covered entities must take into account certain characteristics when providing patients with treatment and advice. With this in mind we ask that when OCR is reviewing complaints and compliance efforts under this rule it tell us that the agency considers the need for covered entities to take into account certain characteristics to provide optimal care. We believe that OCR's issuing this type of reasonable approach would help covered entities provide even better care in the future to marginalized communities

[Italic: Nondiscrimination protections in clinical algorithms and telehealth.]We strongly support the addition of comprehensive nondiscrimination protections to the use of clinical algorithms and telehealth. Even though telehealth has been used in the past the explosion of telehealth due to the COVID-19 pandemic has presented new opportunities for LGBTQI+ patients to engage with and maintain affirming care. At Howard Brown we see clients from all over the state of Illinois and neighboring states. For patients not living in Chicago or in rural areas this would result in them having to travel many hours and for some across state lines in order to see affirming providers. For these reasons telehealth especially during the COVID pandemic was a bridge to help eliminate barriers to affirming care for many. Telehealth has also proven to be an effective alternative to in-person care with a recent study of LGBTQI+ youth and their caregivers showing that 91.7% of patient and 88.9% of caregiver respondents reported the comfort of communicating with providers though telehealth was the same or better than in-person visits [Footnote 12: Appel DE Lett E Wood S Freeman Bauer K Chan J Schwartz LA Petsis D Haust H Dawsher N [2022] Acceptability of telehealth for gender affirming care in transgender and gender diverse youth and their caregivers Transgender Health 7 2 159–164 DOI 10.1089/trgh.2020.0061] Telehealth is here to stay and will be a vital tool to help expand healthcare access and retention for LGBTQI+ patients so having strong nondiscrimination protections in place is vital.

[illegible] telehealth services.Covered California supports HHS's efforts to mitigate the potential harm caused by valuable clinical algorithmic tools in achieving learning or other similar developing technology. Awareness of the potential and actual discriminatory harms caused by clinical algorithms has grown in recent years and Coverse California urges HHS to continue to maintain meaningful protections despite the challenge of building and maintaining the technical knowledge required to implement and maintain these guardrails. Covered California has recently begun to assess QHP issuers' approaches to monitoring algorithms used in health care including clinical algorithms for potential bias.Importantly we note protections against discrimination should be applied beyond clinical algorithms to include all related automated or augmented decision-making tools such as artificial learning or artificial intelligence. As HHS notes in this proposed rule there is a growing body of evidence that confirms that a number of applications of these decision making tools result in the discriminatory allocation of health care resources

[Bold. Clinical Algorithms] We agree with HHS that clinical algorithms have the potential to be discriminatory and particularly harmful to patients from marginalized communities as they may dictate that certain patients must be more ill than other patients before they can receive treatment for life threatening conditions such as kidney disease and heart failure. We urge CMS to adopt a broad definition of "clinical algorithms" to include all clinical automated decision making processes. In addition we urge CMS to monitor implementation of this provision to assure that it is being correctly implemented broadly

would prohibit a covered entity from discriminating against any individual on the basis of race color national origin sex age or disability by using clinical algorithms in its decision-making. This provision is not intended to hinder the use of clinical algorithms but to prevent discrimination when the recent increasing reliance on clinical algorithms in health care decision making. The Preamble notes that covered entities are responsible for ensuring that any action they take based on a clinical algorithm does not result in discrimination prohibited by this part irrespective of whether they played a role in designing the algorithm. The Proposed Rule does not define the term "clinical algorithm."Recommendation: BCBSA supports the goals of this provision. It urges HHS to work with stakeholders first to clarify the meaning of clinical algorithms and to engage with private and public stakeholders on the development and adoption of national industry standards prior to mandating requirements to safeguard against adverse bias and outcomes.Rationale: The current application of technologies could be significantly improved by the establishment of national government clearly defined and supported standards that address algorithm documentation testing and auditing as well as stakeholder education beyond existing. Such standards would provide guidance around transparency reliability trustworthiness and risk mitigation. In lieu of standards best practices at a minimum are needed. The development of definitions national standards and technical implementation guides is necessary to drive care management efficiency and leverage critical data to improve patient outcomes. To foster deployment of novel technologies to scale BCBSA and BCBS Plans are actively engaged in industry-led efforts such as the HL7 Gravity Project while increasing safeguards and privacy protections to enhance the appropriate use of sensitive consumer information as we previously discussed. We encourage HHS to review the work of HL7's Gravity Project and its efforts around identified on of SDOH data sets necessary for addressing the

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NAACP Legal Defense and Education Fund, Inc

National Association of Chain Drug Stores

Howard Brown Health

Covered California

National Health Council

Blue Cross Blue Shield Association

Defining "Reasonable Modifications" and "Fundamental Alterations" In this proposed rule HHS seeks to put covered entities on notice that they cannot use discriminatory clinical algorithms and may need to make reasonable modifications to the use of the algorithms or discontinue doing so would cause a fundamental alteration to the health program or activity. HHS does not provide a definition of "reasonable modification" or "fundamental alteration." Levels of Autonomy in AI/ML Products HHS states "While covered entities are not liable for clinical algorithms that they did not develop they may be held liable under this provision for their decisions made in reliance on clinical algorithms. Covered entities using clinical algorithms in their decision-making should consider clinical algorithms as a tool that supplements their decision-making rather than as a replacement of their clinical judgment." In general MITA currently agrees with this statement and product labeling and supporting materials provided with clinical algorithms are consistent with this concept. This policy however may not appropriately account for ongoing advances in the autonomy of AI and ML products. The American Medical Association's (AMA) recently issued document titled "CPT Appendix S: AI taxonomy for medical services & procedures" [Footnote 2: https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures] stratifies AI products into three levels of autonomy: assistive augmentative and autonomous. The autonomous classification further stratified into three levels of physician involvement and contestability for the algorithm's actions. While the majority of AI and ML products can still be classified as assistive or augmented we do increasingly number of autonomous products with increasing levels of autonomy will be introduced to the market in the coming years

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Medical Imaging & Technology Alliance (MITA)

[Bold: Lack of definition and context.] The proposed rule lacks the specific definitions to effectively execute. For example there is no definition or criteria about what it means to "rely" on a clinical algorithm. In practice most clinical algorithm developers and covered entities claim that the physician is ultimately responsible for the decision (e.g. Clinical Decision Support or "CDS"). It would be helpful to have clarity on the difference between "reliance" in this proposed rule and the 21st Century Cures Act criteria to qualify as CDS. The Act and FDA final guidance on CDS requires specific criteria to qualify as CDS because the influence of algorithms on clinical judgement is a spectrum. If policies are drafted to reinforce non-reliance without defining the spectrum of what it means to rely on an algorithm or clinical judgement then the proposed rule may become ineffective or cause covered entities to do more manual work only to prove non-reliance and avoid the threat of liability. Alternatively a proposed rule that defines reliance including the specific information and modeling that must be provided with a clinical algorithm to prevent reliance would help both clinical algorithm developers and covered entities know the risks they are taking (e.g. if the developer does not do the work to share the information needed for the user to independently assess the results or implements the algorithm in a manner that does not include human judgement then covered entities know they are relying on clinical algorithms if they use it).

Mayo Clinic

- Use of Clinical Algorithms. BCBSA supports the goal of ethical use of clinical algorithms against biased outcomes in healthcare. However given the lack of clear definitions and standards we urge HHS to first clarify the meaning of clinical algorithms and to engage with private and public stakeholders on the development and adoption of national industry standards prior to mandating requirements on providers using such technology. Clear industry-developed standards will establish guidelines for both developers and users of AI to safeguard against adverse bias and outcomes

Blue Cross Blue Shield Association

The preamble to the 2022 Proposed Rule of bias from clinical algorithms. We request that OCR broaden the 2022 Proposed Rule to include any form of automated decision-making systems because of the prevalence of automated decision-making systems used by Covered Entities. At a minimum HHS needs to define the term "clinical algorithms" because it may otherwise be too narrowly construed. Regardless of intent clinical algorithms can have discriminatory impacts. We see this too often with "gender conflicts" in health decisions that lead to misdiagnoses and discrimination in health care settings for transgender and non-binary patients [Footnote 2 Style: Resolution Limited Data Collection for LGBTQI+ Health Promotes Bias National Health Law Program (June 22 2021) https://healthlaw.org/limited-data-collection-for-lgbtqi-health-promotes-bias/]. None of this is relevant or in the use of clinical algorithms is also relevant as health systems invest in care management programs focused on high risk patients. As has been widely documented many of the common algorithms developed to identify patients for these programs were systematically excluding Black patients and other patients of color [Footnote 3: Heidi Ledford Millions of black people affected by racial bias in health-care algorithms Nature (October 24 2019) https://www.nature.com/articles/d41586-019-03228-6]. This was because many were using "utilization of care and cost" as a proxy for overall combined with "severity of diagnosis." People of Color and Black patients in particular used less care and incurred fewer costs for the same level of illness. The data in a commonly cited study found that when "illness rather than cost of care was used to identify patients for care management programs the percentage of Black patients identified went from 17.7% to 46.5%. [Footnote 4 Ziad Obermeyer et al. Dissecting racial bias in an algorithm used to manage the health of populations Journal of Science (Oct 2019) https://www.science.org/doi/10.1126/science.aax2342?cookieSet=1] This is not ja

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We also request that HHS broaden the 2022 Proposed Rule to include any form of automated decision-making systems because of the prevalence of automated decision making systems used by covered entities. At a minimum HHS needs to define the term "clinical algorithms" because it may otherwise be too narrowly construed

Health Care For All

The preamble to the 2022 Proposed Rule of bias from clinical algorithms. We request that OCR broaden the 2022 Proposed Rule to include any form of automated decision-making systems because of the prevalence of automated decision-making systems used by Covered Entities. At a minimum HHS needs to define the term "clinical algorithms" because it may otherwise be too narrowly construed. Regardless of intent clinical algorithms can have discriminatory impacts. We see this too often with "gender conflicts" in health decisions that lead to misdiagnoses and discrimination in health care settings for transgender and non-binary patients [Footnote 2 Style: Resolution Limited Data Collection for LGBTQI+ Health Promotes Bias National Health Law Program (June 22 2021) https://healthlaw.org/limited-data-collection-for-lgbtqi-health-promotes-bias/]. None of this is relevant or in the use of clinical algorithms is also relevant as health systems invest in care management programs focused on high-risk patients. As has been widely documented many of the common algorithms developed to identify patients for these programs were systematically excluding Black patients and other patients of color [Footnote 3: Heidi Ledford Millions of black people affected by racial bias in health-care algorithms Nature (October 24 2019) https://www.nature.com/articles/d41586-019-03228-6]. This was because many were using "utilization of care and cost" as a proxy for overall combined with "severity of diagnosis." People of Color and Black patients in particular used less care and incurred fewer costs for the same level of illness. The data in a commonly cited study found that when "illness rather than cost of care was used to identify patients for care management programs the percentage of Black patients identified went from 17.7% to 46.5%. [Footnote 4 Ziad Obermeyer et al. Dissecting racial bias in an algorithm used to manage the health of populations Journal of Science (Oct 2019) https://www.science.org/doi/10.1126/science.aax2342?cookieSet=1] This is not ja

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Health Care For All

National Disability Rights Network

telehealth services.Covered California supports HHS's efforts to mitigate the potential harm caused by valuable clinical algorithms (tools, machine learning or other similar developing technology). Awareness of the potential and actual discriminatory harms caused by clinical algorithms has grown in recent years and Covered California urges HHS to continue to pursue meaningful protections despite the challenge of building and maintaining the technical knowledge required to implement and maintain these guardrails. Covered California has recently begun to assess QHP issuers' approaches to monitoring algorithms used in health care including clinical algorithms for potential bias. Importantly we note protections against discrimination should be applied beyond clinical algorithms to include all relative automated or augmented decision-making tools such as artificial learning or artificial intelligence. As HHS notes in this proposed rule there is a growing body of evidence that confirms that a number of applications of these decision-making tools result in the discriminatory allocation of health care resources.

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Covered California

While the prohibition against discrimination is foundational effective federal action to mitigate discriminatory outcomes will need to be specific and include guidance for covered entities in how to appropriately assess algorithms for bias. Augmented decision-making tools are being increasingly adopted by a variety of health care entities ranging from individual clinicians to hospital systems to insurers many of whom may not have the resources or technical knowledge to assess whether their tools are giving discriminatory outcomes. In other words the issue at hand is not discriminatory intent; therefore any action must go beyond intentional discrimination and also provide workable solutions. Given the widespread variation in knowledge and technical expertise in this area standardizing actions covered entities should take as well as providing technical assistance and guidance would accelerate progress and reduce harm in this area.

Covered California

The proposed rule guards against the impermissible use of race and ethnicity based inputs in the use of medical algorithms. We support proposals to provide guardrails for the use of race and ethnicity based inputs to medical algorithms which when used inappropriately can result in discrimination against people of color. [Footnote 9 See e.g. Majority Staff House Committee on Ways and Means Fact Versus Fiction: Clinical Decision Support Tools and the (Mis)Use of Race 116th Cong. (Oct. 14 2021)] While race ethnicity and socioeconomic indicators can help improve covered entities' understanding of and response to health disparities these inputs can also create disparities when they interfere with a provider's individualized clinical judgment. For example the use of race and ethnicity data as input variables in medical algorithms and algorithm informed decision-making in nephrology and cardiology among other contexts have contributed to disparities in care between white patients and people of color. This has led to a shift from overreliance on such tools. [Footnote 10 Agency for Healthcare Research and Quality "Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare (Jan. 25 2022) (https://effectivehealthcare.ahrq.gov/products/racial-ethnic-disparities-health-healthcare/protocol); Letter from James L. Madara Executive Vice President and CEO American Medical Association to David Meyers Acting Director Agency for Healthcare Research and Quality (May 3 2021)] As a result we are encouraged that the proposed rule explicitly prohibits the use of clinical algorithms when used in a discriminatory way. The Office for Civil Rights's commitment to a case-by-case factual inquiry into compliance and the development of technical assistance programs to guide implementation appropriately balances the complexity of this issue while ensuring that providers rely primarily on their clinical judgment in treating patients from historically marginalized communities.

U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

and crisis standards of care. The indiscriminate use of race-based clinical algorithms has no place in health care. Proposed Section 92.210 would make explicit that covered entities are prohibited from discriminating through the use of clinical algorithms on the basis of race color national origin sex age or disability under Section 1557. Many clinical algorithms dictate that Black patients in particular must be more ill than White patients before they can receive treatment for a range of life-threatening conditions including for kidney disease heart failure and pregnancy-related complications. Similarly Crisis Standards of Care which are also driven by clinical algorithms have often referred to bias against disabled people people of color and older adults. They typically prioritize care toward patients who are younger and do not have disabilities excluding or deprioritizing those who have certain health conditions those who are presumed unlikely to survive in the intermediate or long term and those presumed to require greater resources to survive the acute episode of illness. This provision in the Proposed Rule is critical in addressing one of the most prevalent forms of systemic discrimination in health care today.We want to make clear that race/ethnicity based algorithms that promote equity should not be lumped in with those that inappropriately exacerbate inequities. We caution covered entities to maintain this nuanced view of race/ethnicity. Race essentialism or biological essentialism has NO place in medicine and health care (race is not a biologic category).

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Alternatively race is a social construct category relative to being a meaningful factor in terms of predictive outcomes that includes the milieu of environmental economical sociological influences on outcomes that individuals have. Where a so-called race-based algorithm derives from an origin of understanding the social question an understanding and appreciation of the history of systemic racism in healthcare and actively drives to reduce disparities in that population that algorithm should be utilized.

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Alliance of Multicultural Physicians

d. Prohibit the use of the clinical algorithm Quality Adjusted Life Years (QALYs) in all health care decision making. Health care decision making should not be determined using a method that discriminates against people with disabilities. Assigning a lower "quality" to a disability or chronic condition actuarially puts people with disabilities at a disadvantage when deciding on life-extending treatments. It is important to note that that utilization of QALYs in priority setting directly assigns a lower value to the lives of persons with disabilities. The Arc of PA is requesting that this discriminatory method of health care decision making is prohibited

The Arc of Pennsylvania

Racial and other systemic oppression permeate current health data collection and affect equity efforts because historical data is used to create screening tools and studies. Essentially "if bias is present in the world, it will be present in the data." [Footnote 51 Trishan Panch et al. Artificial intelligence and algorithmic bias: implications for health systems 8 J. Global Health (2019) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6875681/] Groups who have not had equal access to traditional or managed care had poorer health outcomes or whose data was not collected are not adequately represented in the data used to create screening tools and such tools are likely to incorrectly identify or apply to members of such groups. For example a study found that because Black patients had lower entry to care management programs the gap between care needed and care received for Black patients was larger than for white patients. There the "neutral" factor of previous health care spending was actually found to be a racially biased factor. [Footnote 52 See Ziad Obermeyer et al. Dissecting racial bias in an algorithm used to manage the health of populations (2019) Rose Research & Policy Portal https://rrapolicy.sph.harvard.edu/algorithms-can-replicate-or-remedy-racial-biases-in-healthcare-resource-allocation/] As another example the Framingham Heart Study was found to work well for white patients because 80% of the collected data used to create the study came from white patients, and so the study is less applicable and accurate for non-white patients. [Footnote 53 Id.] Therefore as discussed in more detail in the CCD's comments we urge HHS to ensure this provision also holds accountable both the entities creating such algorithms as well as the entities that employ them.

Institute on Aging

the preamble to the 2022 Proposed Rule of bias from clinical algorithms. We request that OCR broaden the 2022 Proposed Rule to include any form of automated decision-making system because of the prevalence of automated decision-making systems used by covered entities. At a minimum, HHS needs to define the term "clinical algorithms" because it may otherwise be too narrowly construed. Regardless of intent clinical algorithms can have discriminatory impacts. We see this too often with "gender conflicts" in health decisions that lead to misdiagnoses and discrimination in health care settings for transgender and nonbinary patients. [Footnote 2: Skyler Rosellini Limited Data Collection for LGBTQI+ Health Promotes Bias Nation Health Law Program (June 22 2021) https://healthlaw.org/limited-data-collection-for-lgbtqi-health-promotes-bias/] Numerous criminal or in the use of clinical algorithms is also relevant as health systems invest in care management programs focused on high-risk patients. As has been widely documented many of the common algorithms developed to identify patients for these programs were systematically excluding Black patients and other patients of color. [Footnote 3: Heidi Ledford Millions of black people affected by racial bias in health-care algorithms Nature (October 24 2019) https://www.nature.com/articles/d41586-019-03228-6]. This was because many were using "utilization of care and cost" as a proxy for or in combination with "severity of diagnosis." People of Color and Black patients in particular used less care and incurred fewer costs for the same level of illness. The data in a commonly cited study found that when "illness rather than cost of care was used to identify patients for care management programs the percentage of Black patients identified went from 17.7% to 46.5%. [Footnote 4: Ziad Obermeyer et al. Dissecting racial bias in an algorithm used to manage the health of populations Journal of Science (Oct 2019) https://www.science.org/doi/10.1126/science.aax2342?cookieSet=1] This issue

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Every day clinicians learn more about potential biases built into clinical algorithms. For example studies have found racial bias in pulse oximetry measurement that can drastically impact a clinician's decision making and have severe implications for a patient's health. [Footnote 12:]. With this new understanding of the limitations and potential biases of a clinical tool like a pulse oximeter clinicians can now adjust their care decisions to try to achieve better outcomes for the patient. However under this proposed rule it is unclear what potential liabilities a covered entity may have for using a tool that has a known bias built into and may result in decisions that could be construed as discriminatory after the fact. Due to this clinicians may hesitate to use essential and innovative tools for care. Furthermore rulemaking increases the potential for liability for the covered entity. In the proposed rule OCR asks whether they should include more specificity including actions covered entities should take to mitigate potential discriminatory outcomes to be a covered entities. [Build: The ACC believes OCR should provide more specificity to provide covered entities with additional guidance and more detailed examples of actions they should take to mitigate potential discriminatory outcomes including examples based on real-world experiences to help ensure they have sufficient access to the information they need to make informed decisions develop written policies and procedures and understand their liabilities].

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Health Care For All

American College of Cardiology

Alliance of Multicultural Physicians

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ND Protection & Advocacy Project

California Department of Health Care Services

Covered California

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3. A specific issue that warrants immediate correction is discrimination relating to the algorithm bias embedded in the erroneous standards of care and other accepted algorithms. Specifically the value assessment of quality adjusted life year (QALY) a single measure that combines the quality and quantity of life lived and often used in economic evaluations discounts for disability embedding discrimination in the commonly used measure. Payers currently determine cost-effectiveness of a medical intervention based on QALYs (compounded by the lack of data from trials that have not been appropriately inclusive of people with disabilities) thus excluding people with disabilities from appropriate care and treatment. The Rule should prohibit the use of and reliance of QALYs and similar measures that may subjectively discount the value of lives lived with disability. A similarly structured argument can be made against the use of disability adjusted life years (DALYs). The DALY burden for a particular condition is the sum of YLL (years of life lost [YLL] due to premature mortality added to the years lost to disability [YLD]. The Rule should prohibit the use of and reliance of DALYs that may subjectively discount the value of lives lived with disability.

(b)(5) Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

[Bracketed Clinical Algorithms] We agree with HHS that clinical algorithms have the potential to be discriminatory and particularly harmful to patients from marginalized communities as they may include that certain patients must be more ill than other patients before they can receive treatment for life-threatening conditions such as kidney disease and heart failure. We urge CMS to adopt a broad definition of "clinical algorithms" to include all clinical automated decision-making processes. In addition we urge HHS to monitor implementation of this provision to ensure that it is being correctly implemented broadly

National Health Council

evidence informed measures that incorporate the social determinants of health. Now is the time to formally apply an equity lens to the development and reconsideration of all clinical decision-making tools including clinical practice guidelines clinical reports policy statements and technical reports. [Footnote xxxv: Joseph L. Wright Wendy S. Davis Madeline M. Joseph Angela M. Ellison Neha P. Heare Garrett Tiffan L. Johnson the AAP Board Committee on Equity. Eliminating Race-Based Medicine. Pediatrics July 2022. 150 (1): e2022057998. 10.1542/peds.2022-057998] Examples of such decision-making tools are described in the AAP Policy Statement [Hyperlink: https://publications.aap.org/pediatrics/article/150/1/e2022057998/186964/Eliminating-Race-Based-Medicine?autologincheck=redirected?casa_token=&searchresult=1: Eliminating Race-Based Medicine.] As discrimination in algorithms especially in algorithms such as machine learning are dependent on the learning data set we must minimize bias in the development of algorithms through techniques such as limiting the use of incomplete data limiting the use of unrepresentative or skewed data sets or limiting data sets that inherently already contain human bias (such as data collected that amplifies existing systemic bias) among many other methods.

American Academy of Pediatrics

Section 92.210 suggests that liability may result from "over-relying on a clinical algorithm in their decision-making such as by replacing or substituting their own clinical judgment with a clinical algorithm ... if their decision rests upon or results in discrimination." As written HHS seems to propose permitting a Section 1557 claim against the company who created the algorithm based on a design flaw and a claim against the provider for implementing a faulty algorithm. The only remaining recourse a user error for a provider "over-relying" on the clinical algorithm as defined above. One issue is that algorithms are protected trade secrets and thus a "black box" for which the means of getting the output from the input are entirely unclear. [Footnote 15: Id.] A secondary issue presented by the proposal is how to determine the "over-reliance" on the part of the healthcare provider. The proposal instructs that a care decision should not solely be based on algorithmic output but take into account the specific needs and medical history of the patient. However the only way to ensure this would be to increase transparency. Patients must have access to the process in which the health care provider reviews the output of the algorithm and what range of decisions the provider can make in response of that output. This is required information on which to base an appeal of a wrong decision and allow the patient to access the care they need. The burden should not be on patients to determine that the provider "over-relied" on an algorithm that performed discriminatorily rather the burden should be on the provider to prove that their use of a biased algorithm did not result in discrimination. As such the Department should require transparency in how information from clinical algorithms should be used in decision-making. We recommend the following: HHS not simply recommend but require that covered entities establish written policies and procedures governing how information from clinical algorithms should be used in decision-making, monitor for any potential impacts, and train staff on the proper use of such systems.

National Disability Rights Network

Rather than a "high-by-first" approach we ask OCR to first focus its proposed rule on establishing consensus criteria and practices for bias mitigation including requirements for both covered entity and clinical algorithm developers. This can be executed in a similar manner to how covered entities and business associates are equally subject to the practices definitions and criteria in the HIPAA privacy rules because the business associate performs functions on behalf of the covered entity that are intimately tied to patient privacy. Defining standards as a starting point promotes shared responsibility which benefits patients and liability can then flow to the entities that fail to meet the pre-defined expectations. Standards may include requirement transparency (e.g. labelling) for the manufacturers to provide information that enables covered entities to independently assess algorithm performance for their population. Clinical algorithm developers play as important or more of a role in mitigating bias as business associates play in the protection of patient health information. If this proposed rule included specific criteria for defining and assessing bias including standardized practices and safeguards across the sectors covered entities and clinical algorithm developers would work together under a contract to meet the criteria. Mayo Clinic is a member of multiple partnerships and working groups to establish consensus practices for clinical algorithms and we welcome OCR to participate in these partnerships.

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(b)(5) Mayo Clinic

FDA Regulation and Industry Standards:Medical device manufacturers adhere to long-established and widely adopted industry standards ISO 14971 "Medical devices — Application of risk management to medical devices" and ISO 13485 "Medical devices — Quality management systems — Requirements for regulatory purposes". These standards which are updated regularly and represent several decades of collective and codified experience set the foundation for medical device development and embody our commitment to patient safety. This experience translates readily to new technologies—including AI and ML. Existing premarket and postmarket regulatory oversight reinforces this commitment. Our technologies are subject to extensive premarket review by the FDA to determine their safety and effectiveness as well as ongoing postmarket surveillance to identify and mitigate any emergent concerns once introduced to market. FDA authorized medical devices can only be marketed according to the product's FDA regulated label that provides clear instructions for use and identifies the indications and populations for which the device may be used. Data curation practices dataset balancing and algorithm testing are performed based upon FDA requirements related to our device claims. FDA verifies these requirements are met during the regulatory review process. For example medical imaging device developers address age concerns and considerations through careful database stratification and enabling development which is approved through FDA processes. It is for these reasons that while we share the Agency's concerns about bias and discrimination we are concerned that certain provisions in this proposed rule will create undue distrust in well validated clinical algorithms and result in diminished adoption of and access to innovative lifesaving technologies.

Medical Imaging & Technology Alliance (MITA)

ing real world data from its national clinical registry programs to understand historical patterns of clinical treatment compared to evidence-based science. Research based on clinical registry data has contributed to the medical literature highlighting gaps and disparities in quality of care and patient outcomes including by race [Footnote 1: Edmund Arsley D L, Thomas L Wang TY Wiley att SD. Race and Sex Differences in Management and Outcomes of Patients After ST Elevation and Non-ST-Elevation Myocardial Infarction: Results From the NCDR. Clin Cardiol 2016;39(10):585-595. doi 10.1002/clc.22570] [Footnote 2: Farmer SA Kirkpatrick JN Heidenreich PA Curtis JP Wang Y Groeneveld PW. Ethnic and racial disparities in cardiac resynchronization therapy. Heart Rhythm. 2009;6(3):345-351. doi: 10.1016/j.hrthm.2008.12.018.] [Footnote 3: Kumar RS Douglas PS Peterson ED et al. Effect of race and ethnicity on outcomes with drug-eluting and bare-metal stents: results in 423,965 patients in the linked National Cardiovascular Data Registry and centers for Medicare & Medicaid services payer databases. Circulation. 2014;129(13):1395-1403. doi: 10.1161/CIRCULATIONAHA.113.001437] [Footnote 4: Chan PS Rao SV Bhatt DL et al. Patient and hospital characteristics associated with inappropriate percutaneous coronary interventions. J Am Coll Cardiol. 2013;62(24):2274-2281. doi: 10.1016/j.jacc.2013.07.086] [Footnote 5: Ramsey A Keshwani N Khera R et al. Temporal Trends in Racial Differences in 30 Day Readmission and Mortality Rates After Acute Myocardial Infarction Among Medicare Beneficiaries [published online ahead of print 2020 Jan 6] JAMA Cardiol. 2020;5(2):136-145. doi:10.1001/jamacardio.2019.4845]. Data from the ACC NCDR are used by federal agencies such as CMS to drive decisions and coverage with evidence development and national coverage determinations for Medicare beneficiaries. The College has been and remains fully committed to developing quality improvement initiatives to address such gaps or disparities. As one example the

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Most risk prediction models used in clinical care are rendered as either web or app based calculators and require between five and 10 clinical and demographic variables. No model is certainly not relatively simple ones intended to guide point-of-care treatment can ever fully predict the clinical future of an individual patient. Furthermore there are decades long and fervent debates amongst the scientific community as to which models have the best balance of predictive features. These debates often center around a model's accuracy for a given population group—women for instance or people of color. The challenge is that modeling often becomes a zero sum game: making a model more accurate for population A renders it less accurate for population B. Similarly attempts to make it more accurate for every patient population renders it too complicated to be used practically with any patient population. Like everything in medicine there are tradeoffs associated with our choices. What is not debated however is that [both widely utilized risk models are scientifically validated and clinically very effective for guiding therapy preferably in a two-way conversation with the patient]. It is worth noting that risk models are published every day in the medical literature but only a small subset are adjudicated to be sufficiently rigorous and helpful to be used in official ACC guidance and programming.

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Most importantly science are ingrained in the mission and activities of the College. In that end we constantly challenge ourselves to ensure that we are providing the most rigorous up to date and relevant scientific information. We will continue to incorporate new thoroughly vetted scientific data into clinical algorithms as it becomes available including updating and removing published algorithms based on new findings]. As a scientific and social institution we also believe that our first responsibility is in acknowledging that these are not easy questions and do not have easy answers. Accepting that our tools and guidelines include tradeoffs and opportunity costs and then transparently discussing among the scientific clinical and patient communities the nature of these tradeoffs is critical. Furthermore the core philosophy of the ACC remains focused on the individualization of care applying the general guidance of our guidelines and tools to the specific circumstances of individual patients. We frequently engage our clinical and scientific community including under-represented minority clinicians and those that practice in diverse environments aiming to strike the best balance possible. The development of advanced mathematical modeling and large scale multi-source clinical data sets is revolutionizing how the medical community thinks about prognostic risk in a variety of acute and chronic conditions. In cardiology alone there are dozens of different models in use to predict long-term likelihood of cardiac events and thus guide preventive interventions to manage shorter term risk and ultimately to risk adjust clinical outcomes to facilitate accurate measurement and quality improvement. While researchers aspire to create causally calculated models where each of the independent predictive variables is biologically or mechanistically linked to the outcome in question the complexity of human pathophysiology often intervenes. Furthermore to be practical in a clinical setting risk prediction models need to be parsimonious in their construction using relatively few and easily accessible predictive variables

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Another example is the need for further clarity around discrimination bias and disability. In the healthcare setting algorithms are sometimes appropriately designed to include or exclude certain populations that will not benefit from a clinical algorithm [e.g. a screening tool should not be used on a patient already diagnosed with disease]. Instead of a general references to discrimination bias and disability we recommend OCR focus the proposed rule on specific practices for preventing harm. For example HDA regulations [e.g. 21 CFR 820] and international standards [e.g. ISO 14971] have a really set precedent for effectively utilizing risk frameworks that identify and mitigate harms including bias throughout the lifecycle of products. Utilizing this risk-based approach would cause both clinical algorithm developers and covered entities to assess and mitigate bias that causes harm in the context of a specific algorithm. Overall algorithms and their discrimination risk are different than the proposed rule expands upon the existing Section 1557 regulations to prohibit discrimination in health decision making algorithms. While our association understands that HHS included this specification in the proposed rule due to research indicating that clinical algorithms increasingly have the potential to be discriminatory we caution HHS to take care that any technology-based regulations remain evergreen. In addition our members note that while overreliance on algorithms can be problematic they also can lead individuals and institutions to make decisions and offer health based programs to individuals that can very beneficial. It would be very unfortunate if the vital access to services and health programs and activities that promote good health were inadvertently limited due to algorithm limitations. HHS should prioritize appropriate balance when finalizing any algorithm requirements.

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Mayo Clinic

HEALTH PROGRAMS AND ACTIVITIESAs the proposed rule suggests "the intent of proposed § 92.210 is not to prohibit or hinder the use of clinical algorithms." This is for good reason which the Department correctly acknowledges: "[T]he use of algorithms that rely upon race and ethnicity or proxies for race and ethnicity may be appropriate and justified under certain circumstances. The Department also notes that the use of clinical algorithms may result in disparate outcomes when variables are used as a proxy for a protected basis and may also result from correlations between a variable and a protected basis." Given the cutting edge nature of algorithms and the nuanced role they may play in the provision of medicine it is vital that non-discriminatory and beneficial uses of such algorithms not be over-deterred. For example statistics show that Black men in our country are more likely to experience both morbidity and mortality from prostate cancer [Footnote 1: American Cancer Society. Cancer Facts & Figures for African Americans/Black People 2022-2024. Atlanta: American Cancer Society 2022 https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-facts-and-figures-for-african-americans/2022-2024-aff-aa.pdf] Moreover according to that report the disparity is likely attributable to less access to early detection through prostate-specific antigen [PSA] testing. That test is a simple blood test that measures the presence of PSA circulating in an individual's bloodstream and is usually the first step in detecting and thus treating prostate cancer. We urge HHS to consider this and other similar examples and ensure that the final rule supports the appropriate use of race and/or other characteristics in clinical decision making. In this rapidly developing area of medicine and technology there is every likelihood that the benefits of algorithms will be increasingly important to support early detection and appropriate treatment of debilitating even fatal health conditions. To that end if HHS chooses to adopt the flexible "overly rely" standard proposed in this rule we urge it to bear in mind

National Association of Health Underwriters

American Hospital Association

rule. One example is the [Atherosclerotic Cardiovascular Disease] ASCVD Risk Estimator based on the ACC/AHA cardiovascular prevention guidelines. The ASCVD Risk Estimator leverages rigorous population modeling using the Pooled Cohorts Equations and produces a patient's 10-year and lifetime risk estimate for a cardiovascular event, namely a stroke or heart attack. Based on certain presumptions for risk as established in the guideline, a clinician may choose to treat the patient with a series of preventive medications including statins and anti-hypertensive medications as well as counseling the patient on healthy lifestyle choices. [Bold:The ACC had undertaken a detailed empirical review and evaluation of race and ethnicity impacts in the development of its ASCVD Risk Estimator resulting in the following guidance to clinicians acknowledging the model's limitations] "These estimates may underestimate the 10-year and lifetime risk for persons from some race/ethnic groups, especially American Indians, some Asian Americans [e.g., of south Asian ancestry] and some Hispanics [e.g., Puerto Ricans] and may overestimate the risk for others including some Asian Americans [e.g., of east Asian ancestry] and some Hispanics [e.g., Mexican Americans]. Because the primary use of these risk estimates is to facilitate the very important discussion regarding risk reduction through lifestyle change, the imprecision introduced is small enough to justify proceeding with lifestyle change counseling informed by these results." While cautions are important, the decision was made to retain the race variable in the ASCVD Risk Estimator because it materially enhances the accuracy of the overall risk estimate for the racial categories noted. For example, an existing Black in the ASCVD Risk Estimator accurately increases the patient's 10-year and lifetime risk of a cardiovascular event in accordance with the well-reported scientific literature. The ACC also recognizes the dilemma of this variable. On one hand, it is generally acknowledged that racial variables are often surrogates that reflect social, demographic, and economic determinants of health.

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Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard [MRCT Center]

Mayo Clinic

Needless. The ACC appreciates OCR's intentions for expanding the prohibition of discrimination to include the use of clinical algorithms during the decision-making process of a covered entity and agrees with the intent to prohibit discrimination against patients on the basis of protected classes such as race, color, national origin, sex, age, or disability. The College believes it is essential to ensure access to and coverage of healthcare in a nondiscriminatory manner and the inappropriate use of clinical algorithms and decisions made regarding the care of a patient leading to discrimination should be prohibited to ensure the access to and coverage of healthcare remains intact. [Bold: However, the College believes additional regulatory guidance and more specificity is needed to ensure covered entities can continue to practice medicine and treat patients based on the most up to date, clinically appropriate information and the underlying individual factors impacting a patient's health]. Under the proposed rule, OCR states "covered entities are responsible for ensuring that any action they take based on a clinical algorithm does not result in discrimination prohibited by this part, irrespective of whether they played a role in designing the algorithm. The fact that a covered entity did not design the algorithm or does not have knowledge about how the tool works does not alleviate their responsibility to ensure that they do not take actions that result in discrimination." While the College believes clinical algorithms are tools designed to inform the clinical decision-making process and must operate in consultation with the patient on a course of care that best suits the unique needs of each individual patient, the reality is clinicians and patients factor important information such as race, age, gender, or disability status when making care decisions every day. These decisions can result in both access to and the decision to not pursue clinical treatment due to a number of factors. While discrimination often is thought of in terms of denying access to something that would otherwise be accessible based on a protected factor in healthcare

• Explicitly prohibits discrimination in the use of clinical algorithms to support decision-making in covered health programs and activities. Requires plain/descriptions of clinical algorithms for language service provision prepopulated and ASAP.2. Specify language service request processing and decision making; identify corresponding authorities, medical training for decision making and overrides [i.e. when and if administrators may override of medically trained health provider's request for in-person interpreter]

7. Following issuance of the revised Rule, further guidance is necessary for implementation of nondiscrimination in the use of clinical algorithms in decision-making. The MRCT Center fully supports section § 92.210 Nondiscrimination in the use of clinical algorithms in decision-making that states: A covered entity must not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities through the use of clinical algorithms in its decision-making. However, understanding discrimination in the context of the artificial intelligence (AI) and machine learning (ML) that often inform clinical algorithms in decision making is arcane and complex. Data sources that are used in AI/ML are often not representative of the general population or of those affected by the condition. In the development of AI/ML algorithms, one dataset is often divided into two: a training dataset and a validation dataset that "validates" functionality, utility, and predictive validity. That practice however fails to expose any limitations in the representativeness or inclusion of diverse groups often subject to discrimination of the original dataset. In addition to the lack of representation, the data are often impacted by bias (e.g., clinical biases in diagnosis and/or treatment decisions.) The negative consequences have been well documented but the approach to correction has not. We advocate that OCR develop guidance on how to identify and prevent discrimination in the development, testing, and validation of clinical algorithms and to establish standards upon which the regulated community can rely.

[Bold: Impact on the developer/user partnership.] In practice, the relationship between clinical algorithm developer and clinical algorithm user [the covered entity in the proposed rule] must be maintained throughout the lifetime of clinical algorithms to prevent harm to patients including bias. Generally, clinical algorithm developers are best positioned to mitigate the risk of bias and harm due to the researcher's control over the data and development process. Regulated product frameworks, including drugs [21 CFR 210] and medical devices [21 CFR 820] are built on the assumption that the "manufacturer" is best positioned to be accountable for the product they provide. The proposed rule however defaults to the covered entity holding liability for the outcome of clinical algorithms in the absence of well-defined expectations for clinical algorithm developers which is inconsistent with how manufacturers are regulated in other industries. As a result, covered entities become responsible for driving clinical algorithm developers from the back seat without any protections. Under the proposed rule, covered entities are left with the option to (i) establish its own oversight framework in the absence of consensus in the field and/or (ii) manually re-do the data analysis performed by the algorithm, taking away the value the clinical algorithm intends to provide and/or (iii) opt to not use clinical algorithms altogether. These options are not ideal for either developer or covered entity. Developers will need to cater to each customer's unique oversight framework or covered entities will not use or re-do clinical algorithm analysis, both of which negatively impacts patient care.

The proposed rule guards against the impermissible use of race- and ethnicity-based inputs in the use of medical algorithms. We support proposals to provide guardrails for the use of race and other city based inputs to medical algorithms which when used improperly can result in discrimination against people of color [Footnote 9 See e.g. Majority Staff House Committee on Ways and Means Fact Versus Fiction: Clinical Decision Support Tools and the (Mis)Use of Race 116th Long. (Oct. 14 2021).] While race ethnicity and sociodemographic indicators can improve our understanding of and response to health disparities these inputs can also create disparities when they interfere with a provider's individualized clinical judgment. For example the use of race and ethnicity data as input variables in medical algorithms and algorithm-informed decision-making in nephrology and cardiology among other contexts have contributed to disparities in care between white patients and people of color, leading to a shift from overreliance on such tools. [Footnote 10 Agency for Healthcare Research and Quality "Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare (Jan. 25 2022) [https://effectivehealthcare.ahrq.gov/products/racial-disparities-healthcare/protocol], letter from James L. Madara Executive Vice President and CEO American Medical Association to David Meyers Acting Director Agency for Healthcare Research and Quality (May 3 2021).] As a result we are encouraged that the proposed rule explicitly prohibits the use of clinical algorithms when used in a discriminatory way. The Office for Civil Rights's commitment to a case by case factual inquiry into compliance and the development of technical assistance programs to guide implementation appropriately balances the complexity of this issue while ensuring that providers rely primarily on their clinical judgment in treating patients from historically marginalized communities.

Rather than a "high-level" approach we ask OCR to first focus its proposed rule in establishing consensus criteria and standards for bias mitigation including requirements for both covered entity and clinical algorithm developers. This can be executed in a similar manner to how covered entities and business associates are equally subject to the practices definitions and requirements in the HIPAA privacy rules because the business associate performs functions on behalf of the covered entity that are intimately tied to patient privacy. Defining standards as a starting point promotes shared responsibility which benefits patients and liability can then flow to the entities that fail to meet the pre-defined expectations. Standards may include requirement transparency (e.g. labeling) for the manufacturers to provide information that enables covered entities to independently assess algorithm performance for their population. Clinical algorithm developers play as much or more of a role in mitigating bias as business associates play in the protection of patient health information. If this proposed rule included specific criteria for defining and assessing bias including standardized practices and safeguards across the entities (covered entities and clinical algorithm developers) would work together under a contract to meet the criteria. Mayo Clinic is a member of multiple partnerships and working groups to establish consensus practices for clinical algorithms and we welcome OCR to participate in these partnerships.

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[Undue impact on under-resourced covered entities.] Mayo Clinic has dedicated significant resources to improve patient care in the digital age. While Mayo Clinic may be able to develop our own framework under the current version of this proposed rule many covered entities are not. With clinical algorithms quickly changing the landscape of healthcare widening disparity among covered entities' ability to advance care through technology will have a negative impact on patient care. We ask OCR to re-consider the proposed rule with the aim of first realizing standardization on practices to prevent bias rather than create liability without the tools so that all covered entities are equally equipped to execute on the practices to prevent bias. At Mayo Clinic we are developing internal frameworks and sharing ideas through external collaborations and publications. We welcome collaboration with OCR to help create consensus and give all covered entities equal access to the resources needed to prevent clinical algorithm bias.

Use of Clinical Algorithms. BCBSA supports the goal of eliminating use of clinical algorithms against based outcomes in healthcare. However given the lack of clear definitions and standards we urge HHS to first clarify the meaning of clinical algorithms and to engage with private and public stakeholders on the development and adoption of national industry standards prior to mandating requirements on payers using such technology. Clear industry developed standards will establish guidelines for both developers and users of AI to safeguard against adverse bias and outcomes

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Blue Cross Blue Shield Association

clinicians to ensure that they are not potentially held liable for decisions based on the best information available in the medical literature at that time and made after discussing with a patient.] While the proposed rule does state "The [d]epartment notes that the use of algorithms that rely upon race and ethnicity-conscious variables may be appropriate and justified under certain circumstances such as when used as a means to identify evaluate and address health disparities" this comes after a lengthier discussion surrounding potential disparities in care that lead to less favorable treatment on the basis of a patient's race making it confusing for clinicians to understand when it may be appropriate to make decisions in consultation with a clinical algorithm in part on the basis of a protected class. Instead by providing examples and context when clinicians actors and decisions based in part on patient characteristics that are also protected classes OCR will help ensure that covered entities can develop proper policies and guidance to better protect against discrimination occurring while still using scientifically based decision making processes in consultation with the patient. The ACC is also concerned that the overly broad language in the "Use of Clinical Algorithms in Decision Making" proposed regulation does not provide enough nuance specificity and guidance for clinicians and could inadvertently expose clinicians to future accusations of discrimination and potential liability should they use a clinical algorithm to help determine the appropriate care for a patient. [Bold]. The ACC believes that OCR should provide all covered entities including clinicians with additional contextual information that more specifically defines situations where discrimination may occur rather than utilizing patient characteristics that are protected classes to determine the most appropriate course of action". OCR should provide examples of specific actions covered entities may take to mitigate discriminatory outcomes, including protections for clinicians acting in good faith and the best interest of the patient. By providing

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Clinical algorithms are not new to medicine and have been utilized for decades as the most widely accepted devices and practices ranging from simple calculators to rotate a patient's vital signs and health such as a pulse oximeter or decision pathways for guiding patient care to complex augmented decision-making tools utilizing artificial intelligence and machine learning. It is important that OCR appropriately segment different algorithms to ensure simple systems are not grouped together with more advanced systems utilizing innovative new technologies such as artificial intelligence/machine learning. Much like the HSA has developed a threat matrix to understand potential risks HHS should work to ensure that different algorithms are regulated according to their complexity transparency and potential for bias and patient harm.

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No comments are associated with this issue.

Section 1557 is an important tool to address health inequities including disparities in access to abortion care. The Proposed Rule would clarify and strengthen its anti-discrimination protections. LDF agrees with OCR's interpretation that Section 1557 both provides an "independent basis for regulation of discrimination in covered health programs and activities" and is applicable to an expansive range of "health programs and activities" including programs administered by HHS health insurance plans and Medicare Part B. [Footnote 50 Nondiscrimination in Health Programs and Activities 87 Fed. Reg. 47824 47827 (Aug. 4 2022).] LDF also supports OCR's decision to make explicit that Section 1557 prohibits discrimination in telehealth and by clinical algorithms

NAACP Legal Defense and Education Fund, Inc

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U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

1) HHS must finalize provisions without delay that protect against discrimination in health care programs and activities. In the above captioned rule HHS is proposing several provisions that would reinstate safeguards that protect against discrimination in covered health care programs and activities as outlined in Section 1557 of the ACA. These proposed provisions include reinstating the scope of Section 1557 clarifies application to health insurance issuers receiving federal financial assistance prohibits discriminatory uses of clinical algorithms used to support decision-making and that nondiscrimination provisions are applicable to services offered through telehealth technologies. HHS is right to propose these provisions and ANA urges the agency to finalize this proposed rule. ANA is an informed and active stakeholder in the implementation of health care policy. ANA sees the proposed rule rectifying what we saw as the 2020 rulemaking instituting a fundamental change in direction that is antithetical to our principles of health system transformation namely universal access to health care coverage for all citizens and residents. We are pleased that HHS would return key definitions and protection mechanisms that make Section 1557 meaningful to all especially to people who otherwise face discriminatory barriers to care. This is acutely important as nurses and the health care delivery system focus on achieving health equity and identify approaches to overcome health disparities. We believe that existing regulations for Section 1557 and other HHS programs fulfill the intent of Congress to protect people from discrimination in health care that denies them access. Section 1557 should be implemented in a manner that promotes access for those who are subject to discrimination. [Build. As such HHS must finalize proposed Section 1557 provisions that protect against discrimination in health care programs and activities. We urge HHS to act expeditiously on this rulemaking].	(b)(5) American Nurses Association
The direct attestation to nondiscrimination on the basis of sex limited English proficient (LEP) individuals and people with disabilities and the benefit or of the benefit measures that are anticipated to comply with Section 1557 are we commend specifically we support the major clarifications in the rule. The interpretation of Section 1557 to cover all health programs and activities administered by HHS. The interpretation that provisions of Medicare Part B assistance is federal financial assistance and that entities receiving Medicare Part B funds must comply with the Rule. The applicat on to health insurance issuers that receive federal financial assistance. The clarification that the protections against discrimination on the basis of sex as including sexual orientation and gender identity and discrimination on the basis of sex stereotypes and the extension of these protections to CMS regulations. The expectation that compliance will require implementing programs to develop maintain and communicate clear policies and train on the provision of language assistance services for limited English proficient (LEP) individuals and effective communication and reasonable modifications to policies and procedures for people with disabilities. The requirement that implementing entities provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states. The expectation of nondiscrimination based on clinical algorithms. The expectation that nondiscrimination extends to telehealth services and the development of clear processes for requesting exceptions from the expectation of compliance.	Multi Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)
Specifically the Health Connector strongly supports the proposed rule's prohibition on the use of discriminatory clinical algorithms in health care decision making and extension of nondiscrimination protections to telehealth services and benefit design. The Health Connector has sought to enhance its focus on nondiscriminatory benefit and formulary design in recent years as part of its pioneering health equity agenda and welcomes additional clarity and support in these endeavors from the federal regulatory framework governing nondiscriminatory policy. Broadening the applicability of Section 1557 nondiscrimination protections will improve equitable access to health care and coverage for individuals and families across the Commonwealth.	Massachusetts Health Connector
The Proposed Rule requires that covered entities implement policies and procedures to ensure compliance with Section 1557 and to provide training to staff interacting with patients. As part of those requirements and specifically for telehealth the provisions should require covered entities to establish internal processes for communicating with patients before during and after telehealth visits. This will allow for effective communication and continuity of care for patients who have challenges accessing follow up or in person care. For example HHS could require development of pre appointment screening and communication policies to ensure necessary equipment or technology for the appointment or to determine whether the patient has the requisite technological skills for participation. Provisions might also include planning and development of training resources for patients who lack basic familiarity with telehealth prior to the appointment. As communication by the provider for follow up care whether for subsequent telehealth visits referrals or for in-person care should occur in a timely manner to ensure continuity of care.	Attorneys General of California, New York, Massachusetts, and nineteen other States
Finally health practitioners providing abortion services now face increased risk of criminal prosecution civil prosecution or adverse licensing enforcement in states that prohibit abortion services. Fear of potential civil or criminal or licensing consequences may lead some providers to refuse to provide abortion care or information about abortion care altogether. Further although telehealth providers might provide telehealth abortion services to out of state patients where allowed this raises concerns about the privacy of reproductive health information tracked through telehealth applications including whether or not patients seek abortions across state lines. [Footnote 76 See Center For Connected Health Policy Abortion Restrictions Impact on Telemedicine & Privacy (July 2022) https://www.cchpca.org/telehealth-policy-heats-up-with-abortion-decision-plus-telehealth-and-recommendations-from-white-house-more-inciting concerns about increased surveillance). To encourage and improve access to abortion services the Proposed Rule might explicitly reference the security and privacy requirements under HIPAA pertaining to maintaining the security and privacy of protected reproductive health or abortion health services information created and stored for telehealth services or in telehealth applications. The Proposed Rule could further clearly note that these privacy requirements preempt any conflicting state laws that would seek to expose or remove the security protections of this information.	(b)(5) Attorneys General of California, New York, Massachusetts, and nineteen other States
We also support that the proposed rule clarifies prohibitions on discrimination in the delivery of health programs and activities through telemedicine—which includes videoconferencing streaming media terrestrial and wireless communications and the internet. [Footnote 9: 87 Fed. Reg. at 47884 47938 (proposed § 92.211)]. The use of telemedicine has soared particularly to combat the COVID 19 pandemic and it is critical the Department ensure equitable access to telehealth services continues [Footnote 10: Robert Pierce and James Stevermer Disparities in use of telehealth at the onset of the COVID 19 public health emergency JOURNAL OF TELEMEDICINE AND TELECARE (Sept. 13 2020) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7578842/pdf/10.1177_1357633X20953893.pdf. Daniel Young and Elizabeth Edwards Telehealth and Disability: Challenges and Opportunities for Care NATIONAL HEALTH LAW PROGRAM (May 6 2020) https://healthlaw.org/telehealth-and-disability-challenges-and-opportunities-for-care/].	(b)(5) Senate Democrats

None sr mirat on in the delivery of health programs and activ es through telehealth services (§ 92.211)Just ce in Ag ng supports the com ments on nond sc mirat on in telehealth submitted by CCD the Disability and Ag ng Collaborat ve and the Leadership Council of Aging Organizations (LCAO). Wh e recent Medicare data has shown w despread use of telehealth [Footnote 54: CMS Certain Medicare Benef ciaries Such as Urban and Hispanic Benef ciaries Were More Likely Than Others to Use Telehealth During the First Year of the COVID-19 Pandemic (Sept. 2022) https://default.sa.salsalabs.org/T2b57b73-d86b-43e6-b759-2877feb85e3c/c1296b64-f6cc-4611-b6f7-8bf196aac2d2.] inc.luding among ind viduals dua y eligible for Medicaid and Med care we want to emphas ze the im portance of ensuring telehealth s always used to supplement not supplant n person services. This is especially important for older adults with chronic cond ions for whom care d srupt ons can be particularly harmful. According to one study com paring ambulatory care use during the pandemic to pre-pandemic levels d sparities ex sted in delayed and forgone care by race and ethn city rural and urban res dency and Medicare-Medicaid dual eligib ty status. [Footnote 55: Adith Pathak et al. Telehealth for Medicare Beneficiaries with Chronic Conditions No Panacea for COVID-19 Pandemic Access Challenges American Inst tutes for Research (July 28 2022) https://www.air.org/resource/brief/telehealth-medicare-beneficiaries-chronic-conditions-no-panacea-covid-19-pandemic.]

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Just ce in Ag ng

[Italic. Nondiscrim nation protections in clin cal algor thms and telehealth. We strongly support the add tion of comprehens ve nondiscrimination protect ons to the use of clinical algorithms and telehealth. Even though telehealth has been used in the past the expansion of telehealth due to the COVID-19 pandemic has presented new opportunities for LGBTQI+ pat ents to engage with and ma ntain affirming care. At Howard Brown we see clients from all over the state of Illinois and neighbor ng states. For patients not liv ng in Chicago or urban areas this would result in them having to travel many hours and for some across state lines in order to see affirming providers. For these reasons telehealth especially during the COVID pandemic was a bridge to help eliminate barriers to affirm ng care for many. Telehealth has also proven to be an effective alternative to in-person care with a recent study of LGBTQ+ youth and their caregivers show ng that 91.7% of patient and 88.9% of caregiver respondents reported the comfort of com municating with providers though telehealth was the same or better than in-person v sits [Footnote 12: Appe DE Lett E Wood S Freeman Bader K Chan J Schwartz JA Patrik D Faust H Downtho N (2022) Acceptability of telehealth for gender-affirm ng care in transgender and gender diverse youth and their caregivers. Transgender Health 7:2 159–164 DOI: 10.1089/trgh.2020.0166]. Telehealth is here to stay and w ll be a vital tool to help expand hea thcare access and retention for LGBTQI+ patients so having strong nondiscrimination protections in place is vital.

Howard Brown Health

[Bold. H. HHS shou d c ar fy telehealth nondiscrim nation provis ons do not apply to abortion.] HHS shou d c ar fy that proposed § 92.211 on nondiscrimination through te e health services does not apply to pres cr bing abortion pills or referring for abortion.

Ethics & Pub c Policy Center

[Underlined. Te ehea th: CalHHS welcomes the NPRM reaffirm ng the applicat on of nond sc mirat on policies to health programs and activ ties provided through telehealth services. Consistent with the rat onale n the preamble CalHHS agrees this is particularly important given our experience du ing the ongo ng COVID-19 pub ic health emergency (PHE) and the increas ng presence of and reliance on telehealth modalit es throughout the entire health care system. In light of the referenced accessibility challenges and tec hnological gaps apparent in certain locales or with respect to certa n popu at ons California continues to place the highest priority on beneficiary choice and enabling use of the modality that is best for the individua s hea th needs and circumstances. To that effect in recent legislation codifying post-PHE telehea th policies in the Med-Ca program [Footnote 10: See Senate Bill no. 184 (Chapter 47 of the Statutes of 2022), California Welfare and Institutions Code sections 14132.100 14132.725 and 14132.731.] benefic ar es are afforded the right to access any covered services through tradit ona in-person encounters or through an array of approved telehealth modalit es on a volu tary basis. If a benef ciary prefers to access covered care via face-to-face interact on both the Medi-Cal prov der and managed care plan are required to offer or arrange such care according to the beneficiary's choice.

California Department of Health Care Services

Prohibiting discrim nation in telehealth servicesAs HHS noted in proposing these new regulations there is a growing body of evidence illustrating how access to effective telehealth services differs for individuals by race color national origin sex age or disab ty status. A unified federal approach for covered entities would benefit individuals providers and carriers as many variables determ ne whether a patient has access to high quality non discrim natory telehealth services and a piecemeal approach may leave some patients out. When choosing how to prov de telehealth services an issuer or provider rou d choose to contract with a vendor or provide the services in-house and in both cases there are a variety of technical so utions available some of which may work better to provide adequate access. Covered California recommends that HHS require telehealth vendors to integrate the availability of third-party interpretation services to all enrollees in order to provide adequate cultura ly appropriate care to all individuals no matter their preferred spoken language. Covered Ca fornia also encourages HHS to require parity in access and re mbursement between real-time audio-visual telehealth services and those that are accessible to those without high speed internet such as real-time text or y or asynchronously where issues of broadband and digital access are addressed. Understanding the inequity in access to broadband services and the importance of telehealth services Covered California recommends that HHS require issuers to develop and provide enrollees with resources and educational mater als to increase digital literacy among enrollees who do not have experience or comfort with telehealth services.

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Covered Ca fornia

[Bold. Te ehealth.] We support the proposed ru e's provision on telehealth. Telehealth is a tool to improve access to health care for many pat ents. As the use of telehealth expanded during the COV D-19 pandem c access has not been equitable for individuals with limited English proficiency and people with disabilities due to the telehealth p atforms themselves being inaccessible. Therefore we recommend that HHS require telehealth p atforms to allow a third-party interpreter or use of aux liary aids and services. Second all of the com munication about telehealth that occurs prior to a te ehea th appointment (e.g. scheduling system req rements texting connections appo intment reminders and sign-on instructions) must be accessible.

National Health Council

Ensuring that telehealth v sits are included in this Rule and that patients using private insurance are not discr minated against will make care more accessible to many who have faced challenges in obta ning needed care.

Dignity, Inc. dba DignityUSA

Bold. § 92.211. Nondiscrimination in the de very of health programs and activities through telehealth serv ces.] We support the specific addit on of telehealth in th s proposed rulemaking and believe that all ent ties would benefit from a provis on addressing access ility n telehealth given that a significant number of people with d sabilities rely on these services. Telehealth is important for many people with disabilities for whom it may be diff cu t to leave the house regardless of a pandemic but it becomes use ess to them if it is inaccessible including accessibi ty of telehealth. In the 1557 nondiscrimination rule s necessary so that health care providers and all related entities do not overlook and directly or ind rectly d scriminate against beneficiaries with disab ities because of inaccess ble telehealth services. Requir ng covered entities to comply with standards like the Web Content Access ility Guide nes (WCAG) is just the start. The expectation should be for all entities to go beyond and fully incorporate the needs and asks of the disability community in all services in order for there to be a true reduction in health disparity.

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National Disab ty Rights Network

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livery of health programs and activities specifically through telehealth services HHS proposes to require that telehealth services are accessible to individuals with disabilities and provide meaningful program access to LEP individuals. As discussed more fully below, the States welcome this focus on telehealth.

Telehealth services have been essential to the delivery of healthcare services in the States during the COVID-19 pandemic. Funding across states and use of telehealth continues to dramatically improve access to healthcare services for our most vulnerable residents including people with disabilities and people who live in rural communities. But some aspects of telemedicine—including for example patient portals the availability of real-time audio captioning or other video services necessary for interpretation and the compatibility of telehealth platforms with screen reading software—have imposed barriers for LEP individuals and some people with disabilities. [Footnote 60: Rupa S. Valdez et al. Ensuring Full Participation of People with Disabilities in an Era of Telehealth 28 J. Am. Med. Inform. Assn 389 (Feb. 2021) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7717308/; Jorge Rodriguez et al. The Language of Equity in Digital Health: Prioritizing the Needs of Limited English Proficient Communities in the Patient Portal 32 J. of Health Care for the Poor & Underserved 211 (2021) https://muse.jhu.edu/article/786661.] Clarifying the application of the Proposed Rule to telehealth services would help reduce some of these barriers by ensuring that telemedicine platforms are accessible to individuals with disabilities and LEP individuals and by ensuring that qualified interpretation services are available equally through telehealth platforms. It would also ensure needed consistency in access to telehealth services by LEP individuals and individuals with disabilities across state lines. Given the increasing use of telehealth platforms in our States and across the country, the States also agree that covered entities would benefit from specific provisions that address

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Attorneys General of California, New York, Massachusetts, and nineteen other States

Services.[In the wake of the COVID-19 pandemic, use of telehealth to deliver healthcare accelerated among health providers. [Footnote 68: Verma S. Early Impact of CMS Expansion of Medicare Telehealth During COVID-19. Health Affairs Blog. 2020 (July 15 2020) https://www.healthaffairs.org/do/10.1377/hblog20200715.454789/full/.] As a result, telehealth is increasingly instrumental in addressing chronic health issues providing primary care for individuals living where services or specialties are lacking, and ensuring access for persons with income or transportation challenges. [Footnote 69: Pei Xu et al. Pandemic-Triggered Adoption of Telehealth in Underserved Communities: Descriptive Study of Pre- and Postshutdown Trends 24 J. Med. Internet Res. 7 (July 15 2022) https://doi.org/10.2196/38564/.] At the same time, the recent expansion of telehealth highlights disparities in access based on race, language, disability, and economic status. [Footnote 70: See, e.g., Lee Raine, Pew Research Center, Digital Divides — Feeding America (February 8 2017) http://www.newinternet.org/2017/02/09/digital-divides-feeding-america. Thiru Mathew, Amy et al. Telemedicine Barriers and Challenges for Persons with Disabilities: COVID-19 and Beyond 13 Disability Health J. 4 (July 8 2020) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7346769/.] For example, African Americans and rural residents are more likely to lack broadband internet access, and a study found that patients who are other older African American require an interpreter, use Medicaid, or live in areas with low broadband access were less likely to use video visits as compared to phone. [Footnote 71: Julia Chen et al. Predictors of Audio-Only versus Video Telehealth Visits During the COVID-19 Pandemic. 37 J. Gen. Intern. Med. 1188 (2022) https://doi.org/10.1007/s11606-021-07172-y.] Accordingly, regulatory oversight of this growing treatment modality is necessary to ensure telehealth is not used discriminatorily nor in a

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Attorneys General of California, New York, Massachusetts, and nineteen other States

16. Nondiscrimination in the Delivery of Health Programs and Activities through Telehealth (§ 92.211) This provision clarifies that covered entities have an affirmative duty to not discriminate in the delivery of services through telehealth. The duty includes ensuring that such services are accessible to individuals with disabilities and providing meaningful program access to LEP individuals. Such services would include communications about the availability of telehealth services, the process for scheduling telehealth appointments (including the process for accessing on-demand unscheduled telehealth calls) and the telehealth appointment itself. HHS seeks comment on whether the final rule should include a specific provision addressing accessibility in telehealth services and/or specific recommendations for telehealth accessibility standards. Recommendation: BCBSA supports HHS's goal of ensuring access to quality healthcare for individuals with disabilities and LEP individuals and agrees with the proposed approach to include specific provisions relative to nondiscrimination in telehealth, especially since telehealth technology is experiencing rapid changes. Accessibility standards for the provision of telehealth services should be consistent with the standards recommended above under proposed §92.204. Finally, HHS should provide covered entities with at least 18 months to comply with and/or receive attestation from providers and third-party vendors that may comply with the new standard. Rationale: HHS's proposal to reference the requirements under proposed §§92.201, 92.202 and 92.204 will be helpful in maintaining consistency within the rule. Additionally, to avoid confusion and reduce burden for covered entities, accessibility standards for the provision of telehealth services should be consistent with the standards recommended above under proposed §92.204. Specifically, we recommend covered entities that are compliant with WCAG 2.1 Level AA should be deemed to be in compliance with both §92.204 and §92.211. This Proposed Rule

Blue Cross Blue Shield Association

We are pleased that the proposed rule ensures there are affirmative protections for LGBTQI+ individuals in health care. This includes clarifying that nondiscrimination requirements apply to health programs and activities provided through telehealth services and interpreting Medicare Part B as federal financial assistance for the purpose of coverage under federal civil rights statutes the HHS Department enforces.

AARP

Finally, the proposed rule also expands section 1557 protections to ensure that telehealth services are accessible to patients with language access needs. While telehealth was not addressed in previous rules, the expansion of telehealth during the COVID-19 pandemic necessitates its inclusion in this proposed rule. [Footnote 13: Jonathan P. Weiner et al., "In-Person and Telehealth Ambulatory Contacts and Costs in a Large US Insured Cohort Before and During the COVID-19 Pandemic" JAMA Network Open March 23 2021 https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2777719]. While studies vary in the exact magnitude of the increase the use of telehealth clearly increased since the beginning of the COVID-19 pandemic. [Footnote 14: Justin Lo et al. "Telehealth Has Played an Outsized Role Meeting Mental Health Needs During the COVID-19 Pandemic" Kaiser Family Foundation March 15 2022 https://www.kff.org/coronavirus-covid-19/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/.] This is especially true for disabled patients: nearly 40 percent of disabled patients used telehealth during some point of the second year of the pandemic according to a study published in December 2021. [Footnote 15: Larli Friedman and Laura VanFossen Brown, "Telehealth Use By Persons with Disabilities During the COVID-19 Pandemic" International Journal of Telerehabilitation 13 no. 2 (December 1 2021) https://doi.org/10.5195/ijt.2021.6402.] The proposed rule would explicitly clarify that health services delivered by telehealth must be provided in an accessible way and are subject to the regulations of section 1557 as well.

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The Century Foundation

None sr minat on in the De very of Health Programs and Activities Through Telehealth Services (§ 92 211)The COVID-19 pandemic has demonstrated the growing importance of te ehealth services yet it appears that few if any telehealth platforms are adequately prepared tu serve ndividuals w th LEP. We su pport OCR's proposal to proh bit discrimination in the delivery of telehealth however we encourage the addition of more specific standards For example in the absence of the ab lity to integrate v deo nterpreters into telehealth platforms we have heard through community partners that some providers are simultaneously us ng telephonic nterpreter on services with their pat ents w th LEP. Th s presents a confusing and com plex situation for individuals who may already face barriers due to low technology teracy. OCR shou d req re that covered entities must contract w th telehea th providers that can ntegrate interpreter on services into their platform tu provide meaningfu access to ind viduals w th LEP. In add tion all the comm nicat on about telehea th that occurs pr or to a telehealth appointment (e.g. scheduling system requ rements texting connections appo ntment reminders and log on instructions) must be accessible to people w ho have LEP. We caution against use of automatic translation and captioning technology or te e health platforms as a substitute for we interpretation and be eve such technology would not be a greed w th the proposed rule's language around mach ne translation

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The rule also req res covered ent t es to take apropriate steps to ensure that com munication with ndiv dua s with disabilities is as effective as communication w th others in h ealth programs and activ t es We hope to see th s proposal in the final ru e. Add t onally we appreciate HHS bu ding upon nondiscrim nation requirements n health care settings by req ring covered ent t es to ensure that hea th programs provided through electronic and information technology nclud ng via telehealth are accessible for ind viduals w th disabilities to the extent that it does not res lt n fundamental or administrative burdens

Bold: Te e health IEC supports Hyperl nk telehealth, https://ie ere ea p tt edu/ojs/Tele erab/article/v ew/6432 | wh ch can ncrease access to equitab e health care for people with disab t es. Telehealth reduces travel |Hyperlink Travel, https://hea thlaw.org/telehealth and d sab lity challenges and opportun t es for care/| can be particularly difficult for people w th IDD. Public transportation s often a set sched e and does not go everywhere para transit services need to be scheduled in advance are not availab e in all places and can be expensive. Frequently destinat on options are not accessib e by t mobility equipment ndividuals and are expensive. Hospitals and clin cs across nat parking s usually h gh ly hard and might be in short supply. Travel can require a caregiver to accompany the person w th DD. Te ehealth allev ates people with anxiety and other diagnosis to avoid environments they m ght find overwhelming Telehealth also increases the n mber of spec a ists that patients with IDD can access at location would less of a factor n specialty. However health care prov ders need to be aware of disparities in access to technology and the internet |Hyperlink Telehealth, https://healthlaw.org/re e health-and-disability-challenges-and-opportun t es-for-care/| does not work for many physical exams. It s challeng ng for people w th mob ty and sensory disabil es to move n a way that is needed for certain telehealth visits. Some people w th IDD might not be capable of explaining their med cal issues n a telehealth session. Not all telehealth is covered by insurance n addition some people with DD might find telehealth to be challeng ng because of the system be ng complicated and/or not having digital teracy. Many people w th IDD might not have access to the internet and other technology that telehealth req res

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I Recogn ze the critical need for broadband connectivity and assistive technology access for people w th disabilities. Since the start of the pandemic it's been evident the important role broadband connectivity and the ability to access ass st ve technology is for people with d sabilities especially those with medical comorbidities. It enabled ind v dua s to get information utilize telehealth services and address mental hea th issues due to social isolation. Prioritization for expanding broadband connectivity and access to assistive technology will give people w th disabilities the option to utilize online services or formats for their hea thcare n. Enable flexibility of telehealth services to enhance accessibility for people w th disabilities. The COVID-19 pandemic brought about change to the delivery of healthcare. Te ehealth s now an option for many services and needs to be made more access ble. People with d sab lities relatively un telehealth services due to the fact that it eliminates some barriers to health care access. Telehealth el minates transportation barriers alleviates some anxieties for people w th sensory and behavioral disabilities and lowers risk of transmission of viruses by one would get in an in-person setting. Providers need to be trained on how to effectively com municate to patients with disab t es and how to accom modate accessibility needs on a virtual platform.

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We a so encourage OCR to consider how telehealth can expand ndividuals with LEPs' access to health care. For example rather than use interpretation services particularly for sensitive services like menta health individuals with LEP often prefer to work with a provider who speaks and is professionally trained in their native language. However for many such a provider may not be n their immediate vicinity. Telehealth allows access to providers who may be remote from a patient with LEP. We particularly encourage OCR to work with the Centers for Med care and Medicaid services to red uce barriers to ind v dua s with LEP's access to multilingual prov ders who are out of their state.OCR shou d also specify that other growing digital platforms should be accessib e for ndividuals w th LEP We are aware of the growing use and reliance on patient web portals and apps for prov der-patient interact ons that include features such as non-sim ultaneous com munications. Few of these products appear to be available in language We encourage OCR to specify that such platforms are te ehea th services subject to sound sc minat on and access standards

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Throughout the pandemic Coloradans have benefited from accessing care via telehealth and it has become clear that continued access to services n this format is essential to access to care. The Foundation commends HHS for clarifying that nondiscrim nation requirements apply to health programs and activities provided through telehealth services

We also want to applaud the essent a decision tu include coverage of te ehea th under ACA's Sect on 1557 Telehealth has had a pivota impact on expanding hea thcare access to commun t es that have otherwise struggled to receive traditional hea thcare n the past. This change n particular has been groundbreaking for rural communities communities that do not have the necessary means of transportation and communities such as LGBTQI+ people who have trad tionally struggled to find local culturally competent hea thcare prov ders. Allowing for LGBTQI+ people l ving in these communit es to have access to a greater number of providers in their state increases their opportunities to receive equitable care. We implore the Department to ensure that telehealth coverage s nc uded in the F nal rule

We a so recommend ensur ng mandatory mandator n telehealth includes accessibility for people w th LEP and people with disabilities in a aspects of telehealth care—from scheduling to set ng up and us ng a platform tu the actual appointment and follow up.

Bold and Italics: Nondiscr minat on in the Del very of Health Programs and Activities Through Telehealth Services (§ 92.211)||Bold The AAMC supports the proposal treating an affirmative duty for covered entities to not discriminate in the delivery of te ehea th services and to ensure such services are access ble to people w th limited English prof ciency and individuals with d sabilities | The AAMC strongly supports the expansion of telehealth in part for its ability to expand access to care. As such we agree that it is prudent to expressly extend nondiscr minat on protections to health care services and programs provided via telehealth

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National Immigration Law Center

URAC

Institute for Exceptional Care

The Arc of Pennsylvania

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National Immigration Law Center

The Colorado Health Foundation

38 Members of Congress

Justice in Aging

Association of American Medical Colleges (AAMC)

discrimination in telehealth and the recognition of telehealth as a tool to improve access for many patients. In Massachusetts we have seen the importance of telehealth services especially for behavioral health services which continue to be provided via telehealth at high rates. Such a need was highlighted during the COVID-19 pandemic when telehealth proved to be a life saver for people across the country. [Footnote 5: Sanjula Bosp et al. Medicare Beneficiaries in Disadvantaged Neighborhoods Increased Telemedicine Use During The COVID-19 Pandemic. Health Affairs. [May 2022] https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01706] While telehealth has been useful for most populations and should remain an option for care delivery access to telehealth has not been equitable for patients with LEP and people with disabilities. [Footnote 7: Lori Uscher-Pines et al. Experiences of Health Centers in Implementing Telehealth Visits for Underserved Patients During the COVID-19 Pandemic. Rand Corporation. (2022) https://www.rand.org/pubs/research_reports/RRA1840-1.html. [Footnote 8: Mac. d Mariml et al National Survey Trends in Telehealth Use in 2021. ASPE Office of Health Policy. [February 2022) http://www.aspe.hhs.gov/sites/default/files/documents/4e1853c0d4885112b29946d0a58af9ed/telehealth_hps_3.pdf]. Most service platforms are not yet made available at all to people with disabilities or people with LEP. As referenced previously the HCFA Help line hears every day from individuals and families who are unable to access care due to language barriers and the dearth of providers who speak their language or who will arrange for interpreters as required under law. Of course this extends to care provided through telehealth which can both increase access and impose additional barriers. As take up of telehealth increases within the health care system it is also important to enact changes to help address the so-called "digital divide". The gap between people who have ready

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Health Care For All

• Clarifies that nondiscrimination requirements applicable to health programs and activities include those services offered via telehealth which must be accessible to LEP individuals and individuals with disabilities.1. Specify that remote or telehealth care via interpreters with such standard measures of competency or qualification (if required) differ from those of employee interpreters) constitutes substandard provision of care to constituents of any protected groups (hearing impaired limited-English-proficient) 2. Specify that standard interpreter qualification measures apply in any mode of provision of healthcare, including telehealth.3. Assure that all instructions for telehealth portal access and instructions assistance with access to required technology is available [translated or assisted by persons in comprehensible language] 4. Provide plan for non-literate patient use for whom use of technology portals websites instructions all have inherent challenges that may have discriminatory impacts 5. Provide plan for deaf and blind patients or patients with other communication needs for whom use of technology portals websites instructions all have inherent challenges that may have discriminatory impacts.

Through Telehealth Services [§92.211] [Bold. TPCA is very supportive of OCR's proposal to explicitly include telehealth in the nondiscrimination provisions] as it is important that nondiscriminatory languages align for the rising modality of care. Health center patients have greatly benefitted from access to services through telehealth during the COVID-19 pandemic; in 2021 health centers conducted over 26 million virtual visits [embedded hyperlink text [https://bphc.hrsa.gov/sites/default/files/bphc/data-reporting/uds-2021-data-trends-speakers.pdf]. Health centers offer a variety of services to their patients via telehealth. In 2021 54% of visits were for mental health 31% of visits addressed substance use disorder 27% of visits were for enabling services and 18% of visits were medical visits. Offering the option of telehealth to patients is a way to move past social determinant of health barriers that patients face when trying to access health care such as lack of reliable transportation and lack of childcare options.However telehealth has not been equitable for Limited English Proficient [LEP] patients [embedded hyperlink text [https://www.rand.org/pubs/research_reports/RRA1840-1.html], and people with disabilities. [embedded hyperlink text [https://www.aspe.hhs.gov/sites/default/files/documents/4e1853c0d4885112b29946d0a58af9ed/telehealth-hps-ib.pdf)] and service platforms are not yet made available at all to people with disabilities or people with limited English proficiency. As a basic step TPCA recommends OCR to require telehealth platforms be able to provide a third party such as an interpreter or use of auxiliary aids and services. Second all of the communication about telehealth that occurs prior to a telehealth appointment – including scheduling information about system requirements and testing connections appointment reminders and log on details – must be accessible to people with LEP and disabilities. Similarly platforms should be adapted to meet the needs of people who are autistic deaf

(b)(5)

Tennessee Primary Care Association

Telehealth Services [§92.211] WPHCA is very supportive of OCR's proposal to explicitly include telehealth in the nondiscrimination provisions as it is important that nondiscriminatory languages align for the rising modality of care. Community Health Center patients have greatly benefitted from access to services through telehealth during the COVID-19 pandemic; in 2021 Community Health Centers conducted over 26 million virtual visits [embedded hyperlink text [https://bphc.hrsa.gov/sites/default/files/bphc/data-reporting/uds-2021-data-trends-speakers.pdf]. Community Health Centers offer a variety of services to their patients via telehealth. In 2021 54% of visits were for mental health 31% of visits addressed substance use disorder 27% of visits were for enabling services and 18% of visits were medical visits. Offering the option of telehealth to patients is a way to move past social determinant of health barriers that patients face when trying to access health care such as lack of reliable transportation and lack of childcare options.However telehealth has not been equitable for Limited English Proficient (LEP) patients [embedded hyperlink text [https://www.rand.org/pubs/research_reports/RRA1840-1.html], and people with disabilities. [embedded hyperlink text [https://www.aspe.hhs.gov/sites/default/files/documents/4e1853c0d4885112b29946d0a58af9ed/telehealth-hps-ib.pdf)] and service platforms are not yet made available at all to people with disabilities or people with limited English proficiency. As a basic step WPHCA recommends OCR to require telehealth platforms be able to provide a third party such as an interpreter or use of auxiliary aids and services. Second all of the communication about telehealth that occurs prior to a telehealth appointment – including scheduling information about system requirements and testing connections appointment reminders and log on details – must be accessible to people with LEP and disabilities. Similarly

(b)(5)

Wisconsin Primary Health Care Association

platforms should be adapted to meet the needs of people who are autistic deaf

Through Telehealth Services [§92.211] MNACHC is very supportive of OCR's proposal to explicitly include telehealth in the nondiscrimination provisions] as it is important that nondiscriminatory languages align for the rising modality of care. Health center patients have greatly benefitted from access to services through telehealth during the COVID-19 pandemic; in 2021 health centers conducted [underline/gray, over 26 million virtual visits]. Health centers offer a variety of services to their patients via telehealth. In 2021 54% of visits were for Mental health 31% of visits addressed substance use disorder 27% of visits were for enabling services and 18% of visits were medical visits. Offering the option of telehealth to patients is a way to move past social determinant of health barriers that patients face when trying to access health care such as lack of reliable transportation and lack of childcare options. However telehealth has not been equitable for [underlined/blue: Limited English Proficient (LEP) patients] and [underlined/blue: people with disabilities], and service platforms are not yet made available at all to people with disabilities or people with limited English proficiency. As a basic step MNACHC recommends OCR to require telehealth platforms be able to provide a third party such as an interpreter or use of auxiliary aids and services. Second all of the communication about telehealth that occurs prior to a telehealth appointment – including scheduling information about system requirements and testing connections appointment reminders and log on details – must be accessible to people with LEP and disabilities. Similarly platforms should be adapted to meet the needs of people who are autistic deaf or hard of hearing blind deaf/blind movement impaired or otherwise have difficulty in communicating via traditional telehealth modes. [underlined/blue: before the telehealth interaction] providers should assess for visual cognitive intellectual mobility as well as functional needs to maximize the patient's health care experience. MNACHC recommends that OCR consider including notification components associated with this issue and/or need in the instructions below.

Minnesota Association of Community Health Centers

(b)(5)

If the provider feels the provision violates their conscience they should not be forced to abort babies. What is the United States becoming? A fascist country!

The direct application to nondiscrimination on the basis of sex limited English proficient (LEP) individuals and people with disabilities and the clarification of the specific measures that are anticipated to comply with Section 1557 are welcome. Specifically we support the major clarifications in the rule. • The interpretation of Section 1557 to cover all health programs and activities administered by HHS. • The interpretation that provision of Medicare Part B assistance is federal financial assistance and that entities receiving Medicare Part B funds must comply with the Rule. • The application to health insurance issuers that receive federal financial assistance. • The clarification that the protections against discrimination on the basis of sex as including sexual orientation and gender identity and discrimination on the basis of sex stereotypes and the extension of these protections to CMS regulations. • The expectation that compliance will require implementing programs to develop materials and communicate clear policies and train on the provision of language assistance services for limited English proficient (LEP) individuals and effective communication and reasonable modifications to policies and procedures for people with disabilities. • The requirement that implementing entities provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states. • The expectation of nondiscrimination based on clinical algorithms. • The expectation that nondiscrimination extends to telehealth services and • The development of clear processes for requesting exceptions from the expectation of compliance.

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Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

|Subpart D—Procedures|Notification of views regarding application of federal conscience and religious freedom laws (§ 92.302)|It is essential that the final rule include the NPRM's revised approach to religious exemptions. When providers deny medical services for religious reasons those who require the denied care are harmed. Even if patients are able to obtain the needed medical care from another provider the delay in receiving care may cause irreparable harm. Moreover the stress of being denied care – in addition to the fear of facing similar denials in the future – have very real negative impacts. The Trump administration's 2020 version of Section 1557 implemented regulations that improperly disregarded these harms and that exalted providers' religious beliefs over the rights of individuals to receive the medical care that they need. We support the approach being proposed in the current NPRM which contemplates a case-by-case process and expressly acknowledges that the potential harm to third parties must be considered when determining whether to grant an exemption. Such consideration is required by the Establishment Clause in the First Amendment to the Constitution which does not permit the government to grant religious exemptions from neutral laws if doing so would shift burdens to third parties.

Equitas Health

Department to clarify that existing religious refusal laws do not relieve health care providers of the obligation to provide nondiscriminatory care. All countries have a human rights obligation to ensure that religious refusals do not hinder access to quality reproductive care including abortion a principle that has been reiterated by the World Health Organization's 2022 Abortion Care Guideline and the UN Special Rapporteur on Freedom of Religion or Belief. |Footnote 64 WORLD HEALTH ORGANIZATION ABORTION CARE GUIDELINE https://www.who.int/publications/i/item/9789240039483 (Last Accessed: March 8 2022); Committee on Economic Social and Cultural Rights General comment No. 22 (2016) on the right to sexual and reproductive health (art. 12 of the International Covenant on Economic, Social and Cultural Rights) para. 34 U.N. Doc. E/C.12/GC/22 (2016).". Human rights standards are clear on the principle that where religious refusals are permitted they cannot be allowed to infringe on a patient's access to care. The government has an obligation to ensure nondiscriminatory access to care regardless of whether providers avail themselves of existing religious refusal laws. |Footnote 65 Committee on Economic Social and Cultural Rights General comment No. 22 (2016) on the right to sexual and reproductive health (art. 12 of the International Covenant on Economic Social and Cultural Rights) para. 43 U.N. Doc. E/C.12/GC/22 (2016) (noting that "where health-care providers are allowed to invoke conscientious objection States must appropriately regulate this practice to ensure that it does not inhibit anyone's access to sexual and reproductive health care."); CEDAW Committee General Recommendation No. 24: Article 12 of the Convention (women and health) para. 11 U.N. Doc. HRI/GEN/1/Rev.9 (Vol. II) (2004), see also CEDAW Committee Concluding Observations: Croatia para. 31(a) U.N. Doc. CEDAW/C/HRV/CO/4-5 (2015), Human Rights Committee Concluding Observations: Poland para. 23-24 U.N. Doc. CCPR/C/POL/CO/7 (2016). | See

(b)(5)

Center for Reproductive Rights

|Broad Religious Freedom and Conscience Rights|Regarding religion the proposed rule states that HHS is "fully committed to respecting the conscience and religious freedom laws when applying this rule including an organization's assertion that the provision of this rule conflict with their rights under Federal conscience and religious freedom laws." |Footnote 33: 87 Federal Register 47824|As Rachel Morrison Fellow at the Ethics and Public Policy Center argues "the NPRM proposes a process for application of such laws. Proposed regulations would provide a specific means for recipients to notify HHS of their views regarding the application of federal conscience or religious freedom views. HHS would be required to 'promptly consider those views' raise any agency investigation or enforcement activity during consideration and make a 'case-by-case' determination about any applicable legal protections. |HHS notes that a 'case-by-case approach to such determinations . . . will allow it to account for any harm or exemption could have on third parties.'" |Footnote 54: Morrison "HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate on Health Care" https://dedoe.org/commentary/dedoe-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-in-health-care-1|

The Heritage Foundation

Confusion is clear about this even if federal law has not considered all contexts. The Rule makes it impossible for any faith-based entity or medical provider to operate independently under this Rule without government micromanagement. Section 92.402 of the Rule makes the blatant admission that the Department can grant or overrule rights of conscience or religious belief at its own discretion: "OCR may determine at any time whether a recipient is exempt from the application of certain provisions of this part or whether inapplication of the provision is required as applied to specific contexts procedures or health care services based on a Federal conscience or religious freedom law."Further if an exemption is available in one case that doesn't provide a shield in other contexts: "If OCR determines that a recipient is exempt from the application of certain provisions of this part or inapplication of certain provisions is required as applied to specific contexts procedures or health care services based on a federal conscience or religious freedom law that determination does not otherwise limit the application or of any other provision of this part to the recipient or to other contexts procedures or health care services." Clearly this Rule wants the Department to rule not the Constitution or federal laws aimed at protecting our fundamental liberties. There is no doubt that this Rule intends to tie the hands of many health care entities and limit the free practice of providers acting with faith and conscience. The monumental chilling effect of the proposed practice stands in clear violation of this country's First Amendment jurisprudence. Under this rule health care providers are required to beg on their knees with "mother may I" requests to the Department for permission to be ethical doctors and act according to the dictates of their professional judgments their conscience and/or their deeply held religious convictions. Government actors should never be allowed to weaponize an ideology of abortion and "gender affirming care" against the moral practice of medicine by any covered entity who objects to

Concerned Women for America

health care personnel's refusals to provide health care on grounds of religious or moral objection do not jeopardize access to reproductive health care. [International human rights law holds that the right of religious freedom by one individual cannot justify infringement on the human rights of others including women and LGBTQI individuals. [Footnote 101: Ahmed Shaheed Special Rapporteur on Freedom of Religion or Belief, Interim Rep. of The Special Rapporteur on Freedom of Religion or Belief para. 46 U.N. Doc. A/72/365 (Aug 28 2017).] Incorporation of federal refusal laws would encourage more provider discrimination contrary to human rights norms. [Footnote 102: See Human Rights Council Report of the Working Group on the issue of discrimination against women in law and practice para. 95 U.N. Doc. A/HRC/32/44 (Apr. 8 2016) (concluding that "inadequately regulated conscientious objection may constitute a barrier for women when exercising their right to have access to reproductive and sexual health services. The jurisprudence of human rights treaty bodies states that where conscientious objection is permitted States still have an obligation to ensure that women's access to reproductive health services is not limited and that conscientious objection is a personal not an institutional practice.")] The World Health Organization's 2022 Abortion Care Guideline reiterates that "the human rights obligation to ensure conscientious objection does not hinder access to quality abortion care." [Footnote 118: WORLD HEALTH ORGANIZATION ABORTION CARE GUIDELINE 60 (Mar. 8 2022) https://www.who.int/publications/i/item/9789240039483.] The Guideline also states that "[i]f it proves impossible to regulate conscientious objection in a way that respects providers and fulfils abortion seekers' rights conscientious objection in abortion provision may become indefensible." [Footnote 104: Id.] Further the UN Special Rapporteur on Freedom of Religion or Belief has specifically mentioned "the denial of access to reproductive health services" as an example

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(b)(5)

Center for Reproductive Rights

It is hard to overstate the radicalness of the change that the Biden administration wants to impose on our nation. If this rule were to go into effect it would force health insurers to cover a myriad of surgical and pharmacological interventions based on a diagnosis of gender dysphoria and mandate the delusion that it is possible to change a person's biological sex. Anyone who has a minimal grasp of genetics knows that every cell in our bodies reveals our biological sex and no amount of surgeries or cross-sex hormones can change more than someone's exterior appearance. The cost and negative side effects of trying to help a man or a woman pass as a member of the opposite sex are nightmarish. According to traditional Judeo-Christian anthropology it is profoundly immoral to reject God's creation of our bodies. Any health care worker who rejects gender ideology denies that someone can change his or her sex or disagrees that attempts to do so are therapeutic could be targeted for exclusion from the healing professions by Joe Biden and Xavier Becerra's HHS. One of the most disturbing aspects of the proposed rule is its demand for compelled speech. It is profound evil to attempt to force people to say things they believe are lies. Alexander Solzhenitsyn pointed out how the communist regimes in the Soviet Union habitually forced the population to affirm what they knew to be lies and imposed grave penalties on those who refused. How different is the current proposal to force people to use "preferred pronouns" that frequently mean calling a biological male "she" or a biological female "he"? Under this rule if someone does not comply with the demand to use preferred pronouns he could lose his job and even the ability to work in health care.

Texas Catholic Conference of Bishops

Apart from state-level statutory protections HHS states in the proposed rulemaking that they will comply with the federal Religious Freedom Restoration Act (RFRA) and all other legal requirements related to religious liberty and conscience and that recipients may file complaints with OCR if a specific provision or provisions of the proposed rule would violate federal conscience or religious freedom laws. [Footnote 13: See e.g. the Coats-Snowe Amendment the Church Amendments Section 1303 of the ACA Section 1554 of the ACA and the Weldon Amendment.] But these assurances mean little because the department is currently engaged in all court challenges related to Section 1557 as the NPRM itself notes. [Footnote 14: NPRM at 13.] Additionally the NPRM maintains that it would be in the OCR's discretion to determine "at any time" whether a covered entity is wholly exempt from or entitled to a modification of the application of certain provisions of the rules or whether modified application of the provision is required under a federal conscience or religious freedom law.

Kansas Catholic Conference

4. [Bold: HHS Grants Rule.] This Rule discriminates against religious beliefs in social services. 5. [Bold: Religious Liberty & Free Inquiry Rule-Suppresses] faith-based student groups at college campuses. 6. [Bold: Conscience Rule-Removes] protections for health care professionals' conscience rights. 7. [Bold: Equal Treatment for Faith-Based Organizations. See alarmed] faith-based charities, even self-funded plans under ERISA. Our institutions need clarification from the Department on whether their self-funded plans would also be subject to HHS's radical redefinition of sex and attempt to expand abortion access through bureaucratic fiat. We urge the Department not to extend its rule into self-funded plans as doing so would further violate the conscience rights and religious liberty of our institutions and their employees. A further concern is the application of these proposed rules to the nursing pre-med and similar health care programs at our colleges. In its definition of "health program or activity" the proposed rule includes "health education for health care professionals or others" [479.12]. These programs would likely be under the proposed rule's extensive reach thereby forcing our Christian college students to participate in services that violate their conscience and religious liberty rights. Our students would likely have to comply with these new HHS requirements at hospitals where they learn and work potentially forcing them to participate in abortions and sex reassignment procedures. These students' futures would be threatened as they face pressure in their career to participate in procedures that violate their conscience and beliefs. These students need affirmative protections and clarification in the proposed rule that their conscience rights and religious beliefs will not be violated for simply pursuing their chosen careers. HHS claims that these concerns will be fully addressed but we are greatly concerned that the Department's lack of affirmative protections will result in First Amendment violations. The proposed rule lists several court cases that have argued that the redefinition of [t]o include sex] in HHS rules violates the conscience rights and religious liberty of health care providers. HHS admits that these cases have been decided against the Department yet it maintains that it will comply with First Amendment requirements. The proposed rule does not take these court challenges (some of which have even been decided against the Department) into account nor does it offer clarifications that I am assured by the hypocrisy of those who claim to stand for diversity and inclusion and yet do not hesitate to drive out of health care anyone who disagrees with them. Make no mistake the targets of this attack are more than conservative Catholics or Christians. They include many Muslims and Jews and other strong adherents of the world's religions. It would also include liberals who simply cannot accept the nonsensical notion that a woman can become a man or a man a woman. If I goes forward there will be no diversity of views or transgenderism or abortion in health care and tremendous discrimination against huge numbers of people who do not accept radical modern ideology with totalitarian tendencies. How is that in conformity with the so called ideals of "diversity and inclusion"?

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American Association of Christian Schools

protect conscience and religious liberty is ambiguous and needs clarification and strengthening. The Department assures institutions that it will make an "informed case-by-case decision and where applicable protect a recipient's conscience or religious freedom rights" when it conflicts with the proposed rule and further assures institutions that "any relevant ongoing investigation or enforcement activity regarding the recipient shall be held in abeyance until a determination has been made under paragraph (c)" (47686). But this is a weak protection that will result in prolonged investigations and cumbersome processes to assert fundamental rights with no guarantee that the Department will respect the First Amendment rights of health care providers. Indeed the Department even states that it intends "to consider potential harms to third parties that may result from granting a religious exemption in the health care context" thereby ignoring the immediate and egregious harm of health care providers losing their constitutional rights (47842). Despite the lessons taught by the Little Sisters of the Poor (2016) and Burwell v. Hobby Lobby (2014) cases in which the Supreme Court ruled that the government cannot force religious employers to violate their religious beliefs in their health plans the HHS proposed rule refuses to apply a broad protection to religious employers. While HHS states that it "acknowledges and respects laws protecting conscience and religious exercise" such as the Religious Freedom Restoration Act (RFRA) RHA also contains an affirmative obligation on the government to respect and protect religious liberty an obligation that HHS seems to forget in this proposed rule as it only presents RFRA as a defensive argument for individuals to raise on a case-by-case basis when this proposed rule inevitably violates their First Amendment freedoms (47842).

Indeed the lack of clear specific protective language in the rule without justification for the government's compelling interest combined with a total lack of analysis of how the rule utilizes the least restrictive means to accomplish its

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American Association of Christian Schools

We applaud the Department's explicit recognition of federal conscience and religious freedom rights and the need for a formal process for people's rights to be vindicated but the proposed process is meaningless because all that matters is who makes the final determinations and on what basis. While we agree that any investigation should be paused until a final determination has been made we have every reason to believe that the process will exclude the Conscience and Religious Freedom Division and lead to religious and conscience objectors losing and "harmed third parties" winning every time it is clear that HHS has excluded the Conscience and Religious Freedom Division from the rulemaking process because it is nowhere mentioned as part of the process or rulemaking even though the Division was created and staffed with career professionals [Italics: precisely] to address the religious freedom and conscience questions raised by the rule and the proposed process. If an entity or individual believes the Department is violating its federal conscience protection rights (be it with respect to sexual orientation or gender identity or adoption) they must in most cases submit an objection or complaint to OCR—the very entity tasked with evaluating sexual orientation or gender identity and termination of pregnancy discrimination claims. Without the explicit formal required participation of the Conscience and Religious Freedom Division the proposed process has no accountability for HHS and perverse incentives for the Agency to disregard conscience and religious freedom rights.

Ethics & Public Policy Center

Under the rule religious education institutions that hold a traditional and religious view of human sexuality contrary to the Department's definition of [Italics: sex] will be stripped of the freedom to practice biblical beliefs and teach the biblical truths about the creation of man God's design for sexuality and the inherent value of unborn life through their health programs. Under this administration's changing attitudes and conditions it is not unthinkable that schools will be made to force religious schools to participate or be complicit in medical procedures that violate the schools' beliefs and values. The Department's proposed rule will harm hundreds of thousands of Christian college students parents faculty and staff who take seriously God's commands to order their lives according to the truth about sexuality and life

American Association of Christian Schools

[Bold: C. HHS should consult with and follow the recommendations of the Conscience and Religious Freedom Division and protect conscience and religious freedom rights.] Religious health care professionals and faith-based health care organizations live out their faith-based vocation to love and care for the sick and suffering through health care based on the biological scientific reality of the human person and the human body. These professionals and organizations are vital to health care access for the poor and vulnerable especially where Catholic health care alone provides over 15 percent of all health care delivery in America. Regulations that fail to uphold federal protections for medical conscience and religious liberty in health care will lead to decreasing access to care to poor communities and racial minority communities throughout many of the country. This should never occur generally and especially not during the "public health emergency" declared by HHS Secretary Becerra to still exist [Footnote 217: Cf. EPPC Scholars Call on HHS Secretary Becerra to End Covid-19 Public Health "Emergency" (Mar. 15 2022) https://eppc.org/news/eppc-scholars-call-on-hhs-secretary-becerra-to-end-covid-19-public-health-emergency/.]

Ethics & Public Policy Center

In conclusion it is true that Americans need and want access to quality healthcare providers and Section 1557 is meant to ensure that access is provided in a fair nondiscriminatory manner. But by failing to protect the religious and conscience beliefs that motivate many healthcare providers especially related to protection of mothers and unborn children the Department risks jeopardizing its own goal of patient access to care. At a time when our nation needs more not fewer healthcare professionals and facilities to provide treatment and preventative palliative and rehabilitative care for life-threatening health complications forcing providers to participate in abortion and other services in violation of their conscience will drive providers out of the medical field resulting in less care for patients. Indeed the Department acknowledges this by noting that in many areas a religious health care entity is the only one willing and able to serve the population's need for lifesaving care. If the Department intends to drive these providers from the health care field its action will reduce access to needed health care not enhance it.

Charlotte Lozier Institute

[Bold and Italics: Notification of Views Regarding Application of Federal Conscience and Religious Freedom Laws (§ 92.302(b)(2)).] The AAMC appreciates the Department's efforts to outline a framework for evaluating claims under various federal religious freedom and conscience laws during OCR investigations. We agree that the proposed approach allows OCR to maintain its important role in the proper application of federal conscience and religious freedom protections as part of its enforcement of Section 1557. The AAMC supports having a clear process for raising concerns with OCR so that it can determine whether an exemption or modification to the application of a certain provision is appropriate under the corresponding federal conscience or religious freedom law. We have previously commented to HHS that in the context of conscience and individual rights careful balance must be preserved to adequately protect the health and rights of the patient. [Footnote 13: AAMC Comments to HHS OCR Regarding Conscience Rights Proposed Rulemaking (March 2018).] We believe this proposed provision helps achieve such a balance.

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Association of American Medical Colleges (AAMC)

[Italics: Infringement on free speech:] Another concern with the HHS proposed rule is its potential to strip Christian educational institutions of their First Amendment right to free speech. The proposed rule requires that schools that receive HHS funding issue a "notice of nondiscrimination to participants beneficiaries enrollees and applicants of its health programs or activity and members of the public" (47901). The notice includes "a written policy in its health programs and activities that at a minimum states the covered entity does not discriminate on the basis of [sex] including pregnancy sexual orientation gender identity and sex characteristics)" (47914). This notice requirement would violate the free speech rights of religious institutions and force them to issue statements that contradict their religious beliefs. We urge the Department to clarify that notice requirements will not violate the First Amendment free speech or religious free exercise rights of religious educational institutions.

American Association of Christian Schools

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The proposed rule prioritizes patients' rights to access nondiscriminatory health care while clarifying existing laws that ensure a fair process for religious- and conscience-based requests for exemptions or accommodations. We applaud HHS's efforts to ensure patient access to health coverage and care while clarifying when covered entities can claim religious and conscience exemptions. By specifying that objections are limited to those religious freedom and conscience laws permissible under Title I of the ACA, HHS brings the rule in alignment with the statutory text, congressional intent, and a commitment to health equity. [Footnote 1: 42 U.S.C. § 18001.] Further, we applaud HHS's recognition that consideration of requested accommodations must evaluate potential harms that any accommodation has on third parties or affected individuals and how applicable legal standards for these laws, including that any requested accommodations under the Religious Freedom Restoration Act, must be considered on a case-by-case basis. [Footnote 2: 42 U.S.C. §§ 2000bb to 2000bb-4.]

ensures that any religious exemptions do not lead to denials of care. [Italics: 2] A blanket religious exemption to Section 1557's protections is contrary to the purpose of Section 1557. [We strongly support the proposed rule's recognition that Section 1557 does not require the Department to incorporate the language of Title IX's religious exemption, including the religious exemption from Title IX or a new blanket religious exemption to Section 1557's protections would run counter to the operation and purpose of a law prohibiting discrimination within the health care system. A patient's decision to seek health care at a particular institution is frequently dependent upon geographic location, cost, insurance coverage, and the treatments sought. Allowing providers to delay or deny care based on their religious objections has a direct impact on patients and, many times, individuals' lives and health at risk. Religious objections to health care frequently impact LGBTQI+ patients and patients who are pregnant, seek to be pregnant, or seek to avoid pregnancy. Abortion, contraception, sterilization, and fertility care are essential health care services for any patient who may become pregnant and who, therefore, may need one, several, or all of these services in the course of their reproductive life. As discussed in detail above, denial of these services also constitutes sex discrimination under Section 1557. Accordingly, any health care entity subject to 1557 should be required to ensure that patients are able to obtain seamless access to the care they need. The proliferation of Catholic health care system mergers has resulted in entire regions where patients do not have access to a non-religious, nondiscriminatory hospital or health care providers. Due to an acceleration of hospital mergers, people living in rural areas, people with low incomes, and communities of color often rely on these religiously affiliated health care entities, which now make up a large part of the U.S. health care system. [Footnote 62: Susan Haigh & David Crary, Catholic Hospitals' Growth Has an Impact, Reproductive Health care, AP NEWS (Jul. 24, 2024).]

recognition that the law protects people who experience intersectional discrimination. The very purpose of § 1557 is to address long-standing discrimination in health care that has created numerous barriers to quality care for communities of color, people with disabilities, the LGBTQI+ community, and more but especially those who sit at the intersections of these identities. Unfortunately, some organizations use religious objections as a pretext to discriminate against sexual and reproductive health care and gender-affirming care. [Footnote 15: Emily London and Maggie Siddiqi, Religious Liberty Should Do No Harm, American Progress, (April 22, 2019) https://www.americanprogress.org/article/religious-liberty-no-harm/]. While such beliefs may be genuine among those who possess them, religious orthodoxy must not erase individuals' right to access health care or coverage simply because they are part of an unfavored group. In Massachusetts, the Boston area has the greatest concentration of providers who no deliver gender-affirming care so access is relatively good compared to other areas of the state. Still, providers affiliated with religious groups dominate the local health care markets in some parts of the Boston area as well as in some other areas of the Commonwealth. While some patients in Massachusetts and beyond may be able to switch to a provider that does discriminate based on religious beliefs, this is not an option for all affected people in all health care markets, particularly those living in rural areas with fewer available health care options. Even those who have access to other providers may experience severe consequences due to delayed care and the mental anguish provoked by facing denials of needed medical services. We support HHS's proposed approach of evaluating religious exemptions on a case-by-case basis while considering the effects on third parties such as patients. The Religious Freedom Restoration Act states that "governments should not substantially burden religious exercise without compelling justification."

We further oppose the interpretation of Section 1557's incorporation of Title IX to exclude that law's longstanding religious exemption [See 20 U.S.C. § 1681(a)(3)] and its abortion neutrality provision [See 20 U.S.C. § 1688] which protects the rights of healthcare providers and entities like doctors, nurses and hospitals to refrain from involvement in abortion. [See Doerfinger, B. (2021). "The 'Equality Act': Threatening Life and Equality" available at https://daiinstitute.org/the-equality-act-threatening-life-and-equality/ detailing the history and purpose of Title IX's religious exception and abortion neutrality provision.]

As noted above, we are pleased that HHS proposed not to incorporate the Title IX of the Education Amendments of 1972 religious exemption and abortion neutrality exception commonly referred to as the Danforth Amendment into the rule and agree that HHS is not bound to incorporate these provisions in its Section 1557 regulation. [Footnote 15 20 U.S.C. §1681 et seq.] Applying these provisions to health care delivery has detrimental impacts on care and we applaud HHS for recognizing that they should not be incorporated into Section 1557.

We likewise strongly support HHS's proposal not to graft onto the ACA any categorical exemption from Title IX which would be inconsistent with the text, structure, history, and purpose of the Section 1557 statute and would be deeply harmful to patients. The exceptions enacted with respect to Title IX were designed for and in many cases tailored to the education context and would make little sense if imported wholesale into the ACA. HHS lacks authority to inject such exceptions into a statute where Congress declined to extend them. This is especially true with respect to Title IX's uniquely broad religious exemption which stands in stark contrast to narrower religious or conscience exceptions Congress has chosen to adopt with respect to health care.

We also support the omission of Title IX's religious exemption which is harmful and has no place in a healthcare non-discrimination rule. Including the Title IX religious exemption would exceed HHS's authority as the ACA references Title IX only to identify the grounds of discrimination or it addresses for the basis of sex and its enforcement mechanisms not to incorporate Title IX more broadly. Most of the Title IX exemptions make no sense at all in the healthcare context. That is particularly true of Title IX's extremely broad religious exemption which would wreak havoc if applied to the ACA by allowing healthcare providers to deny essential healthcare services based on disapproval of a particular group or for other non-medical reasons thereby putting the health and well-being of already vulnerable individuals at risk. Particularly for urgent or emergent healthcare needs a patient often has little to no ability to choose a particular provider in order to avoid a provider or institution that withholds care based on religious doctrine even if the patient is aware of such restrictions (which is not typically the case). Moreover, there are already numerous federal laws that allow healthcare providers to invoke a conscience objection to providing certain kinds of care making an additional religious exemption unnecessary. The case by case approach proposed in section 92.302 is far preferable to the sweeping Title IX exemptions which does not allow the Department to consider the potential harm of granting an exemption.

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U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Center for Reproductive Rights

Health Care For All

(b)(5)

Charlotte Lozier Institute

U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

InterACT: Advocates for Intersex Youth

Equitas Health

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[Italics] Religious liberty concerns]We are greatly concerned with the lack of clarity on the proposed rule's religious liberty protections. While Title IX contains a strong religious liberty exemption the HHS rule declines to incorporate these vital protections leaving religious institutions in the lurch. The proposed rule states that Title IX's "exception for an educational institution controlled by a religious organization" does not apply to Section 1557 because "incorporation of Title IX's religious exception would ... seriously compromise Congress's principal objective in the ACA of increasing access to health care" (47841). But the omission of Title IX's religious exemption is glaring because the statutory religious exemption is central to Title IX and necessary to the religious educational institutions that would be affected in this proposed rule. To the extent that the HHS proposed rule would affect Christian educational institutions the rule should clearly incorporate Title IX's religious exemption that was designed to protect religious educational institutions from violating their sincerely held religious beliefs. The reasons HHS purports to not incorporate Title IX's religious exemption disappear when the regulations directly affect Christian educational institutions as these proposed rules would do.

3. [Bold Title IX's] Enshrines gender identity and sexual orientation ideology in education. This is harmful to minors and is a violation of Catholic religious liberties.

[illegible] limit the religious exemption of Title IX of the Education Amendments of 1972 which is harmful and has no place in a health care nondiscrimination rule. Including the Title IX religious exemption would exceed HHS's authority and if applied to the ACA would allow health care providers to deny essential health care services based on disapproval of a particular group or for other non-medical reasons thereby putting at risk the health and wellbeing of already vulnerable individuals. A blanket religious exemption would be both contrary to the purpose of Section 1557 and unnecessary. It is vital to acknowledge that the inclusion of the religious exemption from Title IX or a new blanket religious exemption would be detrimental to the operation of a law precluding discrimination in the context of health care. We appreciate that when considering exemptions from Title IX HHS recognized that education and health care are quite different contexts particularly in the choice of and access to services. The decision to seek health care at a particular institution is often driven by geographic location cost insurance coverage and the type of care being sought. Allowing denials of care based on religious objections can have a direct impact on patients including putting someone's life and health at risk. There is clear evidence from across the country of health care institutions and providers refusing to provide a range of services based on personal or religious objection including abortion miscarriage management contraception fertility services gender-affirming care and end-of-life care. [Footnote 2: See Catholics for Choice Is Your Health Care Compromised? How the Catholic Directives Make for Unhealthy Choices CATHOLICS FOR CHOICE (2017) https://www.catholicsforchoice.org/wp-content/uploads/2017/01/2017_Catholic-Healthcare-Report.pdf, Amy Chen & Hayley Panan Health Care Refusals & How They Undermine Standards of Care Part II The Impact of Health Care Refusals Discrimination and Mistreatment on LGBTQI Patients and Families NAT'L HEALTH L. PROG. (June 13 2022)]

We also support the omission of Title IX's religious exemption which is harmful and has no place in a health care nondiscrimination rule. Including the Title IX religious exemption would exceed HHS's authority as the ACA references Title IX only to identify the grounds of discrimination it addresses (on the basis of sex) and its enforcement mechanisms not to incorporate Title IX more broadly. Most of the Title IX exemptions make no sense at all in the health care context. That is particularly true of Title IX's extremely broad religious exemption which would wreak havoc if applied to the ACA by allowing health care providers to deny essential health care services based on disapproval of a particular group or for other non-medical reasons thereby putting the health and wellbeing of already vulnerable individuals at risk. Particularly for urgent or emergent care a patient often has no ability to choose a particular provider in order to avoid a provider or institution that withholds care based on religious doctrine even if the patient is aware of such restrictions [which is not typically the case]. Moreover there are already numerous federal laws that allow health care providers to invoke a conscience objection to providing certain kinds of care making an additional religious exemption unnecessary.

Religious Exemption And Abortion Neutrality Provision Second the NPRM proposes to exclude Title IX's religious exemption and abortion neutrality provisions from incorporation into the Section 1557 regulation. The Department narrowly construes Section 1557's incorporation by reference of Title IX to include only what it claims is the prohibited basis for discrimination (i.e. sex) [italics but not] the exceptions set forth in Title IX. A district court considering a previous version of the Section 1557 regulations which interpreted Section 1557's scope of incorporation of Title IX similarly to the present NPRM issued a nationwide injunction against it. In Franciscan Alliance v. Burwell 227 F. Supp.3d 660 (2016) the court stated Congress specifically included in the text of Section 1557 "20 U.S.C. 1681 et seq." That Congress included the signal "et seq." which means "and the following" after the citation to Title IX can only mean Congress intended to incorporate the entire statutory structure including the abortion and religious exemptions. Title IX prohibits discrimination on the basis of sex but exempts from this prohibition entities controlled by a religious organization when the proscription would be inconsistent with its religious tenets. Title IX also categorically exempts any application that would require a covered entity to provide abortion or abortion-related services. Therefore a religious organization refusing to act in accordance with its religious tenets on the basis of sex does not discriminate on the ground prohibited by Title IX. Failure to incorporate Title IX's religious and abortion exemptions nullifies Congress's specific direction to prohibit only the grounds proscribed by title IX. That is not permitted. Franciscan Alliance at 690-91 (internal citations and footnotes omitted) The Department disagrees with the conclusion of Franciscan Alliance and says that it is not bound by the decision. The NPRM does not explain why the reasoning of Franciscan Alliance is wrong; however despite the NPRM's omitted explanation a first rule should contemplate the Department's divergence from established

We also support the omission of Title IX's overly broad religious exemption. There are already many federal laws around conscientious objections for healthcare providers so an additional religious exemption in Section 1557 is unnecessary. Title IX's religious exemption in particular is extremely broad and could be interpreted to allow providers to deny essential healthcare services to marginalized and vulnerable communities. We ask that HHS require that any entity receiving a religious exemption under proposed section 92.302 include the existence and scope of such exemption in its required notices. Patients should be aware ahead of time if certain healthcare organizations may refuse to serve them based on religious objections.

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American Association of Christian Schools

Kansas Catholic Conference

Center for American Progress

Colors+

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Charlotte Lozier Institute

Howard Brown Health

spectrum of reproductive health care. Due to a culture that stigmatizes abortion care and a coordinated effort by anti-abortion policymakers to restrict access to abortion care and coverage, many were not able to access abortion care prior to the Dobbs decision. In the fallout of the Dobbs decision, individuals especially People of Color, people with low incomes, immigrants, young people, people with disabilities and LGBTQI+ individuals are facing numerous logistical and legal barriers to accessing care with an increased threat of arrest and prosecution as states seek to criminalize abortion care. [Footnote 1. Samantha Artiga et al. What are the Implications of the Overturning of Roe v. Wade for Racial Disparities? Kaiser Family Foundation. July 15, 2022. https://www.kff.org/racial-equity-and-health-policy/issue-brief/what-are-the-implications-of-the-overturning-of-roe-v-wade-for-racial-disparities/.] The consequences of the Dobbs decision will fall especially heavily on those who experience intersectional discrimination. In the wake of Dobbs it is critical that abortion care is clearly and consistently included within "pregnancy or related conditions" throughout the final rule. HCFA's Helpline handles on average 1,000 calls per year from pregnant individuals seeking coverage for pregnancy-related services including abortions. Many of these callers are seeking abortion services and ensuring they continue to have access to make safe health care decisions is paramount. Our organizations also support HHS's proposal to repeal 45 CFR 92.6(b) the Title IX religious refusals exception and abortion exception commonly referred to as the Danforth Amendment. The preamble rightly asserts that the ACA references Title IX only to identify that it prohibits discrimination on the basis of sex as well as procedures its enforcement provisions rather than importing all aspects Title IX much of which is irrelevant in a health care context. While most of the Title IX exemptions are inapplicable the religious exemption is specifically problematic because it could shield discriminatory denials of access to care for trans- and gender-expansive people

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We also support the omission of Title IX's religious exemption which is harmful and has no place in a health care nondiscrimination rule. Including the Title IX religious exemption would exceed HHS's authority as the ACA referenced Title IX only to identify the grounds of discrimination it addresses (on the basis of sex) and its enforcement mechanisms not to incorporate Title IX more broadly. Most of the Title IX exemptions make no sense at all in the health care context. That is particularly true of Title IX's extremely broad religious exemption which would wreak havoc if applied to the ACA by allowing health care providers to deny essential health care services based on disapproval of a particular group or for other non-medical reasons thereby putting the health and wellbeing of already vulnerable individuals at risk. Particularly for urgent or emergent care a patient often has no ability to choose a particular provider in order to avoid a provider or institution that withholds care based on religious doctrine even if the patient is aware of such restrictions (which is not typically the case).

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Health Care For All

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USCUS Sexted for Social Change

interest and no alternate way to serve that interest that would better accommodate religious freedom the standard which would satisfy a RFRA action. Tellingly the NPRM states in contrast to Title IX and the educational context,[S]tudents and families typically make a choice to attend religious educational institutions patients seeking health care are much more likely to be driven by considerations of availability convenience urgency geography cost insurance network restrictions and other factors unrelated to the question of whether the health care provider is controlled by or affiliated with a religious organization. There are an increasing number of communities in the United States with limited options to access health care from non-religiously affiliated health care providers. As a practical matter, for many patients and their families may have little or no choice about where to seek care particularly in exigent circumstances or in cases where the quality or range of care may vary dramatically among providers. Moreover health care consumers are not always aware that the healthcare entities from which they seek care may be limited in the care they provide. Incorporation of Title IX's religious exemption would therefore seriously compromise Congress's principal objective in the ACA of increasing access to health care. NPRM at p. 47840. This a legerdemain between educational and health care institutions is unconvincing. Under the Common Rule of 2000 Title IX [including its abortion exclusion] already applies to agencies which provide health care such as the Department of Veterans Affairs. In fact the situation that led Congress to realize the need for an abortion neutral amendment was one involving students at the University of California who objected to paying student health fees for a student health care service elective abortions only to be told among other things that the university was required to provide abortions by Title IX. In any case the Department's argument on this point suggests that it believes there is a compelling state interest to force healthcare

Charlotte Lozier Institute

We strongly support the Proposed Rule's recognition that Section 1557 does not require the Department to incorporate the language of Title IX's religious exemptions

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[Bold: 6. The Proposed Rule would harm religious liberty.]] [Bold: A. Section 1557 incorporates Title IX's religious exemption. Title IX limits its religious exemption which states that Title IX's prohibition against sex discrimination "shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization." [Footnote 201: 20 U.S.C. § 1681(a)(3).] Section 1557 prohibits discrimination on "the ground prohibited under" Title IX specifically "20 U.S.C. § 1681 (last visited)." [Footnote 202: 42 U.S.C. § 18116 (emphasis added).] Section 1557 citation of Title IX's statutory scheme demonstrates that the "more natural understanding," is that all of Title IX's provisions including its exemptions are incorporated. Congress didn't need to expressly incorporate Title IX's exemptions by because I did so my reference to the statutory provisions (20 U.S.C. § 1681 (italics: et seq.). If Congress just wanted to prohibit discrimination based on sex generally it could have said to explicitly. Rather Congress incorporated the four civil rights statutes because those discrimination prohibitions reflected careful balance of various concerns and competing interests by Congress. Contrary to HHS's assertion the proposed regulations do not reflect Section 1557's statutory language or Congressional intent

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Ethics & Public Policy Center

As a textual matter applying sex discrimination prohibitions to a religious institution to the extent it "would not be consistent with the religious tenets of such organization" is not a ground prohibited under Title IX. Further Title IX's prohibition against sex discrimination is in 20 U.S.C. § 1681(a) as is the religious exemption [(§ 1681(a))(3)]. Title IX's sex discrimination prohibition cannot be read separate and apart from the exemptions, especially those in the same section to say otherwise would be arbitrary and fearsome and contrary to law.

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Ethics & Public Policy Center

The Proposed Rule states that "the application of the Title IX exception for entities controlled by religious organizations in part could raise distinctive concerns in the health care context that are not typically present in education programs and activities." [Footnote 203: 87 Fed. Reg. 47841.]. The Department gives several examples such as "the ability of affected parties to choose or avoid a certain religiously affiliated health care institution and the urgency of the need for services provided by the covered entities." [Footnote 204: Id.] In a legerdemain patients seeking health care are much more likely to be driven by considerations of availability convenience urgency geography cost insurance network restrictions and other factors unrelated to the question of whether the health care provider is controlled by or affiliated with a religious organization." HHS fails to provide support for this statement making its reasoning arbitrary and capricious. Countless patients including the undersigned seek health care specifically from a provider that shares their religious beliefs even if such a provider is less convenient further away or costs more. HHS states that in many communities patients may have no other option than to seek health care from religiously affiliated providers indicating that patients do have preferences regarding the religious nature of the health care provider and do make care decisions based on such affiliation. HHS cannot disregard the statutory contours of the Section 1557 of the ACA and its obligations under the First Amendment RFRA and federal conscience and religious freedom protection laws to promote the ACA's general principal objective of "increasing access to health care." [Footnote 205: 87 Fed. Reg. 47840.]

Ethics & Public Policy Center

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HHS also claims that a case-by-case analysis of burden and interests is required under RFRA "something the Title IX exemption does not allow." [Footnote 206: 87 Fed. Reg. 47840.] But this is inapposite. Different laws can have different and overlapping religious protections with differing standards. It is not inconsistent or contradictory for Title IX to give a blanket exemption where a requirement would violate a religious tenet while RFRA requires a substantial burden [and no compelling interest achieved by the least restrictive means].

We also support the omission of Title IX's religious exemption which is harmful and has no place in a health care nondiscrimination rule. Including the Title IX religious exemption would exceed HHS's authority as the ACA referenced Title IX only to identify the grounds of discrimination it addresses (on the basis of sex) and its enforcement mechanisms not to incorporate Title IX more broadly. Most of the Title IX exemptions make no sense at all in the health care context. That is particularly true of Title IX's extremely broad religious exemption which would wreak havoc if applied to the ACA by allowing health care providers to deny essential health care services based on disapproval of a particular group or for other non-medical reasons thereby putting the health and wellbeing of already vulnerable individuals at risk. Particularly for urgent or emergent care a patient often has no ability to choose a particular provider in order to avoid a provider or institution that withholds care based on religious doctrine even if the patient is aware of such restrictions [which is not typically the case]. Moreover there are already numerous federal laws that allow health care providers to invoke a conscience objection to provide certain kinds of care making an additional religious exemption unnecessary. The case-by-case approach proposed in Section 92.302 is far preferable to the sweeping Title IX exemption which does not allow the Department to consider the potential harm of granting an exemption.

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Ethics & Public Policy Center

Eating Disorders Coalition for Research, Policy & Action

In the Proposed Rule HHS refuses to incorporate Title IX's religious exemption contrary to law demonstrating that it does not value religious rights. Indeed HHS under Secretary Becerra has systematically targeted or ignored conscience and religious freedom protections such as by sidelining HHS's Conscience and Religious Freedom Division abandoning the case of a nurse legally forced to participate in abortion rescinding protections for faith-based adoption and foster care agencies in three states and proposing to rescind conscience protection regulations. [Footnote 215: Rachel N. Morrison In It's First Year Biden's HHS Relentlessly Attacked Christians and Unborn Babies THE FEDERALIST (Mar. 16 2022) https://thefederalist.com/2022/03/18/in-its-first-year-bidens-hhs-relentlessly-attacked-christians-and-unborn-babies/ ("Listing the anti-religion and pro-abortion acts of the Biden-Becerra HHS[.]) HHS even refused in federal court to "disavow enforcement" of Section 1557 to require medical professionals to perform gender-transition surgeries or abortions in violation of their sincerely held religious beliefs. [Footnote 216: Franciscan All. v. Becerra No. 23-11174 at *10 (5th Cir. Aug. 28 2023).]

Ethics & Public Policy Center

of 45 CFR 92.6(b) the Title IX religious refusals exception and abortion exception commonly referred to as the Danforth Amendment. HHS correctly determined that the 2020 rule improperly applied these provisions to Section 1557. Application of these provisions in Section 1557 of the 2020 rule has been enjoined in court largely because applying these provisions to the health care context could have life-threatening implications. A recent court decision in the Fifth Circuit has confirmed that the challengers' Administrative Procedures Act claim is moot. Therefore we agree with HHS that these ongoing court cases do not constrain this new rulemaking and that these provisions should be repealed. Moreover the delegation language of the Administrative Procedure Act [APA] only permits department regulations "to implement" the underlying statute of Section 1557 not to limit the statute contrary to Congress's intent. Any silence on incorporation of the Danforth Amendment is not an oversight on the part of Congress but rather an intentional omission as "Congress legislates with knowledge of our basic rules of statutory construction" [Footnote 14: McNary v. Haitian Refugee Ctr. 498 U.S. 479 496 (1991) (referring to presumption favoring judicial review of administrative action). See also United States v. Fausto 484 U.S. 439 453 n.9 (1988) (Stevens J. dissenting) (Court presumes that "Congress is aware of this longstanding presumption favoring repeals by implication] and that Congress relies on it in drafting legislation".] Section 1557 incorporates the bases of discrimination prohibited by Title IX, it does not incorporate the Title IX exemptions. Indeed incorporation of the Danforth Amendment in the Section 1557 regulation would be contrary to congressional intent of the underlying law and ultimately harms patients. The legislative intent behind Section 1557 was "to expand access to care and coverage and eliminate barriers to access" as the government has a "compelling interest in ensuring that individuals have nondiscriminatory access to health care" [Footnote 15: Nondiscrimination in

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providers we strongly oppose any health care entity or individual provider that refuses to provide based on their personal beliefs the comprehensive care a patient needs including abortion contraception or fertility care and gender-affirming care. A provider's personal religious beliefs should never dictate the care a patient receives. The very purpose of Section 1557 is to address longstanding discrimination in health care that has created numerous barriers to quality care for communities of color people with disabilities the LGBTQ+ community and others but especially those who sit at the intersections of these identities. Religious exemptions have been used to discriminate [embedded hyperlink text [https://www.americanprogress.org/article/religious-liberty-no-harm/]] against sexual and reproductive health care LGBTQ+ care and actively exacerbate health inequities. Rural communities people with low incomes and communities of color often rely on religiously affiliated health care entities as they make up a large part of the U.S. health care system and are often located in communities that have been marginalized from care. In fact women of color [embedded hyperlink text [https://lawrightsreligion.law.columbia.edu/sites/default/files/content/BearingFruit.pdf]] disproportionately give birth in Catholic hospitals and are therefore refused many facets of comprehensive sexual and reproductive health care. We are pleased the proposed rule does not incorporate Title IX's religious exemption which would undermine Section 1557's protections for patients and result in refusals of care. We also appreciate the Department's recognition that any request for an exemption should be an individualized inquiry. [Bold: The Danforth Amendment. The application of the Danforth Amendment also known as Title IX religious refusal exception and abortion exception is inappropriate in the health care context and HHS correctly proposes to repeal 45 CFR 92.6(b). HHS correctly determined that the 2020 rule improperly applied these provisions to Section 1557. Application of these provisions to Section 1557 via the 2020 rule

Physicians for Reproductive Health

Division of Title IX's Religious Exemption. In this proposed rule HHS reverses the 2020 regulation by omitting the Title IX's religious exemption. The Endocrine Society applauds HHS for omitting this exemption which is harmful and has no place in a health care nondiscrimination rule. Including the Title IX religious exemption would exceed HHS's authority as the ACA referenced Title IX only to identify the grounds of discrimination it addresses (on the basis of sex) and its enforcement mechanisms not to incorporate Title IX more broadly. Title IX's extremely broad religious exemption would allow health care providers to deny essential health care services based on disapproval of a particular group or for other non-medical reasons. This provision is particularly serious when applied to transgender individuals and puts their health and wellbeing at risk. Particularly for urgent or emergent care a patient often has no ability to choose a particular provider in order to avoid a provider or institution that withholds care based on religious doctrine even if the patient is aware of such restrictions which is not typically the case. Moreover there are already numerous federal laws that allow health care providers to invoke a conscience objection to providing certain kinds of care making an additional religious exemption unnecessary. The case-by-case approach proposed in this rule is far preferable to the sweeping Title IX exemption which does not allow the Department to consider the potential harm of granting an exemption.

Endocrine Society

Additionally many Americans prefer to receive care from a provider who shares their religious views or the pro-life-affirming perspective on the dignity of unborn life. Although the proposed regulation seeks to assure faith-based or pro-life health care providers that the Department will follow existing laws those assurances ring hollow. The Department's proposal to explicitly exclude Title IX's religious exemption and abortion neutrality provisions from the scope of Section 1557 clearly communicates that its finger is on the scale of unfettered access to abortion at the expense of those healthcare providers that have genuine religious or moral objections.

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Moreover we strongly support HHS's proposal as in the 2016 rule not to import the religious exemption and other exceptions under Title IX into Section 1557 that are limited to certain education programs or activities. The proposal clarifies the Trump Administration's 2020 rule that incorporated the application of such exemptions in its preamble but not explicitly in the rule itself. Nothing in Section 1557's anti-discrimination prohibition supports the incorporation of the cited statutes' exceptions including Title IX's religious exemption [Footnote 8: 42 U.S.C. § 18116.] Specifically incorporation of Title IX's exceptions is inappropriate here because those exceptions were crafted for education programs and activities where students choose which educational institution to attend in order to best fit their needs including single-sex schools or religiously affiliated schools. Individuals who need health care services however especially historically disadvantaged individuals such as people of color individuals with disabilities and LGBTQI+ individuals among others may have little to no choice regarding where they can obtain services. We strongly support HHS's proposal not to import the religious exemption and other exceptions under Title IX as they are contrary to the plain statutory text of Section 1557 inapplied outside of the education context and deeply harmful to individuals accessing health care services.

(b)(5) — Charlotte Lozier Institute

We also support the omission of Title IX's religious exemption which is harmful and has no place in a health care nondiscrimination rule. Including the Title IX religious exemption would exceed HHS's authority as the ACA references Title IX only to identify the grounds of discrimination it addresses (on the basis of sex) and its enforcement mechanisms not to incorporate Title IX more broadly. Most of the Title IX exemptions make no sense at all in the health care context. That is particularly true of Title IX's extremely broad religious exemption which would wreak havoc if applied to the ACA by allowing health care providers to deny essential health care services based on disapproval of a particular group or for other non-medical reasons thereby putting the health and well-being of already vulnerable individuals at risk. Particularly for urgent or emergent care a patient often has no ability to choose a particular provider in order to avoid a provider or institution that withholds care based on religious doctrine even if the patient is aware of such restrictions [which is not typically the case]. Moreover there are already numerous federal laws that allow health care providers to invoke a conscience objection to providing certain kinds of care making an additional religious exemption unnecessary. The case-by-case approach proposed in section 92.302 is far preferable to the sweeping Title IX exemption which does not allow the Department to consider the potential harm of granting an exemption.

U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

The Proposed Rule Creates a Separate Process for Raising Potential Religious Freedom Objections We support HHS's proposal to not import the Title IX exemptions and create a separate fact-specific process that balances the interest of providing nondiscriminatory health care and the conscience and religious freedom laws [Footnote 22: Id. at 47841 47918 19 [Proposed § 92.302)]. HHS's decision to provide a case-by-case analysis will better ensure that patients will not be refused the care they need because of discriminatory practices. Retaining the previous religious refusal and abortion exception would cause delays in abortion care in order to determine compliance which given the existing barriers to abortion would permit providers treating patients in medically dangerous situations to put their further at risk [Footnote 35: See e.g. ACOG Committee on Health Care for Underserved Women Opinion 815 [Dec. 2020] Https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/12/increasing-access-to-abortion]. We request the Department consider requiring institution's or provider's notice requirements be transparent about any refusal of care granted so people can be fully informed about any potential lack of full health care access.

Eating Disorders Coalition for Research, Policy & Action

Senate Democrats

[Subpart D—Procedures]Notification of views regarding application of federal conscience and religious freedom laws [§ 92.302]It is essential that the final rule include the NPRM's revised approach to religious exemptions. When providers deny medical services for religious reasons those who require the denied care are harmed. Even if patients are able to obtain the needed care from another provider the delay in receiving care may cause irreparable harm and the stress of being denied care and fear of facing similar denials in the future have very real negative impacts. The 2020 version of 1557 implementing regulations improperly disregarded those harms and elevated providers' religious beliefs over the rights of individuals to receive the care they need. We support the approach being proposed in the current NPRM which contemplates a case-by-case process and expressly acknowledges that the potential harm to third parties must be considered when determining whether to grant an exemption. Such consideration is required by the Establishment Clause in the First Amendment to the Constitution which does not permit the government to grant religious exemptions from neutral laws if doing so would shift burdens to third parties.

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Colorado

Eating Disorders Coalition for Research, Policy & Action

[Body: Notification of Views Regarding Application of Federal Conscience and Religious Freedom Laws §92.302)Additionally HHS OCR proposes to adopt a process by which recipients of federal financial assistance may inform the Department of their views that the application of a specific provision or provisions of this part to them would violate Federal conscience or religious freedom laws so that the Department may as appropriate make a determination that recipients are exempt from or entitled to a modification of the application of a provision or provisions of this proposed rule. While not incorporating the Title IX religious exemption HHS OCR stated that it is fully committed to respecting conscience and religious freedom laws when applying this rule. HHS OCR sought comment on this approach.][Body: NCPA welcomes that HHS OCR is proposing to recognize recipients including pharmacists may have a right to object to specific provisions in the proposed rule since they would violate federal conscience or religious freedom laws. That said NCPA requests clarity that HHS OCR would allow pharmacists to not dispense certain prescriptions for reasons of religion or conscience if they are doing so within their scope of practice and that they give affected patients information on where to obtain these medications. NCPA supports such a right for pharmacists without requiring pharmacists to inform HHS OCR that they are exercising such right and without requiring HHS OCR to make a determination that recipients are exempt from or entitled to a modification of the application of a provision or provisions of the proposed rule. NCPA believes that additional stipulations on pharmacists' right to object based on conscience and religious grounds would infringe on that right and add undue burden to the practice of pharmacy.]

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NCPA

The AAFP supports HHS' efforts to further clarify that physicians are still able to decline to participate in a procedure under religious or conscience objections and we appreciate that HHS has provided clear guidance on how an individual or organization can do so under § 92.302 of this proposed rule.

American Academy of Family Physicians

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The case-by-case approach proposed in section 92.302 is far preferable to the sweeping rule exemption which does not allow the Department to consider the potential harm of granting an exemption.

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which an individual or organization may invoke that a provision of this regulation violates their federal conscience or religious freedom laws. Under this proposal individuals or organizations will not be required to perform any activity that may conflict with their conscience and/or religious protections before the Office for Civil Rights (OCR) has made a determination about their claim. The AAFP recognizes and respects the rights of health care professionals to decline to participate in an emergency care that violates their personal code of ethics as long as a physician makes an appropriate referral for the patient to seek that care elsewhere. [Hyperlink: https://www.aafp.org/about/policies/all/physician-patient-relationship.html.] [Bullet] We appreciate HHS reaffirming conscience protections. The AAFP is also committed to ensuring that patients have access to health care regardless of actual or perceived race, color, religion, gender, sexual orientation, gender identity, ethnic affiliation, health status, disability, economic status, body habitus, or national origin. The AAFP makes a clear distinction between declining to participate in a procedure based on moral grounds versus denying access to care to an individual patient. [Hyperlink: https://www.aafp.org/dam/AAFP/documents/advocacy/legal/reality/ConscienceObjection_0121LIB.pdf]. Declining to participate in a procedure based on moral grounds is a protected right, declining to care for specific groups of people or individuals without adequate notice or an appropriate referral is an unacceptable shirking of health care professionals' responsibility to care for patients and is contrary to the key underpinnings of the Code of Medical Ethics. [Hyperlink: https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview] The AAFP joined other medical societies in filing an amicus brief that distinguishes between legal requirements under emergency and non-emergency care. [Hyperlink: https://democracyforward.org/wp-content/uploads/2022/08/U.S._v._Idaho_Amicus_Brief.pdf]. The emergency

American Academy of Family Physicians

Not filed or of views regarding application of federal conscience and religious freedom laws.[§ 92.302]For the reasons discussed by the National Center for Lesbian Rights we support the proposed approach which contemplates a case by case process and expressly acknowledges that HHS must consider the potential harm to third parties when determining whether to grant an exemption. As discussed above we recommend that HHS require covered entities to disclose any such exemptions in the notice of nondiscrimination.

Justice in Aging

[Bullet] The proposed conscience and religious objection process is an empty gesture. "The Proposed Rule states that HHS is 'fully committed to respecting conscience and religious freedom laws when applying this rule (including an organization's assertion that the provisions of this rule conflict with their rights under Federal conscience and religious freedom laws.'" [Footnote 207: 87 Fed. Reg. 47841.] As such the Proposed Rule proposes in § 92.302 "to adopt a process by which recipients may inform the Department of their views that the application of a specific provision or provisions of this part to them would violate federal conscience or religious freedom laws so that the Department may as appropriate make a determination that recipients are exempt from or entitled to a modification of the application of a provision or provisions of this part." [Footnote 208: 87 Fed. Reg. 47828.] Proposed regulations would provide a specific means for recipients to notify HHS of their views regarding the application of federal conscience or religious freedom laws. [Footnote 209: 87 Fed. Reg. 47885.] HHS would be required to "promptly consider those views" pause any agency investigation or enforcement activity during consideration and make a "case-by-case" determination about any applicable legal protections. [Footnote 210: 87 Fed. Reg. 47885.] HHS notes that a "case-by-case approach to such determinations . . . will allow it to account for any harm an exemption could have on third parties." [Footnote 211: 87 Fed. Reg. 47886.]

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We ask that HHS include in the notice requirement that any entity receiving a religious exemption under proposed section 92.302 include the existence and scope of such exemption in its required notices. It would be misleading and inaccurate to require entities to tell participants and beneficiaries and the public generally that the entity does not discriminate if the entity does in fact discriminate in certain circumstances and has been granted permission to do so.

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Notice Requirements and Enforcement It is important that the implementation and enforcement of the § 1557 be comprehensive enough to meet the intended nondiscrimination requirements of the ACA. Our organizations strongly support the requirements related to notice of nondiscrimination enforcement and procedures. We offer recommendations to enhance the scope of the nondiscrimination protections.Notice of Nondiscrimination We strongly support the requirements related to the notice of nondiscrimination. When the notice of nondiscrimination was removed from prior rulemaking many individuals never received information about their rights, did not know how to access interpreters auxiliary aids and services, and did not know how to file a complaint or a grievance.We ask that HHS include in the notice requirement that any entity receiving a religious exemption under proposed section 92.302 include the existence and scope of such exemption in its required notices. It would be misleading and inaccurate to require entities to tell participants and beneficiaries and the public generally that the entity does not discriminate if the entity does in fact discriminate in certain circumstances and has been granted permission to do so.

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Health Care For All

5. [Bullet] Requiring entities that receive a religious exemption to provide notice of that exemption. While entities will be required to issue a notice of nondiscrimination on the proposed rule does not require that they provide notice if they have received an exemption. Requiring an exemption notice would allow for individuals to make informed decisions in their choice in providers and their care. We ask that an exemption notice — that includes the scope of said exemption — be included as a requirement in section 92.302.

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EXEMPTION [The States support the notification procedures set forth in proposed § 92.302 which allow recipients to "inform HHS of their views that the application of a specific provision or provisions of Section 1557 would violate federal conscience or religious freedom laws. The Proposed Rule recognizes that a blanket exemption from the provisions of Section 1557 is inadvisable. 87 Fed. Reg. at 47886. While there may be fact-sensitive case-specific instances when a covered entity is exempt due to federal conscience and religious freedom laws no covered entity can be exempt from compliance with all provisions of Section 1557 in all circumstances. Id. [Footnote 77: For example federal healthcare refusal laws do not override the Emergency Medical Treatment and Labor Act's protections that require that stabilization and treatment for a patient seeking emergency care." As such the proposed notice provisions are superior to previous provisions regarding the application of federal conscience and religious freedom laws. The Proposed Rule allows the recipient of federal funds to notify HHS of its belief that a specific provision or provisions of the regulation as applied to it would violate federal conscience or religious freedom laws. 87 Fed. Reg. at 47886. The notification will then prompt HHS to consider the relevant facts as applied to the covered entity in order to assess an exemption's applicability. Id. at 47885-6. HHS's determination would be with respect to a particular recipient's certain provisions or modified application of certain provisions of the regulation and certain contents procedures or healthcare services. Id. at 47886. Critically the application of other provisions of Section 1557 to other contexts procedures or healthcare services would remain. Id. This approach hews more closely to the Congressional intent of the ACA to expand healthcare access while still recognizing that there may be circumstances where the application of federal conscience and religious freedom laws is appropriate. [Footnote 78: Even the most recent holding of Franciscan Alliance v. Becerra 553 F. Supp. 3d 361 (N.D.

Attorneys General of California, New York, Massachusetts, and nineteen other States

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Our view is that the proposed rule attempts to hide its religious liberty violations by utilizing third-party actors such as health insurers. By applying the rule to health insurers Christian schools and colleges that offer or provide health insurance to its employees would become complicit in the delivery of abortion services and sex reassignment surgeries in violation of their sincerely held religious beliefs. With the proposed rule's direct or indirect funding qualification this rule would likely reach into every aspect of a school's health-related program. This requirement serves only to draw in those who object to these services and to make them complicit in merely pregnant acts that violate their religious beliefs. In 2011 HHS attempted to force religious institutions to be complicit in such services through its contraceptive mandate refusing to provide a religious exemption for employers such as the Little Sisters of the Poor. The Supreme Court rejected the HHS mandate in a unanimous ruling in Zubik v. Burwell (2016) affirming the fundamental conscience rights of religious institutions. The ruling also resulted in a 2018 HHS final rule updating the religious exemption for religious institutions. But this current HHS proposed rule attempts to undo that progress and to ignore the Supreme Court's firm ruling protecting conscience and religious rights. Requiring a middleman via insurers or contracted health care services without offering any alternative conscience or religious liberty protections and no shield for our institutions and will likely result in further needless litigation.

However religious liberty is not a concession from the benevolence of a government agency but a protected right under the First Amendment of the U.S. Constitution and statutes like RFRA. The proposed rules not only misread the Bostock v. Clayton County decision which was limited to the Title VII employment context but also minimizes the religious liberty interests that Catholic healthcare providers have [Footnote 15: 590 U.S. (2020)] forcing Catholic healthcare facilities and medical professionals to choose between their work or violating their sincerely held religious beliefs or requiring them to provide or pay for procedures that they find unconscionable is unconstitutional [Footnote 16: Cf. Burwell v. Hobby Lobby Stores Inc. 573 U.S. (2014) (slip op. at 35) (holding unconstitutional a contraceptive mandate that requires a closely held corporation to provide certain contraceptives in violation of their conscience); Fulton v. Philadelphia 593 U.S. (2021) (slip op. at 25) (Alito J. concurring) (holding unconstitutional a city policy that forced a church charity to either engage in conduct that the Church viewed as contrary to a traditional understanding of marriage or to abandon caring for orphaned and abandoned children)]. Furthermore if these rules were to go into effect it could also run afoul of the First Amendment's Free Speech Clause and hamstring religious expression in Catholic healthcare ministries [Footnote 17: See e.g. Kennedy v. Bremerton 597 U.S. (2022) (slip op. at 11) ("Where the Free Exercise Clause protects religious exercise, we see whether, consequentially or not, the Free Speech Clause provides overlapping protection for expressive religious activities")]. In any event even if Bostock could be read to apply to other contexts the court's opinion in that case recognized that "RFRA operates as a kind of super statute displacing the normal operation of other federal laws it might supersede Title VII's commands in appropriate cases" [Footnote 18: 590 U.S. at - (slip op. at 32)].

In the Proposed Rule HHS refuses to incorporate Title IX's religious exemption contrary to law demonstrating that it does not value religious rights. Indeed HHS under Secretary Becerra has systematically targeted or ignored conscience and religious freedom protections such as by sidelining HHS's Conscience and Religious Freedom Division abandoning the case of a nurse illegally forced to participate in abortion rescinding protections for faith-based adoption and foster care agencies in three states and proposing to rescind conscience protection regulations [Footnote 213: Rachel N. Morrison In Its First Year Biden's HHS Relentlessly Attacked Christians and Unborn Babies THE FEDERALIST (Mar. 18, 2022) https://thefederalist.com/2022/03/18/in-its-first-year-bidens-hhs-relentlessly-attacked-christians-and-unborn-babies/ ("Listing the abortion-promoting and pro-abortion acts of the Biden-Becerra [HHS]."). HHS even refused in federal court to "disavow enforcement" of Section 1557 to require medical professionals to perform gender transition surgeries or abortions in violation of their sincerely held religious beliefs. [Footnote 214: Franciscan All. v. Becerra No. 21-11174 at *10 (5th Cir. Aug. 26 2022).]

FFOC) (5th Cir. Sept. 23 2022) which held that HHS could not force both non-profit and for-profit religious employers and healthcare providers to pay for and perform surgeries procedures counseling and treatments that seek to alter one's biological sex even if such actions violate the employers' or providers' religious beliefs. [Footnote 215: Christian Emp'rs All. v. EEOC Case No. 1:21-cv-195 (D.N.D. May 16 2022).] Specifically the federal district court enjoined HHS from "interpreting or enforcing Section 1557 of the ACA and any regulations against the Alliance's present or future members in a manner that would require them to provide offer perform facilitate or refer for gender transition services" and "in a manner that prevents restricts or compels the Alliance's members' speech on gender identity issues." [Footnote 216: Id.] On good evidence it is clear HHS never consulted the career professionals in the Conscience and Religious Freedom Division to solicit their views on these matters that are squarely in their expertise. HHS's litigation positions are even more evidence that the agency does not respect or recognize conscience and religious rights in the Section 1557 context. It is apparent that HHS does not believe these should be conscience and religious exemptions to Section 1557 regulations and it is doubtful that OCR would seriously give effect to these legal protections through the proposed notice and process when its litigation positions say otherwise. To the extent that health care entities and professionals not fly HHS of their conscience or religious objections to requirements under Section 1557 regulations HHS should not make publicly accessible a list of religious objectors. This would open the door for those who do not agree to single out target or harass those institutions and professionals of conscience and faith. HHS should also issue a guarantee that if a party or professional notifies the Agency of a possible or actual objection that HHS will not abuse its authority by then investigating or targeting that entity or professional for possible violations of law. To do so would chill the benefits of

We urge HHS to implement all sections of this rule—particularly the provisions allowing covered entities to proactively notify HHS of the understanding that Section 1557 does not apply to them—in a manner that prioritizes transparency and acknowledges the potential impacts for patients who will be seeking coverage or care and may face denial of critical services from those providers against their harm to patients. If the Department is correct that the potential harm to third parties must be weighed as part of any Religious Freedom Restoration Act (RFRA) analysis of whether to grant exemptions in the health care context. We urge the Department to make this element of the assessment for the application of federal refusal laws including RFRA clear in the final rule. The Department has proposed that health care entities seeking an exception to the anti-discrimination provisions of Section 1557 can claim that a requirement violates RFRA or a federal refusal law and receive an individualized assessment for an exemption based on their religious objection. We agree that these exceptions if granted at all be assessed by the Department on a case-by-case basis. That assessment must include a fact-specific inquiry and assessment of the burden on religious exercise in conjunction with the potential impact on a patient or potential patient seeking health care in the context of discrimination in health care the government has the strongest compelling interest to prevent. Longstanding discrimination in health care that has created numerous attitudinal structural and systemic barriers to quality health care for communities of color people with disabilities the LGBTQI+ community and more but especially those who sit at the intersections of these identities. Religious exemptions have been and continue to be used to discriminate against patients in need of reproductive health care and LGBTQI+ competent care and have actively exacerbated health disparities. [Footnote 68: See e.g. NAT'L WOMEN'S LAW CTR. Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide (Feb. 18 2022) https://nwlc.org/resource/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/.]. RFRA was intended to be a shield to protect religious minorities not to be used as a sword to discriminate or to harm third parties such as patients attempting to access health care. Determinations by the Department of whether an exemption should be granted should clearly explain

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American Association of Christian Schools

Texas Catholic Conference of Bishops

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U.S. House Committees on Energy and Commerce Ways and Means and Education and Labor

Center for Reproductive Rights

|Subpart D—Procedures||Bold—Notification of views regarding application of federal conscience and religious freedom laws (§ 92.302)|| It is essential that the final rule include the NPRM's revised approach to religious exemptions. When providers deny medical services for religious reasons those who require the denied care are harmed. Even if patients are able to obtain the needed care from another provider the delay in receiving care may cause irreparable harm and the stress of being denied care and fear of facing similar denials in the future have very real negative impacts. The 2020 version of 1557 implementing regulations improperly disregarded those harms and elevated providers' religious beliefs over the rights of individuals to receive the care they need. We support the approach being proposed in the current NPRM which contemplates a case by case process and expressly acknowledges that the potential harm to third parties must be considered when determining whether to grant an exemption. Such consideration is required by the Establishment Clause in the First Amendment to the Constitution which does not permit the government to grant religious exemptions from neutral laws if doing so would shift burdens to third parties. This revision is especially important in consideration of the aforementioned case in Texas but also several religious exemption cases across the country which have allowed for providers and insurers to deny essential healthcare services to vulnerable communities.

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SIECUS: Sexuality Information and Education Council of the United States

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SIECUS: Sexuality Information and Education Council of the United States

to reassure that it is fully committed to respecting conscience and religious freedom laws when applying this rule including an organization's assertion that the provisions of this rule conflict with the rights under federal conscience and religious freedom laws." [See NPRM at p. 47841.] Similarly with respect to its exclusion of the abortion neutrality provision the Department notes that "there are several other statutory and regulatory provisions related to the provision of abortions that may apply to an entity covered by Section 1557" and states that the OCR will apply these provisions consistent with the law. [Id. at p. 47879.] The Department specifically mentions the Weldon Amendment the Coats Snowe Amendment and the Church Amendment. The Department seeks comment on this approach [i.e. relying on other federal religious and conscience protections rather than specifically incorporating Title IX's religious exemption and abortion neutrality provision.] CLI expresses grave concern that expressions of generalized reliance are not sufficient to protect the religious and conscience rights of those who oppose the practice of abortion. First Title IX clearly forbids use of its sex discrimination standard to force objecting entities to violate their religious beliefs about it. In contrast the Religious Freedom Restoration Act [RFRA] is more general and provides a mechanism for a party who believes its religious beliefs have been violated to seek recourse. While protective in some respects this latter approach requires litigation which can be costly and time-consuming for the person or entity protecting its rights and places a strain on judicial resources. In contrast the Title IX religious exemption acts the burden on the Department not to burden those rights in the first place. CLI requests further explanation as to whether the Department's proposed reliance on these other protections is a secure guard given the Administration's commitment to passing the Women's Health Protection Act and the Equality Act both of which would nullify RFRA as a defense against abortion mandates.

Charlotte Lozier Institute

The Proposed Rule states that "the application of the Title IX exception for entities controlled by religious organizations in particular could raise distinctive concerns in the health care context that are not typically present in education programs and activities." [Footnote 203: 87 Fed. Reg. 47841.] The Department gives several examples such as "the ability of different parties to choose or avoid a certain religiously affiliated health care institution and the urgency of the need for services provided by the covered entities." [Footnote 204: Id.] It alleges that "patients seeking health care are much more likely to be driven by considerations of availability convenience urgency geography cost insurance network restrictions and other factors unrelated to the question of whether the health care provider is controlled by or affiliated with a religious organization." HHS fails to provide support for this statement making its reasoning arbitrary and capricious. Countless patients including the undersigned seek health care specifically from a provider that shares their religious beliefs. Even if such a provider is less convenient further away or costs more HHS states that in many communities patients may have no other option than to seek health care from religious affiliated providers indicating that patients do have preferences regarding the religious nature of the health care provider and do make care decisions based on such affiliation. HHS cannot disregard the statutory contours of the Section 1557 of the ACA and its obligations under the First Amendment RFRA and federal conscience and religious freedom protection laws to promote the ACA's general principle objection of "increasing access to health care." [Footnote 205: 87 Fed. Reg. 47841.]

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HHS also claims that a case-by-case analysis of burden and interests is required under RFRA "something the Title IX exemption does not allow." [Footnote 206: 87 Fed. Reg. 47840.] But this is inapposite. Different laws can have different and overlapping religious protections with differing standards. It is not inconsistent or contradictory for Title IX to give a blanket exemption where a requirement would violate a religious tenet while RFRA requires a substantial burden jured no compelling interest achieved by the least restrictive means]

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Moreover there are already numerous federal laws that allow health care providers to invoke a conscience objection to providing certain kinds of care making an additional religious exemption unnecessary. The case by case approach proposed in section 92.302 is far preferable to the sweeping Title IX exemption which does not allow the Department to consider the potential harm of granting an exemption.

SIECUS: Sexuality Information and Education Council of the United States

We also support the rule's acknowledgment that when a Religious Freedom Restoration Act claim or other religious exemption request is made it must be analyzed on a case-by-case basis. The potential harm to third parties must be considered when deciding whether to grant a religious exception as well as the government's compelling interest in eradicating discrimination and ensuring timely access to healthcare. Patients who are denied care experience exceptional harm in the resulting delay in care and future hesitance to seek out care as needed. Recent data from the Center for American Progress show that 12 percent of transgender respondents and 20 percent of transgender respondents of color experienced a denial of care based on the provider's religious beliefs or the stated religious tenets of the healthcare facility in the past year while 33 percent of intersex respondents had this experience. As required by the Establishment Clause in the First Amendment of the Constitution the government is not permitted to grant religious exemptions from neutral laws. Doing so shifts the burden to third parties without considering the harm to third parties

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providers to invoke a conscience objection to providing certain kinds of care meaning that an additional religious exemption is unnecessary. HHS has proposed that health care entities that seek an exception to the anti-discrimination provisions of Section 1557 can claim that a requirement violates the Religious Freedom Restoration Act (RFRA) or a federal refusal law and receive an individualized assessment for an exemption based on the religious objection. We support the case-by-case approach in § 92.302 of the Proposed Rule over the sweeping Title IX exemption. Due to the potential for harm we appreciate the Department's acknowledgment that weighing the potential harm to third parties when considering whether to grant exceptions in the healthcare context should be part of a RFRA analysis and urge the Department to make this element of the assessment for the application of federal refusal laws including RFRA clear in the Final Rule. We also agree with the Department's statement that a rule that substantially burdens religious practice could still be imposed if it was based on a compelling interest and achieved by the least restrictive means. [Footnote 12: Nondiscrimination in Health Programs and Activities 87 Fed. Reg. 47824 47839 (proposed Aug. 4 2022).] RFRA was intended to protect religious minorities not to be used as a means to discriminate or to harm third parties. [Footnote 13: See Emily Cannon & Maggie Siddiqi "Religious Liberty Should Do No Harm Center for American Progress (Apr. 2019) https://www.americanprogress.org/wp-content/uploads/2019/03/ReligiousLiberty-report-6.pdf ("The purpose of [RFRA] is to 'protect the free exercise of religion' while clearly defining and more robustly protecting the right of religious liberty for all Americans. It passed with widespread bipartisan support and was championed among faith communities civil rights advocates and politicians alike . . . In 2014 however the U.S. Supreme Court decision in Burwell v. Hobby Lobby marked a major shift in the interpretation of religious exemptions from religiously neutral laws. Rather than

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religious freedom protections under federal law. HHS acknowledges that its Section 1557 regulations will implicate conscience and religious freedom concerns as it proposes a process in § 92.302 to handle such conflicts. [Footnote 218: Further, in its 2021 notification HHS stated: "In enforcing Sec. or 1557 as stated above, OCR will comply with the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb et seq., and all other legal requirements." U.S. Dep't Health & Human Servs., Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, 3 (May 10, 2021), https://www.hhs.gov/sites/default/files/our- bostock-not ification.pdf.] Since the proposed rule would implicate conscience and religious freedom concerns, HHS should request input from the career professionals at the Conscience and Religious Freedom Division and follow their expert recommendations. There has been a concerning trend by HHS to cut the Division out of review of proposed rules that implicate conscience and religious freedom rights. Indeed, HHS has only made it more difficult across the board for the Agency to enforce vital conscience and religious protections in healthcare. It should not do so here. While HHS has paid lip service to conscience and religious freedom rights in its proposed rule, it has blatantly disregarded and ignored those rights including by effectively dismantling its Conscience and Religious Freedom Division and crippling its Office for Civil Rights (OCR) to receive complaints and enforce religious protections under the Religious Freedom Restoration Act and the First Amendment. [Footnote 219: Rachel N. Morrison, In Its First Year, Biden's HHS Relentlessly Attacked Christians and Unborn Babies, THE FEDERALIST (Mar. 18, 2022), https://thefederalist.com/2022/03/18/in-its-first-year-biden-hhs-relentlessly-attacked-christians-and-unborn-babies/ (listing the anti-religion and pro-abortion acts of the Biden-Becerra HHS).] And most recently by proposing to rescind the 2019 Conscience Rule. [Footnote 220: Rescission of the

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The removal of the delegation of authority from OCR to enforce RFRA and the First Amendment said that "Department components in consultation with OGC have the responsibility and are best positioned to evaluate RFRA-based requests for exemptions, waivers and modifications of program requirements in the programs they operate or oversee. Department components further are best situated to craft exemptions or other modifications when required under RFRA and to monitor the impact of such exemptions or modifications on programs and those they serve. Moreover, they are best positioned to evaluate how the programs must be run to comply with the Free Exercise Clause and the Establishment Clause of the First Amendment." [Footnote 221: 86 Fed. Reg. 67067 (Nov. 24, 2021).] [Delegation of Authority], see also Letter from Lisa J. Pino, Director, Office for Civil Rights, to Xavier Becerra, Secretary of Health & Human Services, Delegation of Authority under the Religious Freedom Restoration Act and the Religious Freedom Clause of the First Amendment to the U.S. Constitution (Nov. XX, 2021), https://www.lankford.senate.gov/imo/media/doc/HHS%20RFRA%20Memo.pdf.] But OCR is the "department component" for this rule. Despite its withdrawn authority, HHS must explain whether OCR has RFRA and First Amendment authority to evaluate any violations and receive complaints under its OCR rule. In the proposed rule, the Agency must explain how it will fulfill its statutory duty to protect and enforce conscience protection laws with its 1557 regulations while at the same time processing to rescind the Conscience Rule giving effect to those protections.

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[Bold: D. Requiring third-party health insurance issuers to cover medical interventions that violate conscience and religious rights of employers violates the First Amendment Free Exercise Clause and RFRA.] HHS is proposing to regulate third-party insurers to include coverage of gender transition interventions and possibly elective abortions. To the extent that these third-party insurers are regulated, HHS should recognize the conscience and religious rights of those who are required to purchase insurance plans. HHS cannot use a third party to do what it could not do directly. In an ongoing case out of Washington State, the Ninth Circuit held that a church's Free Exercise Clause claim to state law requiring health insurance providers provide plans with abortion coverage created a redressable injury in fact. [Footnote 222: Cedar Park Assembly of God of Kirkland, Washington v. Kreidler, No. 22-35507 (9th Cir. Jul. 22, 2021).] Apart from violating the First Amendment, such a regulation of health insurance providers to coerce employers [in an attempted end run of [Italics: Hobby Lobby]] would also violate RFRA as there is no compelling government interest in requiring employers with conscience and religious objections to pay for gender transition interventions and abortions and there are many lesser restrictive means for the government to provide and pay for such services without using unwilling employers' insurance plans.

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[Bold: E. The Proposed Rule must recognize federal laws protecting conscience and religious freedom.] As explained above, HHS and OCR has gone out of its way to ignore and minimize any conscience and religious protections and its attacks of those who hold contrary views based on conscience or religious beliefs. The Proposed Rule recognizes in name some federal conscience or religious freedom protection laws: RFRA, the Coats-Snowe Amendment, the Church Amendments, Section 1303 of the ACA, Section 1553 of the ACA, and the Weldon Amendment. [Footnote 225: 87 Fed. Reg. 47842.] and explains that "OCR will apply such provisions consistent with law." [Footnote 224: 87 Fed. Reg. 47879.] But in the regulations proposed (§ 92.206(c)) states: "Nothing in this section requires the provision of any health service where the covered entity has a legitimate nondiscriminatory reason for denying or limiting that service, including where the covered entity typically declines to provide the health service to any individual or where the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual." [Italics: However, a provider's belief that gender transition or other gender-affirming care can never be beneficial for such individuals for its compliance with a state or local law that reflects a similar judgment] is not a sufficient basis for a judgment that a health service is not clinically appropriate." [Footnote 225: 87 Fed. Reg. 47918. [emphasis added.]] This religious hostility plain and simple and contradicts HHS's obligations under various federal conscience and religious protection laws. While recognizing certain federal conscience and religious protections, it does not. HHS fails to explain how these laws would interact with its clearly conflicting requirements under the proposed regulations. This approach does not ensure that all constitutional and statutory rights are protected as the Department promises. The current regulations should be retained.

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consideration "potential harms to third parties that may result from granting a religious exemption in the health care context" which is particularly relevant under a RFRA analysis. [Footnote 226: 87 Fed. Reg. 47842.] But apart from RFRA, the other conscience and religious freedom protection laws create affirmative protections separate and apart from any third-party harms.] [Bold: F. The Church Amendments provide robust protection for objections to participating in or providing for gender transitions.] The Church Amendments enacted in the 1970s protect the conscience rights of individuals and entities that object to performing or assisting in the performance of abortion or sterilization procedures if doing so would be contrary to the provider's religious beliefs or moral convictions. [Footnote 227: 42 U.S.C. § 300a-7 et seq.] Since many of the gender transition treatments are sterilizing such as genital surgeries, cross-sex hormones and puberty blockers (especially when followed by cross-sex hormones) HHS must make clear that no provider will be required to provide such sterilizing treatments contrary to their religious beliefs or moral convictions. [Bold: G. HHS must apply RFRA to its regulations at the outset.] In proposing this Rule, HHS must analyze its regulatory action under the Religious Freedom Restoration Act (RFRA) and refrain from imposing a substantial burden on religious exercise absent a compelling interest imposed by the least restrictive means. The government does not have a compelling interest in forcing health care providers to end the life of another human being through abortion or assisted suicide or to sterilize adults or minors including through gender transition surgeries and hormones. As the Supreme Court made clear in [Italics: Fulton v. City of Philadelphia], 141 S. Ct. 1868 (2021) the government does not have a compelling interest in enforcing its nondiscrimination policies generally. Rather any interest must reference the specific application of the requirements to those specifically affected. Indeed the Court in [Italics: Fulton], stated: "so long as the government can achieve its

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|Bold and Underline: Notification of Views Regarding Application of Federal Conscience and Religious Freedom Laws (§ 92.302)|NACDS urges caution with respect to OCR's proposal to provide a specific means for recipients to notify the Department of their belief that the application of a specific provision or provisions of this regulation as applied to it would violate federal conscience or religious freedom laws. It seems to us that OCR should refer to a court of competent jurisdiction to make such determinations instead

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National Association of Chain Drug Stores

Bold, F. HHS must recognize application of Section 1303 of the ACA |The Proposed Rule recites Section 1303 of the ACA which contains special rules related to abortion but fails to appreciate or its implications. Under Sec. 1303 nothing in the ACA "shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage funding or procedural requirements on abortions including parental notification or consent or the performance of an abortion on a minor." Footnote 245: 42 U.S.C. § 18023(c)(1) | Thus any suggestion that the Proposed Rule preempts state abortion laws is contrary to law. Further Section 1805 states:Nothing in this Act shall be construed to have any effect on Federal laws regarding (1) conscience protection, (2) willingness or refusal to provide abortion, and (3) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion. [Footnote 246: 42 U.S.C. § 18023(c)(2)(A)] | Thus it would be contrary to law for HHS's regulations to undercut federal conscience protections related to abortion regarding insurance coverage for abortion. States are allowed to opt out of abortion coverage: "A State may elect to prohibit abortion coverage in qualified health plans offered through an Exchange in such State if such State enacts a law to provide for such prohibition." [Footnote 247: 42 U.S.C. § 18054(a)(1).] Further nothing in the ACA requires any qualified health plan to provide coverage of abortion services as part of its essential health benefits for any plan year. Footnote 248: 42 U.S.C. § 18023(b)(1)(A) |

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In the 2016 Proposed Rule the Department acknowledged that its recommended nondiscrimination rule may conflict with religious beliefs. Although the Department said the regulation would not displace the federal Religious Freedom Restoration Act or laws and regulations protecting people from having to perform, pay for, or refer for abortion against their will, it provided no guidance as to how the proposed regulations would be limited if at all by those laws and regulations. Moreover, it proposed no moral or religious accommodations. It is unlikely that a religious exemption even if proposed at some later date would have adequately protected the freedom of conscience of physicians, insurers, employers, health care providers and taxpayers given the breadth of the rule. [Footnote 35: The Department asked for comment "on whether the regulation should include any specific exemptions" and if so, whether any should track the exemption process for certain religious institutions found in Title X regulations. Ibid. 54173. |We anticipate that the new rule will have the same problems. The practical impact of the proposed regulation could spread across the field of health care and to employers and taxpayers generally. |Bold, Physicians | Doctors, gynecologists, psychologists and counselors, among others, could be forced to participate directly in treatments or procedures in violation of their moral or religious beliefs. - |Bold, Hospitals, health clinics, nursing homes, and other health care organizations. The impact on many health care entities would be twofold. Like physicians, they could be forced to participate directly in procedures in violation of their moral or religious beliefs. They would also be forced to pay for coverage of the same procedures in their own employee health plans. [Footnote 36: The proposed regulation listed specific covered entities that would be required to ensure their own employee health benefits program adhere to the proposed nondiscrimination rule. Ibid. 54170 | The proposed regulations could require health care organizations to open their bathrooms, locker rooms, and showers, facilities, to

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[illegible] as "universally accepted," when it is rejected out of hand by biologists and others who view it as an "ideological stance" akin to asserting a religious belief. [Footnote 122: Colin Wright (@SwPeWright) Twitter (March 31, 2021: "The notion that we all have a gender identity is a religious framework. It's not an empirical fact, but rather an ideological stance. I don't have a gender identity. I simply acknowledge that I'm male and express myself according to my own individual personality. I am not 'cis.'" https://twitter.com/SwPeWright/status/1377772254839587658 | Faith-based advocates also contest the use of the term "cisgender" as an offensive repudiation of both science and faith. "There is no need to call women 'cisgender women' says Bill Donahue of the Catholic League. "Nature and nature's God have made it crystal clear that there are only two sexes: man and woman." [Footnote 123: Ian M. Glatt, Catholic League calls out Air Force gender ideology 'friction' for leadership exclusion of 'cisgender' men, The Christian Post (Sept. 29, 2022) https://www.christianpost.com/news/catholic-league-slams-air-force-for-gender-ideology-friction.html.]

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|Bold: D. Requiring third-party health insurance issuers to cover medical interventions that violate conscience and religious rights of employers violates the First Amendment Free Exercise Clause and RFRA. HHS is proposing to regulate third-party insurers to include coverage of gender transition interventions and possibly elective abortions. To the extent that these third-party insurers are regulated, HHS should recognize the conscience and religious rights of those who are required to purchase insurance plans. HHS cannot use a third party to do what it could not do directly. In an ongoing case out of Washington State, the Ninth Circuit held that a church's Free Exercise Clause claim to state law requiring health insurance providers provide plans with abortion coverage created a redressable injury in fact. [Footnote 222: Cedar Park Assembly of God of Kirkland, Washington v. Kreidler, No. 21-35507 (9th Cir. Jul. 22, 2021).] Apart from violating the First Amendment, such a regulation of health insurance providers to compel employers [in an attempted end-run of Italics: Hobby Lobby] would also violate RFRA as there is no compelling government interest in requiring employers with conscience and religious objections to pay for gender transition interventions and abortions and there are many lesser restrictive means for the government to provide and pay for such services without using objecting employers' insurance plans.

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[illegible] health care from a physician I trust and who has my best interests at heart. It is also contrary to scientific evidence and medical facts, making this regulation harmful to those in the medical industry and patients alike. I am a Catholic woman. I am currently pregnant and I am pro-life. I cannot imagine receiving medical care from a physician who does not share this view and specifically have sought out a doctor who is pro-life so they can support me and my baby. This regulation threatens the conscience rights of pro-life doctors who want to make the best decisions for both patients. How will I be able to find medical care that I feel safe with and that is truly supportive of me and my baby if my doctor has to leave the medical industry to preserve their conscience? There is an increasing distrust in establishment in general in our society, hindering the medical establishment. Only 23% of Americans express trust in the medical healthcare system. [Footnote 1: https://www.nejm.org/doi/full/10.1056/NEJMp1407373] Regulations like this would decrease trust in the healthcare system because it would alienate patients from the physicians they want to treat them. Physicians who may suffer a reduction in quality of care as a result of "moral injury" which is described here: "Moral injury can occur in response to a traumatic event, but it can deeply hurt individuals or families who are not related. The resulting distress may lead to PTSD, depression, and other disorders, in which feelings such as guilt, shame, betrayal, and anger are predominant although these feelings may occur in the absence of a formal disorder. Although most research that has been conducted has focused on military veterans, moral injury can occur outside of the military context." |Footnote 2 https://www.ptsd.va.gov/professional/treat/cooccurring/moral_injury.asp| They may also resign because they have strong personal convictions or because other professional opinion that abortion and gender transition are not in the best interest of their patients. There needs to be an extremely firm foundation to

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We first want to express our full agreement with the comments submitted by the U.S. Conference of Catholic Bishops which can be found here:https://www.usccb.org/sites/default/files/about/general-counsel/rulemaking/upload/2022-comments-1557-regulations-final_.pdfHealthcare must serve all be accessible and affordable. However we have serious concerns that as currently drafted the proposed regulations fundamentally disregard life and religious liberty.We strongly disagree with any proposed abortion mandate under Section 1557. It is our sincerely held belief that all life must be safeguarded from conception to natural death. We call on HHS to exercise any requirements to provide perform cover or refer for abortion or any benefit or service related to abortion. We also call on HHS to withdraw any proposed requirements requiring gender transition procedures. Many health care providers especially religious affiliated ones provide healthcare services for all because of their religious and moral views about the dignity and sanctity of human life. The very thought of the Government requiring someone to violate their sincerely held religious beliefs violates the very basis of our religious freedoms enshrined in our Constitution.

In addition to our brief comments we fully support and affirm the more complete and detailed comments submitted by the U.S. Conference of Catholic Bishops which can be found here https://www.usccb.org/sites/default/files/about/general-counsel/rulemaking/upload/2022-comments-1557-regulations-final_.pdf Health care must respect life and dignity be accessible and affordable to all honor conscience rights and be comprehensive and high quality. Unfortunately the proposed regulations go beyond access to care in ways that fundamentally disregard life and liberty. It is especially alarming that HHS appears to be considering imposing an abortion mandate under Section 1557. Interpreting a non-discrimination law to require the taking of innocent life in the womb would be both unprecedented and unlawful. We insist that HHS follow the law and exclude any requirements to provide perform cover or refer for abortion or any benefit or service related to abortion. We also strongly urge HHS to withdraw its proposed requirements on gender transition procedures. Many health providers insurers and plan sponsors especially those with a religious affiliation provide evidence-based health services and coverage because of their religious and moral views about the dignity and sanctity of human life. No one should be required as a condition of practicing medicine or participating in the market for health plans to violate the very religious and moral convictions that prompt them to provide those services or offer those benefits in the first place. Health care workers religious hospitals and other faith-based medical facilities must be free to exercise their best clinical judgment and act in accordance with the conscience

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Pennsylvania Catholic Conference

Virginia Catholic Conference

discrimination and finally applaud HHS efforts to ensure that all persons have access to health care and health care coverage. However we oppose language in the proposed regulations that could require health care providers to perform procedures that are harmful to patients force these providers to act contrary to sound professional judgments and compel them to violate deeply held religious or moral convictions. It is gravely problematic and unjust that the currently proposed Section 1557 regulations could serve to mandate the performance of various harmful gender transition procedures regardless of an objecting health care provider's religious or medical judgment.Additionally the proposed regulations pose risk providing what is in effect an abortion mandate the proposed repeal of the current cross-reference to the abortion neutrality provision of Title IX coupled with the invitation for public comment on whether and how to incorporate the Title IX abortion-neutrality provision raises serious concerns about what these regulations will require with regard to abortion.It would be gravely unjust to impose regulations that fail to uphold the fundamental right to religious liberty and rights of conscience. This right is deeply imbedded in our law and woven into the very fabric of our country and it must be safeguarded. To the extent these regulations would require or coerce health care providers insurers or other stakeholders to violate religious and moral convictions they run counter to foundational principles enshrined in law and must be opposed. At their core these objectionable provisions within the proposed regulations violate human dignity and ultimately serve to harm rather than protect persons including the most vulnerable. We urge the Department to protect religious liberty and rights of conscience and exclude from the regulations any requirement for the provision or coverage of abortion or any related benefit or service. Further language that could be interpreted to mandate the provision or coverage of harmful gender transition procedures or treatments should be

Montana Catholic Conference

We strongly oppose the proposed rule. This rule would endanger the lives and health of vulnerable persons and force health institutions and professionals to violate their religious beliefs. Under this rule it would be considered discrimination for a health care worker or Catholic hospital to object to cooperating in harmful gender transition procedures based on their religious belief or their professional judgment. The proposed rule also fails to protect the right of health care workers and providers not to perform or participate in abortions. It gravely concerns us that HHS is seeking to compel cooperation with inherently harmful procedures. Abortion objectively terminates the life of a vulnerable and innocent human being. Gender transition procedures involve the unjustifiable mutilation of healthy sexual organs or the use of medicine to interfere with the normal functioning of the reproductive and endocrine systems. These procedures are fundamental violations of human dignity and are morally objectionable. The rule's failure to respect the basic right to religious liberty is also deplorable. It goes against the long tradition in American law to guarantee the freedom of conscience from legal coercion. It is particularly disturbing because HHS has repeatedly sought to suppress this right in litigation over abortion and gender transition

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to the 2016 Proposed Rule the Department acknowledged that its recommended nondiscrimination rule may conflict with religious beliefs. Although the Department said the regulation would not displace the federal Religious Freedom Restoration Act or laws and regulations protecting people from having to perform pay for or refer for abortion against their will it provided no guidance as to how the proposed regulations would be limited if at all by those laws and regulations. Moreover it proposed no moral or religious accommodations. It is unlikely that a religious exemption even if proposed at some later date would have adequately protected the freedom of conscience of physicians insurers employers health care providers and taxpayers given the breadth of the rule. [Footnote 35: The Department asked for comment "on whether the regulation should include any specific exemptions" and if so whether any should track the exemption process for certain religious institutions found in Title IX regulations. Ibid. 54173.]We anticipate that the new rule will have the same problems. The practical impact of the proposed regulation could spread across the field of health care and to employers and taxpayers generally: [Ibid: Physicians.] Doctors gynecologists psychologists and counselors among others could be forced to participate directly in treatments or procedures in violation of their moral or religious beliefs. - [Ibid.] Hospitals health clinics nursing homes and other health care organizations. The impact on many health care entities would be twofold. Like physicians they could be forced to participate directly in procedures in violation of their moral or religious beliefs. They would also be forced to pay for coverage of the same procedures in their own employee health plans. [Footnote 36: The proposed regulation listed specific covered entities that would be required to ensure their own employee health benefits program abide by the proposed nondiscrimination policy. Ibid. 54210.] The proposed regulations could require health care organizations to open their bathrooms locker rooms and shower facilities to

New York State Catholic Conference

The Heritage Foundation

honor should concern itself with the well-being of patients and providers. And a basic moral principle is at stake for health care providers: the "central duty to do no harm." Our society has long recognized that medical care involves two parties—the patient and the doctor. Patients should be free to seek treatment, and doctors should be free to exercise their judgment about the right treatment for patients. We are concerned that the proposed rule on Section 1557 will violate this principle. Using it, the State could force doctors to offer treatment they oppose. As noted above, many doctors reasonably believe that to remove healthy organs or to give young people puberty-blocking drugs would harm their patients—whatever the subjective wishes of the patient. Healthy organs are not deadly tumors, and puberty is not a disease. [Italics] Proposed regulations may violate conscience concerning abortion [In addition to the preceding concerns, the proposed regulation may threaten the freedom of conscience of physicians, health care entities and individuals who have religious or moral objections to abortion. For nearly four decades, the federal government has prohibited discrimination against individuals and health care providers who do not wish to pay for, cover, or perform abortions. However, the proposed regulation could prohibit discrimination in health care "on the basis of sex," further defined to include discrimination on the basis of "termination of pregnancy" i.e., abortion. [Footnote 38: Ibid. 84211] In the preamble to the 2016 regulation, the Office for Civil Rights cited existing conscience protections for individuals, physicians and other health care entities. Yet those conscience laws were not explicitly applied in the text of the proposed regulations, and it was unclear how the regulations would have interacted with these existing policies. It was also unclear what "discrimination" based on termination of pregnancy would look like in practice. Would it prevent any differential treatment of a woman who has had an abortion, is seeking one, or both? Would the regulation have prohibited pro-life

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Conscience is clear about this even if federal law has not considered all contexts. The Rule makes it impossible for any faith-based entity or medical provider to operate independently under this Rule without government nurse-over. Section 92.302 of the Rule makes the blatant admission that the Department can grant or overrule rights of conscience or religious belief at its own discretion: "OCR may determine at any time whether a recipient is exempt from the application of certain provisions of this part or whether modified application of the provision is required as applied to specific contexts, procedures or health care services based on a Federal conscience or religious freedom law. "Further, an exemption is available in one case that doesn't provide a shield in other contexts: "If OCR determines that a recipient is exempt from the application of certain provisions of this part or modified application of certain provisions is required as applied to specific contexts, procedures or health care services based on a Federal conscience or religious freedom law that determines or does not otherwise limit the application of any other provisions of this part to the recipient or to other contexts, procedures or health care services." Clearly, this Rule wants the Department to rule not the Constitution or federal laws aimed at protecting our fundamental liberties. There is no doubt that this Rule intends to tie the hands of many health care entities and limit the free practice of providers acting with faith and conscience. The monumental chilling effect of the proposed practice stands in clear violation of this country's First Amendment jurisprudence. Under this rule, health care providers are required to beg on their knees with "mother may I" requests to the Department for permission to be ethical doctors and act according to the dictates of their professional judgments, their conscience and/or their deeply held religious convictions. Government actors should never be allowed to weaponize an ideology of abortion and "gender affirming care" against the moral practice of medicine by any covered entity who objects to

Concerned Women for America

For a comprehensive review of our concerns including amoral orders we would respectfully ask that you take note of comments offered by the United States Conference of Catholic Bishops (USCCB) and our allies at the National Catholic Bioethics Center, the Catholic University of America, the National Association of Catholic Nurses and the Council for Christian Colleges and Universities. Here is a summary of our grave concerns regarding Nondiscrimination in Health Programs and Activities, RIN 0945-AA17. 1. (Bold) The Contraceptive Mandate: (that) requires religious organizations to provide insurance coverage for contraceptives. This is a violation of Catholic religious liberty. 2. (Bold: Section 1557)- This section will force doctors to perform gender transition procedures including surgeries and mandates insurance coverage of them. This is a violation of Catholic religious liberty.

Kansas Catholic Conference

rules published in 87 Fed. Reg. 47824 (Aug. 4, 2022) on Section 1557 of the Affordable Care Act (ACA) (Section 1557) which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. While there are many laudable provisions in the Notice of Proposed Rulemaking (NPRM) such as provisions to increase access to healthcare for Limited English proficient (LEP) persons and to address healthcare disparities for underserved communities, our comments primarily concern two aspects of the proposed rules' inclusion of various sexual orientation and gender identity (SOGI) provisions and its repeal of 45 CFR 92.6(b) which was included in the 2020 rule that amended Title IX regulations to expressly include Title IX's statutory abortion neutrality provision [Footnote 1: "Proposed Rules for "Nondiscrimination in Health Programs and Activities" [to be published Aug. 4, 2022] (to be codified at 42 CFR Parts 438, 440, 457 and 460, 45 CFR Parts 80, 84, 86, 91, 92, 147, 155 and 156) available at https://public-inspection.federalregister.gov/2022-16217.pdf. As currently written, the proposed HHS Section 1557 rule could function as both an abortion mandate and a gender transition procedure mandate. As the nurses we affirm all the comments submitted by the United States Conference of Catholic Bishops (USCCB), the National Association of Catholic Nurses (NACN), the Catholic Medical Association (CMA), the Catholic University of America (CUA), the National Catholic Bioethics Center (NCBC), and the Council for Christian Colleges and Universities (CCCU), including those related to abortion or gender identity, patient privacy and religious freedom. Footnote 4: United States Conference of Catholic Bishops, et al., Letter to Department of Health and Human Services, Office for Civil Rights, on Nondiscrimination in Health Programs and Activities, RIN 0945-AA17 (Sept. 7, 2022), available at

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https://www.usccb.org/sites/default/files/about/general-counsel/-/media/Files/About/General-Counsel/Comments-1557-regulations-Final.pdf. We also

Texas Catholic Conference of Bishops

to access healthcare from "non-religiously affiliated healthcare providers." 87 Fed. Reg. at 47843. Further, HHS is aware that healthcare consumers do not know that their healthcare providers may limit care due to their religious affiliation. Id. at 47840–41. This problem is exacerbated by the ever-increasing rate of consolidation in the U.S. healthcare industry with the ten largest Catholic health systems having grown more than fifty percent in the last twenty years. "Footnote 49: See Tara Solomon, et al., Bigger and Bigger: The Growth of Catholic Health Systems, at 3 (2020) https://www.communitycatalyst.org/resources/publications/document/2020-Cath-Hosp-Report-2020-31.pdf. | Today, one in every six hospital beds is in a Catholic facility. "Footnote 50: Id. at 4.] These and other religiously affiliated hospitals operate under the protection of federal conscience and religious objection laws that permit them to prohibit the provision of key reproductive health services, including contraception, sterilization, abortion, and fertility services. "Footnote 51: See, e.g., U.S. Conference of Catholic Bishops, Ethical and Religious Directives for Catholic Health Care Services 16–19 (Nov. 2018) https://www.usccb.org/about/doctrine/ethical-and-religious-directives/upload/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06.pdf." But providing information regarding these services is different from providing or directly referring for the services themselves. The Proposed Rule could ensure that patients in these covered entities are fully informed of their health status and medical choices and that physicians cannot discriminatorily withhold information on [Footnote 52: These principles of informed consent are also reflected in federal conditions of funding which require healthcare providers to meet certain health and safety standards. CMS Conditions of Participation are qualifications that healthcare organizations must meet in order to begin and continue participating in federally funded healthcare programs such as Medicare

Attorneys General of California, New York, Massachusetts, and nineteen other States

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97 6(b) a provision in the 2023 Rule that expressly included Title IX's statutory abortion-neutrality provision [Footnote 19: See 45 CFR 86.1(b)]. That provision does not require or prohibit any person or public or private entity to provide or pay for "any benefit or service including the use of facilities related to an abortion." The Department says it believes it could be beneficial to include a provision specifically prohibiting discrimination on the basis of pregnancy-related conditions as a form of sex-based discrimination. However, the Department's definition would encompass "termination of pregnancy" (i.e. abortion). For example, where the Department notes various statutory provisions related to conscience rights in the abortion context, they note that in some emergency situations an abortion may be considered "stabilizing treatment" under Emergency Medical Treatment and Active Labor [EMTALA]. "[N]otwithstanding any directly conflicting state laws or mandates that might otherwise prohibit or prevent such treatment." [emphasis added]" First we dispute the premise that abortion [i.e. intentionally targeting unborn life for termination as opposed to other therapeutic interventions] is ever medically necessary [Footnote 20: See e.g. John A. DiCamillo and Jozef D. Zaloudek Medical Interventions During Pregnancy In Light of Dobbs Not" Catholic Bioethics Center on Health Care and the Life Sciences Vol. 47 No. 8 [Aug. 2022] available at https://static1.squarespace.com/static/5e5aaa1a1a2e8e6a1a1d1dcd/t/6a2ffda74 62c1dh0164bfbh2c/1660933798095/F%26M_August_22_unsane.pdf. Amicus Brief of the Catholic Health Care Leadership Alliance [CHCLA] et al. in State of Texas v. Becerra Case 5:22-cv-00185-H [N.D. Texas 2022] at 10 available at https://static1.squarespace.com/static/5e5aaa1a1a2e8e6a1a1d1dcd/t/6a0d8db7 eb5d76e83d95e072e1/1778152455062/D Ex70+ +Am cheBriefofCHLA+Final.pdf ["Defendants" have created unnecessary confusion given the fact that everyone agrees that "medical treatments to save the life of the mother that unintentionally

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Texas Catholic Conference of Bishops

We are concerned that the proposed regulation will have serious effects on the practice of medicine freedom of conscience and choice in health care coverage. The 2016 Rule appeared to operate on the presumption that the question of gender reassignment surgery is settled when respective physicians and researchers believe it is not the proper treatment for gender dysphoria. Whether or not one agrees with Dr. McHugh and other medical professionals' concerns about such procedures they should retain the freedom to practice medicine according to their best judgments without governmental penalty.

The Heritage Foundation

[Bold: D. Requiring third party health insurance issuers to cover medical interventions that violate conscience and religious rights of employers violates the First Amendment Free Exercise Clause and RFRA.] HHS is proposing to regulate third party insurers to include coverage of gender transition interventions and possibly elective abortions. To the extent that these third-party insurers are regulated HHS should recognize the conscience and religious rights of those who are required to purchase insurance plans. HHS cannot use a third party to do what it could not do directly. In an ongoing case out of Washington State the Ninth Circuit held that a church's Free Exercise Clause claim to state law requiring health insurance providers provide plans with abortion coverage created a redressable injury in fact. [Footnote 22: Cedar Park Assembly of God of Kirkland Washington v. Kreidler No. 20-35502 [9th Cir. Jul. 22 2021].] Apart from violating the First Amendment such a regulation of health insurance providers to compel employers [in an attempted end-run of [Italics: Hobby Lobby]] would also violate RFRA as there is no compelling government interest in requiring employers with conscience and religious objections to pay for gender transition interventions and abortions and there are many lesser restrictive means for the government to provide and pay for such services without using subjecting employers' insurance plans.

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No comments are associated with this issue.

Comments associated with this issue are recorded in the subsections below.

[Bold: Enforcement mechanisms.] HHS supports strong enforcement of Section 1557 and welcome HHS' recognition in the preamble that the law protects people who experience intersectional discrimination. HHS must therefore make explicit at § 92.301 and throughout implementing regulations that Section 1557 creates a health-specific anti-discrimination cause of action that is subject to a singular standard regardless of a plaintiff's protective identity or identities. Ensuring strong enforcement and clear mechanisms for intersectional discrimination in this way would also enable a person to state a claim under Section 1557 on a disparate impact theory for discrimination based on race. This approach is necessary to avoid inconsistent application of Section 1557 and to ensure Section 1557 provides adequate redress for those living at the intersection of multiple identities.

Physicians for Reproductive Health

[Bold: Enforcement mechanisms.] We support strong enforcement of Section 1557 and welcome OCR's recognition that the law protects people who experience intersectional discrimination. This can include individuals who are LEP and also face discrimination due to their race/ethnicity age sex and/or disability. We support clear accessible procedures for filing investigating and remediating discrimination complaints.

Farmworker Justice

To further address disparities in access to quality care we encourage the incorporation of an enforceable standard for covered entities that would ensure that accessible medical diagnostic equipment is widely available.

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U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

The Final Rule Must Ensure Robust Enforcement of Section 1557 To address inequity in health care in America Section 1557 needs to be enforced plain and simple. We are therefore pleased the Proposed Rule provides concrete and nuanced enforcement of these critical civil rights provisions consistent with existing law and the clear and unambiguous intent of Section 1557.

Alliance of Multicultural Physicians

The proposed rule is critical to our very existence. We must not be denied the health care we need because of discrimination based on our gender identity and/or sexual orientation. The rule will make it easier for us to access the care we need and will help protect us from discrimination not only in our medical providers' offices but also from our insurers. Additionally it recognizes our right to gender affirming care. By directing the Office for Civil Rights to enforce nondiscrimination protections based on gender identity and sexual orientation it will serve as a deterrent and a means for recourse from healthcare discrimination targeting us.

Sam & Devereux Foundation for Transgender Youth

However we are deeply concerned with the [minor] proposed requirement that providers including physicians must write and implement Section 1557–specific policies and procedures identify a Section 1557 Compliance Coordinator and train their employees on these new standards.Physicians' offices are overwhelmed by administrative tasks that stem from a multitude of federal regulations and requirements including ongoing quality reporting utilization management and medical review/audits. Indeed many allergy/immunology [A/I] practices are small and have limited administrative and clinical staff that can be diverted from patient care activities to manage yet another compliance program. Considering the year over year reductions in payments to Medicare physicians coupled with high inflation and extreme workforce challenges we are frustrated that the Department is proposing this unfunded mandate on physician offices. And while we support the intent of this new policy our practices simply lack the financial and staffing resources to properly comply should the Department proceed with finalizing this proposal HHS must develop template Section 1557 policies and procedures and compliance guidance that physician offices can easily incorporate into their existing compliance manuals. HHS should also develop educational materials that assist practices with training activities and with testing staff understanding of the policies. HHS should develop patient notices and other patient education materials for practices. These resources should be downloadable from the HHS website and made available free-of-charge.

American Academy of Allergy Asthma and Immunology [AAAAI]

Importantly any enforcement action resulting from a Section 1557 complaint should start with enhanced education and the provision of technical assistance so providers can come into compliance without sanctions or penalties.

reinstatement of this section and appreciate the clear language in the preamble confirming that enforcement mechanisms include a private right of action. We encourage HHS to also include clear language about the private right of action in the text of the rule. We recommend further strengthening Section 1557's proposed enforcement procedures by explicitly recognizing the existence of intersectional discrimination and its comport with the statutory language of Section 1557.

"While the statute incorporates separate existing civil rights laws, it does so collectively in a single provision that recognizes the possibility that someone – say a Black LGBTQ woman with a disability – could face discrimination based on race, sex and disability." [Footnote 17: Jamille Fields, Asbrook & Katie Keith, ALA Section 1557 As A Tool For Anti-Racist Health Care, HEALTH AFF. (Dec. 8 2021), https://www.healthaffairs.org/do/10.1377/forefront.20211207.962085/.] We also recommend regarding HHS's authority to find noncompliance with Section 1557 where a covered entity and not only health programs and activities conducted by recipients and State Exchanges fails to comply with OCR's information requests in a timely, complete and accurate manner. Data collection, whether required through a specific provision in the final 1557 rule or through HHS's existing authorities or both, will be an increasingly important component of civil rights enforcement under the final rule. HHS must have the authority to require full, timely and ongoing access to the granular data compiled by covered entities as part of their compliance obligations under the final rule. We would urge HHS to explicitly include guidance noting that the statutory language of Section 1557 permits plaintiffs to use any enforcement mechanism "available under" the statute and that as may assert disparate impact claims under Section 1557. This clarification is especially timely because the district court in [Italics] Rumble v. Fairview Health Services[] determined that Congress intended to create a new cause of action independent of the enforcement mechanisms for the statutes [Bold]. III. The Final Rule Must Ensure Robust Enforcement of Section 1557. Considering the enormity of discriminatory conduct in health care, Section 1557 requires rigorous enforcement in order to ensure marginalized groups can access quality health care. We are therefore pleased the proposed rule provides for robust enforcement of these critical civil rights provisions consistent with existing law and the clear unambiguous intent of Section 1557. Clarifications can be made in the final rule to ensure that even stronger enforcement mechanisms and remedies are available to patients. [Bold] A. The proposed rule must be clarified to ensure the availability of strong enforcement mechanisms and remedies[] We support strong enforcement of Section 1557 and welcome the department's recognition that the law protects people who experience intersectional discrimination. To that end we suggest that the department include explicit references to intersectional discrimination throughout implementing regulations including Section 92.301. Section 92.301 must ensure that HHS will have clear and accessible procedures for individuals to file and the agency to investigate and remediate discrimination complaints including intersectional discrimination complaints. The department must make explicit throughout implementing regulations that Section 1557 creates a health-specific anti-discrimination cause of action that is subject to a single standard regardless of a plaintiff's protected class or classes.

We further request that the Department postpone any enforcement action associated with Section 1557 until after the Department has provided these educational resources and technical assistance to allow rheumatology practices to come into compliance without penalty.]

We also support strong enforcement of Section 1557 and the Department's recognition in the preamble that the law protects people who experience intersectional discrimination. This encompasses individuals who experience health care discrimination at the intersection of two or more protected characteristics (for example some combination of sexism (e.g. people who are pregnant or capable of pregnancy or LGBTQ+) racism xenophobia (e.g. people with limited English proficiency (LEP)) ableism or age-ism. We urge the Department to provide greater clarity in the final rule regarding the protections and enforcement mechanisms available for intersectional discrimination under Section 1557. For example the Department should amend the proposed regulatory text at § 92.101(a)(1) to clarify that intersectional discrimination is prohibited. Specifically we recommend this provision to be amended as follows: [a] Table. General. [1] Except as provided in Title I of the ACA an individual must not on the basis of race color national origin sex age disability or any combination thereof be excluded from participation in be denied the benefits of or otherwise be subjected to discrimination under any health program or activity operated by a covered entity. In addition §92.301 should ensure that the Department will have clear and accessible procedures for individuals to file and the agency to investigate and remediate discrimination complaints including intersectional discrimination complaints. The Department should also make clear throughout the final rule that Section 1557 creates a health-specific anti-discrimination cause of action that is subject to a single standard regardless of a plaintiff's protected class or classes.

AHMA further requests that HHS postpone any enforcement action associated with Section 1557 until after the HHS has provided these educational resources and technical assistance to allow pediatric physician practices to come into compliance without penalty.

Procedures and Enforcement: As a general principle we encourage HHS to create procedures and enforcement mechanisms that are clear easily accessible and recognize the intersectionality of people's lived experiences. In the context of older adults this includes acknowledging the ways in which the effects of systemic discrimination compound over the lifecycle. HHS can achieve this by explicitly recognizing intersectional discrimination in the regulatory language, providing for waiver of the Age Discrimination Act's administrative exhaustion requirement for intersectional claims that include age; applying Title VI procedural provisions for administrative enforcement of intersectional claims including age; recognizing disparate impact, instituting a mandatory deadline for OCR to respond to administrative complaints, and pairing enforcement with robust outreach and education.

We support clear accessible procedures for filing investigating and remediating discrimination complaints including intersectional claims. Our recommendations that follow are to further clarify and strengthen the ability for older adults to seek redress for discrimination.

[Italics] Private Right of Action[]We appreciate HHS's acknowledgement of a private right of action under Sec. 1557 in the preamble discussion of the enforcement mechanisms. [Footnote 56: 87 Fed. Reg. at 47885.] Enforcement Mechanisms [§ 92.301(a)] (Citing Cummings v. Premier Rehab Keller, P.L.L.C., 142 S. Ct. 1562, 1569-70 (2022)) "It is beyond dispute that private individuals may sue to enforce [Section 504 and Section 1557]" of the ACA)." However we urge HHS to state this clearly and unambiguously in the rule itself as it did in the 2016 rule. Clarifying the right to bring a civil action in the rule will advance enforcement of Sec. 1557 by informing protected individuals that they can enforce their rights under this statute themselves in court and are not limited to administrative remedies. Specifically we recommend amending § 92.301 to include language similar to what was in the 2016 rule: "An individual or entity may bring a civil action to challenge a violation of Section 1557 or this part in a United States District Court, as well as the covered entity is found or transacts business." Sec. 1557 provides that the "Secretary [of HHS] may promulgate regulations to implement this section." [Footnote 58: 42 U.S.C. § 18116(c).] We urge HHS to assert its authority and direct or to explicitly recognize a cause of action that is intersectional and allow enforcement mechanisms available under any of the underlying statutes. [Bold] Specifically we recommend adding regulatory language to § 92.301 that provides for a private right of action without administrative exhaust or for intersectional claims including those involving age discrimination.

(b)(5)

National Disability Rights Network

(b)(5)

The Leadership Conference on Civil and Human Rights

Coalition of State Rheumatology Organizations (CSRO)

Center for Reproductive Rights

American Podiatric Medical Association

(b)(5)

Justice in Aging

(b)(5)

Justice in Aging

Justice in Aging

Justice in Aging

(b)(5)

Applying the Age Act procedures to all claims involving age discrimination puts older adults at a disadvantage because the Age Act procedures require a claimant to exhaust administrative remedies before they may file a civil action. [Footnote 59: 45 C.F.R. § 91.50(a).] The administrative exhaustion requirement imposes significant hurdles on an individual's ability to seek recourse for discrimination based on age. They must file an administrative complaint within 180 days of the event, compared to 60 days to lose the right to relief. [Footnote 60: 45 C.F.R. § 91.42(a).] To be legally sufficient, they must report facts in the complaint that can be difficult to ascertain. [Footnote 61: 45 C.F.R. 91.42(b).] And then they must wait 180 days for HHS to investigate before they can proceed with a claim in court. [Footnote 62: 45 C.F.R. § 91.50(a).] No other cause of action under Section 1557 imposes such a requirement. Title VI procedures do not. [Footnote 63: 28 C.F.R. § 42.101 et seq. (providing Title VI administrative procedures without any exhaustion requirement).] Lack of consistency in administrative procedural requirements will only undermine enforcement of intersectional claims and thwart the statute's intent to fight discrimination in healthcare. For example an older adult who experiences transphobia, racism and ageism should not be forced to either forgo their age claim or proceed through onerous administrative exhaustion to seek a remedy in court for the intersectional discrimination they experienced.

(b)(5)

Justice in Aging

reorganization that the law protects people who experience intersectional discrimination. The very purpose of § 1557 is to address long-standing discrimination in health care that has created numerous barriers to quality care for communities of color, people with disabilities, the LGBTQI+ community, and more but especially those who sit at the intersections of these identities. Unfortunately, some organizations use religious objections as a pretext to discriminate against sexual and reproductive health care and gender affirming care. [Footnote 15: Emily Hamilton and Maggie Siddiqi, Religious Liberty Should Do No Harm, American Progress (April 22, 2019), https://www.americanprogress.org/article/religious-liberty-no-harm/.] While such beliefs may be genuine among those who possess them, religious orthodoxy must not decide individuals' right to access health care or coverage simply because they are part of an unfavored group. In Massachusetts, the Boston area has the greatest concentration of providers who deliver gender affirming care, so access is relatively good compared to other areas of the state. Still, providers affiliated with religious groups dominate the local health care markets in some parts of the Boston area as well as in some other areas of the Commonwealth. While some patients in Massachusetts and beyond may be able to switch to a provider that does discriminate based on religious beliefs, this is not an option for all affected people in all health care markets, particularly those living in rural areas with fewer available health care options. Even those who have access to other providers may experience severe consequences due to delayed care and the mental anguish provoked by facing denials of needed medical services. We support HHS's proposed approach of evaluating religious exemptions on a case-by-case basis while considering the effects on third parties such as patients. The Religious Freedom Restoration Act states that "governments should not substantially burden religious exercise without compelling justification."

Private Right of Action: The NHC supports the inclusion of a private right of action under Section 1557. Without this important tool, patients that are discriminated against are left without appropriate recourse. A private right of action will allow patients to receive redress for facing discrimination and hold those who discriminate responsible.

Health Care For All

[Bold, Intersectional Claims that Involve Age Should Be Allowed to Proceed without Administrative Exhaustion]We appreciate HHS's recognition in the preamble of the unique and compounding harms intersectional discrimination causes older adults and others. We support clear, accessible procedures for filing, investigating, and remediating discrimination complaints, including intersectional claims. As Sec. 1557's own statute enforceable by private right of action, in the courts an older adult who is discriminated against based on age (Black) and race, national origin, sex, and/or disability should not be at a disadvantage for seeking recourse due to the Age Act's administrative exhaustion requirements. Therefore, we recommend that HHS revise regulatory language in the final rule that clarifies that administrative exhaustion is [italics: not] required to bring an intersectional claim including age under Sec. 1557. We urge HHS to identify other ways to address intersectional discrimination. The regulatory provisions of the rule itself including making an explicit reference to intersectional discrimination in the regulatory text of Sec. 92.101. Many older Black and Latina adults fear that age bias combined with other biases such as race and gender lead providers to dismiss their concerns and fail to provide the treatment the adults deserve. [Footnote 6: How Discrimination in Health Care Affects Older Americans, and What Health Systems and Providers Can Do, The Commonwealth Fund, https://www.commonwealthfund.org/publications/issue-briefs/2022/jan/how-discrimination-in-health-care-affects-older-americans (2022).] These negative experiences cause distrust, thus affecting the quality of life because adults no longer feel comfortable seeing a provider. [Footnote 7: Id.]

National Health Council

The Proposed Rule must ensure stronger private enforcement of Section 1557 and allow separate impact claims to be brought. Scholars note that "private parties play a more important role in enforcing regulatory law in the U.S. legal system than in other advanced economies," and that private parties "bring significant additional resources to the task of enforcing public law . . . [as] state and federal agencies are chronically under-resourced and overworked." Indeed, since Fiscal Year 2016, civil rights case receipts have increased by 252 percent, leaving the Department's Office for Civil Rights with a backlog of complaints. We therefore offer strong support for the Proposed Rule's clarification that a private right of action exists for claims of discrimination under Section 1557, as judicial enforcement is necessary to protect patients and other beneficiaries from discriminatory conduct. We're concerned however that the Proposed Rule suggests private litigants are unable to bring disparate impact claims in court. Race and similar bias in healthcare may not manifest as "no colored signs" or doctors who openly refuse to treat patients of color. Without a disparate impact theory of liability, a private right of action will ring hollow for people of color and other systemically marginalized groups. The Department must therefore make explicit in regulation that Section 1557 creates a "health-specific anti-discrimination cause of action that is subject to a singular standard regardless of a plaintiff's protected class status." This would enable a person to state a claim under Section 1557 on a disparate impact theory for discrimination based on race. This approach is necessary to avoid inconsistent application of Section 1557 and to ensure Section 1557 provides adequate redress for those living at the intersection of multiple identities.

Center for Elder Law & Justice

(b)(5)

IDEA is strongly supports OCR's interpretation that a private right of action exists for all claims of discrimination under Section 1557. Either "private parties play a more important role in enforcing regulatory law in the U.S. legal system than in other advanced economies" and "bring significant additional resources to the task of enforcing public law . . . [as] state and federal agencies are chronically under-resourced and overworked." [Footnote 51: Michael Sant'Ambrogio, Private Enforcement in Administrative Courts, 72 Vanderbilt L. Rev. 423 (2019), https://scholarship.law.vanderbilt.edu/vlr/vol72/iss2/2.] Private enforcement of Section 1557 is crucial because the federal government has limited capacity to address health care discrimination claims as demonstrated by the backlog of cases currently before OCR. [Footnote 52: U.S. DEP'T OF HEALTH & HUMAN SERVS. HHS FY 2023 BUDGET IN BRIEF (2022), https://www.hhs.gov/about/budget/fy2023/index.html.] Judicial enforcement by private individuals will help protect patients and other beneficiaries from discriminatory conduct.

Alliance of Multicultural Physicians

(b)(5)

NAACP Legal Defense and Education Fund, Inc.

rights norms and obligations.A. International human rights law prohibits discrimination on the basis of sex, including discrimination based on termination of pregnancy, sexual orientation and gender identity.[We support the Administration's efforts to advance access to nondiscriminatory health care which will bring U.S. policy closer into compliance with international human rights law. Human rights are based on the principles of universality and non-discrimination as set forth in the Universal Declaration of Human Rights [UDHR] "[A] human beings are born free and equal in dignity and rights." [Footnote 80: Universal Declaration of Human Rights, adopted Dec. 10, 1948, art. 1, 2, G.A. Res. 217A (III), U.N. Doc. A/810, at 71 (1948).] Equality and non-discrimination are core principles of international human rights law and non-discrimination is a crucial obligation for all core human rights treaties including the International Covenant on Civil and Political Rights [ICCPR] [Footnote 81: International Covenant on Civil and Political Rights, adopted Dec. 16, 1966, art. 2, 2, G.A. Res. 2200A (XX), U.N. GAOR, 21st Sess., Supp. No. 16, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171, entered into force Mar. 23, 1976.] [hereinafter ICCPR] Article 26 of the ICCPR establishes equality before the law and forbids discrimination "on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status." This list is deliberately not exhaustive and the Human Rights Committee and other bodies have affirmed that "other status" encompasses sexual orientation and gender identity. [United Nations High Commissioner for Human Rights, Discriminatory Laws and Practices and Acts of Violence Against Individuals Based on Their Sexual Orientation and Gender Identity, para. 7, U.N. Doc. A/HRC/19/41 (Nov. 17, 2011).] [hereinafter UNHCHR Discriminatory Laws and Practices] [which the United States ratified in 1992 [Footnote 82: OHCHR Status of Ratification Interactive Dashboard, http://indicators.ohchr.org/ (last visited Sept. 30, 2022).] and the Covenant on [Bold: IX. The proposed rule is correct to restore a private right of action and recognize intersectional discrimination but more can be done to clarify that intersectional discrimination is prohibited.][We agree with the Department's decision to restore an individual's private right of action to enforce Section 1557. A private right of action is essential to ensuring that individuals who experience discrimination on the basis of sex in health care are not solely reliant on the Department to enforce the law and may be entitled to compensation for the harm they experienced.

No comments are associated with this issue.

We support the proposal in § 92.303(a) to apply Title VI procedural provisions with respect to administrative enforcement actions except those based exclusively on age. However for proposed § 92.303(b) we request that HHS clarify that for administrative enforcement it will treat intersectional claims involving age and other protected identities under the same procedural provisions as Title VI. One ongoing deterrent to filing administrative complaints with OCR is the lack of a mandatory response deadline from the Department in Title VI procedures. [Bold: We ask HHS to consider implementing a 90-day deadline for OCR to resolve complaints and a 120 day deadline for more involved complaints under Sec. 1557.] The lack of a response deadline deters victims of discrimination who may try to find other solutions or workarounds outside of administrative enforcement. While this may work in some situations it does not usually resolve underlying issues between a covered entity and an individual or group of patients. For example an LGBTQI+ older adult who has been discriminated against by their provider may be no one to find another provider or forgo the service as opposed to filing a complaint and waiting for OCR to formally investigate. Providing a deadline empowers individuals by properly setting expectations. Although some may find 90 or 120 days too long to address real time harm we believe this is an appropriate balance between promptly and efficiently resolving complaints while addressing administrative burden and resources of potentially complex investigations.

Procedures for health programs and activities administered by the Department [§ 92.304] We agree with the proposed approach to apply Sec. 504 procedures. We strongly encourage HHS and OCR specifically to be as proactive as possible in enforcing these regulations with respect to its own programs. Several examples of discriminatory policies we have provided in this comment are about Medicare and other programs administered by HHS and we urge HHS to address those without delay.

Comments associated with this issue are included in the subsections below.

AAMA also supports the clarification that "federal financial assistance" extends to Medicare Part B providers such as physicians and other outpatient providers and that 1557 nondiscrimination prohibitions shall apply.

In addition we strongly support the Department's reinterpretation of "federal financial assistance" such that its nondiscrimination prohibitions would extend to Medicare Part B providers such as physicians and other outpatient providers. We further support extending the nondiscrimination prohibition to Medicare Part B providers such as physicians and other outpatient providers.

The direct attention to nondiscrimination on the basis of sex limited English proficient (LEP) individuals and people with disabilities and the clarification of the specific measures that are anticipated to comply with Section 1557 are welcome. Specifically we support the major clarifications in the rule. • The interpretation of Section 1557 to cover all health programs and activities administered by HHS. • The interpretation that provision of Medicare Part B assistance is federal financial assistance and that entities receiving Medicare Part B funds must comply with the Rule. • The application to health insurance issuers that receive federal financial assistance. • The clarification that the protections against discrimination on the basis of sex as including sexual orientation or and gender identity and discrimination on the basis of sex stereotypes and the extension of these protections to CMS regulations. • The expectation that compliance will require implementing programs to develop maintain and communicate clear policies and train on the provision of language assistance services for limited English proficient (LEP) individuals and effective communication and reasonable modifications to policies and procedures for people with disabilities. • The requirement that implementing entities provide notice of the availability of language assistance services and auxiliary aids and services in English and at least the 15 most common languages spoken by LEP persons of the relevant state or states. • The expectation of nondiscrimination based on clinical algorithms. • The expectation that nondiscrimination extends to telehealth services and. • The development of clear processes for requesting exceptions from the expectation of compliance.

[Bold and Italics: Medicare Specific Interpretations and Centers for Medicare & Medicaid Services (CMS) Amendments]The AAMC supports Department proposals to promote consistency across HHS programs regarding policies and requirements that prohibit discrimination including proposals for CMS to amend regulations to apply these protections in all its programs including fee for service and managed care programs.

Underlined: Medicare Part B] CalHHS agrees with extending Section 1557 protections via the definition of federal financial assistance to the receipt of Medicare Part B to align with treatment of Medicare Part A.

Change in this provision - specifically Part B meets the definition of Federal Financial Assistance (FFA)We strongly support the revised definition of Federal Financial Assistance (FFA) that at long last include payments made under Medicare Part B. The relationship between Part B providers and HHS is not distinguishable from that of other providers who are already treated as recipients of FFA. The exclusion of Part B has historically been based on flawed reasoning, furthermore this exclusion is rooted in a history of racism as it developed as a way for some medical providers to exclude Black patients and other patients of color from their practices. As such bringing Part B within the ambit of FFA and Section 1557 not only addresses this racist history but also furthers the core goal of the ACA to broaden and to strengthen civil rights protections in the healthcare

(b)(5)

(b)(5)

Center for Reproductive Rights

Center for Reproductive Rights

Justice in Aging

Justice in Aging

American Podiatric Medical Association

Coalition of State Rheumatology Organizations (CSRO)

American Academy of Allergy, Asthma and Immunology (AAAAI)

(b)(5)

(b)(5)

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Association of American Medical Colleges (AAMC)

California Department of Health Care Services

Equitas Health

We also commend the Department's important clarification that Section 1557 applies to Medicare Part B. For decades the Department made the mistake of determining that Medicare Part B payments were not "federal financial assistance." As noted in one article "[a]s a result a hospital could pass Title VI certification and through the racially exclusionary admission practices of its medical staff remain segregated." Moreover many patients have been unable to sue their doctors for discrimination on the basis of race color or national origin under Title VI. The Proposed Rule addresses this problem by applying a reasonable interpretation of "federal financial assistance" and clarifying that Medicare Part B providers are covered entities under Section 1557 A. of these clarifications in the Proposed Rule are an important step in addressing racism and other forms of discrimination in all health care settings by ensuring the Department has broad enforcement authority

(b)(5)

Alliance of Multicultural Dentists

|Other Provisions|Change in Interpretation - Medicare Part B Meets the Definition of Federal Financial Assistance|We strongly support the revised definition of Federal Financial Assistance (FFA) that at long last include payments made under Medicare Part B. The relationship between Part B providers and HHS is not distinguishable from that of other providers who are already treated as recipients of FFA. The exclusion of Part B has historically been based on flawed reasoning and has roots in racism as it came about at least in part to respond to the desires of some physicians to exclude Black patients from their practices. Bringing Part B within the ambit of FFA and 1557 not only addresses this problematic history but also furthers the core goal of the ACA to broaden and strengthen civil rights protections in health care

Citizens

The impasse the courts and experts within HHS created in 1557 protections for additional provider types. The 2020 rule held that Medicare Part B payments are not federal financial assistance and the proposed rule by the Biden administration would change this interpretation to hold that Medicare Part B payments do constitute federal financial assistance. [Footnote 11: Centers for Medicare and Medicaid Services "Nondiscrimination in Health and Health Education Programs or Activities Delegation of Authority" Federal Register June 19 2020 https://www.federalregister.gov/documents/2020/06/19/2020-11758/nondiscrimination-in-health-and-health-education-programs-or-activities-delegation-of-authority]. As the rule points out this is in line with other Medicare payments being considered financial assistance. Medicare Part A payments for example have been considered federal financial assistance under every set of regulations for section 1557 [Footnote 12: Keith "Revised ACA Anti-Discrimination Rule"].

The Century Foundation

payments to health care providers and entities are federal financial assistance for the purposes of civil rights enforcement [Footnote 3: Id. at 47887 47912 |Proposed § 92.4); Katie Keith "HHS Proposed Revised ACA Anti-discrimination Rule" HEALTH AFFAIRS (Jul. 27 2022) https://www.healthaffairs.org/content/forefront/hhs-proposes-revised-aca-anti-discrimination-rule]. In practical effect this clarification will ensure a single standard across Medicare providers that will reduce confusion and ensure that the nearly 65 million older adults and people with disabilities covered by the Medicare program have the same protections regardless of whether they receive care in a hospital outpatient hospital or physician's office [Footnote 4: CMS May 2022 Medicaid and CHIP Enrollment Trends Snapshot https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/may-2022-medicaid-chip-enrollment-trend-snapshot.pdf, ASPE Office of Health Policy Issue Brief: Medicare Beneficiary Enrollment Trends and Demographic Characteristics Mar. 2 2022 https://aspe.hhs.gov/sites/default/files/documents/f81a4fbba0b331c71b6e8bc6b512e25d/medicare-beneficiary-enrollment-ib.pdf]. These changes will be particularly important for ensuring access to care and language assistance services for the estimated 14 percent of Medicare beneficiaries with disabilities and eight percent of Medicare beneficiaries who have limited English proficiency (LEP) |Footnote 5: ASPE Office of Health Policy at 7] |Footnote 6: CMS: Understanding Communication and Language Needs of Medicare Beneficiaries (Apr. 2017) https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Issue-Briefs-Understanding-Communication-and-Language-Needs-of-Medicare-Beneficiaries.pdf|

Senate Democrats

|Body: Change in Interpretation - Medicare Part B Meets the Definition of Federal Financial Assistance" We strongly support the revised definition of Federal Financial Assistance (FFA) that at long last include payments made under Medicare Part B. The relationship between Part B providers and HHS is not distinguishable from that of other providers who are already treated as recipients of FFA. The exclusion of Part B has historically been based on flawed reasoning and has roots in racism as it came about at least in part to respond to the desires of some physicians to exclude Black patients from their practices. Bringing Part B within the ambit of FFA and 1557 not only addresses this problematic history but also furthers the core goal of the ACA to broaden and strengthen civil rights protections in health care

(b)(5)

|Body: Change in Interpretation - Medicare Part B Meets the Definition of Federal Financial Assistance" We strongly support HHS's decision to revisit the interpretation that Medicare Part B meets the definition of Federal Financial Assistance. We believe the statutory text of 1557 specifically does include Part B providers and are glad that the Department has revisited and updated this definition.

SIECUS: Sex Ed for Social Change

|Body: V. The proposed rule makes the vital clarification that Section 1557 applies to Medicare Part B. In keeping with the statutory intent of Section 1557 and better interpretation of the law |We strongly support OCR's proposal to treat Medicare Part B payments as federal financial assistance and Part B providers and suppliers as recipients under Section 1557 Title VI Title IX Section 504 and the Age Act. This change in interpretation is well supported by how the Part B program has evolved the fact that most Part B providers are already receiving other forms of federal financial assistance as well as the clear intent of the Section 1557 statute to ensure nondiscriminatory access to health care. This change will also eliminate confusion for older adults and people with disabilities and help ensure that people with Medicare have the same protections and rights regardless of the Medicare servicer they choose the Medicare covered service they are receiving or whether they are in Original Medicare or Medicare Advantage. Ensuring that all Medicare providers are subject to this rule will also help increase access to quality health care for underserved communities who face the most discrimination and barriers as many Medicare providers also serve people with other forms of insurance. These patients will benefit from the providers' compliance with Section 1557

National Disability Rights Network

Change in Interpretation - Medicare Part B Meets the Definition of Federal Financial Assistance" We strongly support the revised definition of Federal Financial Assistance (FFA) that at long last include payments made under Medicare Part B. The relationship between Part B providers and HHS is not distinguishable from that of other providers who are already treated as recipients of FFA. The exclusion of Part B has historically been based on flawed reasoning and has roots in racism as it came about at least in part to respond to the desires of some physicians to exclude Black patients from their practices. Bringing Part B within the ambit of FFA and 1557 not only addresses this problematic history but also furthers the core goal of the ACA to broaden and strengthen civil rights protections in health care

Center for Reproductive Rights

Eating Disorders Coalition for Research, Policy & Action

We also commend the department's clarification that Section 1557 applies to Medicare Part B. [Footnote 15: Fed Reg. at 47887-90.]. For decades the department erred in determining that Medicare Part B payments were not "federal financial assistance." As noted in one article "[a]s a result a hospital could pass Title VI certification and through the racially exclusionary admission practices of its medical staff remain segregated." [Footnote 16: Smith David B. "The Golden Rules for Eliminating Disparities Title VI Medicare and the Implementation of the Affordable Care Act." Health Matrix: The Journal of Law Medicine vol. 25 no. 1 2015 pp. 33-59. https://scholarlycommons.law.case.edu/healthmatrix/vol25/iss1/4] Moreover many patients have been unable to sue their health care providers for discrimination on the basis of race color or national origin under Title VI. The proposed rule addresses this problem by applying a reasonable interpretation of "federal financial assistance" and clarifying that Medicare Part B providers are covered entities under Section 1557. [Footnote 17: The Proposed Rule clarifies this by defining "federal financial assistance" as "any grant loan credit subsidy contract (other than a procurement contract but including a contract of insurance) or any other arrangement by which the federal Government directly or indirectly provides assistance or otherwise makes assistance available in the form of funds services of Federal personnel or real or personal property for less than fair market value."] These clarifications are an important step in addressing discrimination in all health care settings.

(b)(5)

The Leadership Conference on Civil and Human Rights

[Italics: Medicare Part B is Federal Financial Assistance.] We strongly support HHS's proposal to treat Medicare Part B payments as federal financial assistance (FFA) and Part B providers and suppliers as recipients under 1557 Title VI Title IX Section 504 and the Age Act. [Bold: We recommend that in the final rule HHS clarify that this change in interpretation is applicable across 1557 and the underlying statutes (Title VI Title IX Section 504 and the Age Act).] We also recommend HHS reiterate this change of interpretation in discussing the applicability of Sec. 1557 in § 92.2.[Most importantly this change will eliminate confusion for older adults people with disabilities and advocates in accessing health care and enforcing their rights and help ensure that people with Medicare have the same protections and rights regardless of the Medicare provider they choose the Medicare-covered service they are receiving or whether they are in Original Medicare or Medicare Advantage (MA). Bringing all Medicare providers under this rule will also help increase access to quality health care for all members of marginalized communities who face significant discrimination and barriers whether or not they are Medicare enrollees. For example if all Medicare providers are required to comply with this rule transgender people of color will benefit as many Medicare providers serve people with other forms of insurance. This change in interpretation is well supported by how the Part B program has evolved the fact that most Part B providers are already receiving other forms of FFA and the clear intent of the Sec. 1557 statute. Justice in Aging's experience explaining this loophole to advocates has been challenging because the justifications HHS previously relied on were strained and made little sense in the context of the modern health care delivery system. We look forward to this simplification.

Justice in Aging

We are pleased that the proposed rule ensures there are affirmative protections for LGBTQIA+ individuals in health care. This includes clarifying that nondiscrimination requirements apply to health programs and activities provided through telehealth services and interpreting Medicare Part B as federal financial assistance for the purpose of coverage under the federal civil rights statutes the HHS Department enforces.

AARP

[Bold: Medicare Part B Meets the Definition of Federal Financial Assistance.] We strongly support HHS's proposal to treat Medicare Part B payments as federal financial assistance (FFA) and Part B providers and suppliers as recipients under 1557 Title VI Title IX Section 504 and the Age Act. This change in interpretation is well supported by the evolution of how the Part B program operates the fact that most Part B providers are already receiving other forms of FFA and the clear intent of the Sec. 1557 statute. [We believe] simple confusion for older adults and people with disabilities who are not in the position to know whether their Medicare provider receives other FFA. And most importantly it will help ensure that people with Medicare have the same protections and rights regardless of the Medicare provider they choose the Medicare-covered service they are receiving or whether they are in Original Medicare or Medicare Advantage. Bringing all Medicare providers under this rule will also help increase access to quality health care for older marginalized communities such as LGBTQIA+ and BIPOC who face the most discrimination and barriers as many Medicare providers also serve people with other forms of insurance.

Center for Elder Law & Justice

From the beginning the underlying reasons for the exclusion of Medicare Part B providers were discriminatory. [Footnote 1: David Barton Smith Racial and Ethnic Health Disparities and the Unfinished Civil Rights Agenda Health Affairs (Mar/Apr 2005) https://www.healthaffairs.org/doi/full/10.1377/hlthaff.24.2.317.] making HHS's previous position to continue this exclusion under Sec. 1557 improper. Nonetheless even the previous justifications for the exclusion are no longer applicable. First we agree with HHS that there is no longer a valid basis for treating Part B differently than Part A given the vast similarities in how the programs currently operate and how providers are paid. In both Part A and Part B the program subsidizes the health care services provided to the Medicare enrollee by paying financial assistance to the providers and suppliers. As HHS notes the operation of Medicare Part B has changed since the program began and now provides payment directly to providers for health services rendered instead of the Part B enrollee paying for the services out of pocket and receiving reimbursement from Medicare. This change renders the prior any historical justification for not treating Part B as federal financial assistance moot. We also agree with HHS's reasons for treating all providers enrolled in the Medicare Part B program both "participating" and "non participating" as recipients of FFA. Namely non-participating providers agree to provide Medicare-subsidized health services to Part B enrollees and are thus indirect recipients of FFA. Furthermore both participating and non participating providers must sign an assurance of compliance with these civil rights laws as a condition of receiving federal funds. Finally we agree with HHS that the rationale for excluding Part B as a contract of insurance is no longer applicable and that even if it were a contract of insurance payment. The statutory language of Sec. 1557 explicitly [Italics: includes] "contracts of insurance" within the definition of FFA.

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Justice in Aging

As Catholics we want to be clear that we support the Proposed Rule's provision that any facility accepting Medicare payments would be subject to nondiscrimination requirements. Since one in six hospital beds are in Catholic facilities or formerly Catholic facilities whose purchase contracts make abiding by the U.S. Conference of Catholic Bishops' Ethical and Religious Directives [USCCB ERDs] part of the condition of sale we are very much aware that LGBTQIA people often face more challenges in obtaining medically necessary and appropriate care in these settings. Catholic health networks are often the only or closest facility available in many rural areas and in some lower income urban neighborhoods. Many of the USCCB ERDs make it impossible or very difficult for LGBTQIA people to obtain health care services without facing discrimination or denials of care.

Dignity, Inc dba DignityUSA

rule would apply to all health programs and activities that fall within the Department's jurisdiction which we understand to include Medicare Medicare Advantage and Part D Prescription Drug Programs. With that in mind [bold italic] we urge the Department to direct the Centers for Medicare and Medicaid Services (CMS) to eliminate the Self-Administered Drug (SAD) Exclusion List policies which we believe to be discriminatory against patients with physical behavioral or other disabilities. Many medications – particularly highly complex drugs and biologics – have a "physician-administered" formulation and a "self-administered" formulation. By law Medicare Part B does not cover drugs which are "usually" self-administered "by the patient" [footnote 1: See definition at 50 2 A. Usually at https://www.cms.gov/Regulations and Guidance/Guidance/Manuals/Downloads/bp102c15.pdf] [Footnote 2: See definition at 50 2 E. By the Patient at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf]. To implement this statutory distinction CMS has directed its Medicare Administrative Contractors (MACs) to determine whether medications are usually self-administered by the patient via use of criteria established in sub-regulatory manuals. In this case the Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services.According to the manual when a drug is determined by a MAC to be self-administered and is thus added to the SAD Exclusion List it becomes "bold underline. excluded from Part B coverage." Effectively this means that patients who are unable to administer the drug themselves – even if the inability to self-administer is due to a physical behavioral or other disability – must pay [bold underline: entirely] out-of-pocket for the physician-administered formulation. Although this was certainly not Congress' or CMS' intent this approach not only amounts to a de facto denial of coverage for disabled individuals in need of a drug on the SAD Exclusion List it also amounts to a denial of coverage [/italic]

The States further support HHS's change in interpretation to now specifically include Medicare Part B within the definition of federal financial assistance. See id. at 47887-90. The nature of payments made through Medicare Part B includes reimbursement to subcontractor entities providing Part B services and those providers should not be allowed to engage in discriminatory conduct. See id. at 47886.

We also commend HHS for continuing to advance non-discrimination policies to help preserve access to care by proposing to interpret Medicare Part B funds as federal financial assistance that requiring providers and suppliers subsidized by those funds to comply with Section 1557 implementing regulations.

WPHCA also strongly support OCR's proposal to treat Medicare Part B payments as federal financial assistance [FFA] and Part B providers and suppliers as recipients under 1557 Title VI Title IX Section 504 and the Age Act. This change in interpretation is well supported by how the Part B program has evolved the fact that most Part B providers are already receiving other forms of FFA and the clear intent of the § 1557 statute. It will eliminate confusion for older adults and people with disabilities and help ensure that people with Medicare have the same protections and rights regardless of the Medicare provider they choose the Medicare covered service they are receiving or whether they are in Original Medicare or Medicare Advantage. Bringing all Medicare providers under this rule will also help increase access to quality health care for underserved communities who face the most discrimination and barriers as many Medicare providers serve people with other forms of insurance.WPHCA agrees with HHS' judgment that the statutory text of Section 1557 is clear: Congress intended that the law apply to these entities and addresses these issues. That is WPHCA strongly supports HHS' restoration of and improvements to § 92 207 including its inclusion of specific forms of prohibited discrimination

We further commend HHS's proposal to interpret Medicare Part B funding as federal financial assistance thereby expanding the application of Section 1557 to Part B providers. This change will ensure that Medicare beneficiaries have the same nondiscrimination protections regardless of which part of Medicare they are enrolled in. We urge HHS to finalize these policies as proposed.

Inclusion of Medicare Part B providers We strongly support the revised definition of federal financial assistance [FFA] that at long last includes payments made under Medicare Part B. The previous exclusion of Medicare Part B physicians was based on outdated interpretations of civil rights laws and insurance. [Footnote 13 Frank Matthew. "Section 1557 of the ACA Should Not Allow Some Physicians to Discriminate." Health Affairs Forefront. 6 Jan. 2016 www.healthaffairs.org/do/10.1377/forefront.20160106.052554]. The inclusion of Medicare Part B providers in the proposed rules comprehensive nondiscrimination requirements would close decades-long gaps in discrimination policy and eliminate providers ability to deny services or discriminate under the umbrella of Part B.

Inclusion of Medicare Part B providers We strongly support the revised definition of Federal Financial Assistance [§ 92.4]We strongly support the Department's proposal to treat Medicare Part B payments as federal financial assistance (FFA) and Part B providers and suppliers as recipients under Section 1557 Title VI Title IX Section 504 and the Age Act. This change in interpretation is well supported by how the Part B program has evolved the fact that most Part B providers are already receiving other forms of FFA and the clear intent of the Section 1557 statute. It will eliminate confusion for older adults and people with disabilities and help ensure that people with Medicare have the same protections and rights regardless of the Medicare provider they choose the Medicare covered service they are receiving or whether they are in Original Medicare or Medicare Advantage. Bringing all Medicare providers under this rule will also help increase access to quality health care for underserved communities who face the most discrimination and barriers as many Medicare providers serve people with other forms of insurance.

[Italics] Medicare Part B In particular we strongly support OCR's proposal to treat Medicare Part B payments as federal financial assistance [FFA] and Part B providers and suppliers as recipients under 1557 Title VI Title IX Section 504 and the Age Act. This change in interpretation is well-supported by how the Part B program has evolved the fact that most Part B providers are already receiving other forms of FFA and the clear intent of Section 1557. It will eliminate confusion for older adults and people with disabilities and help ensure that people with Medicare have the same protections and rights regardless of the Medicare provider they choose the Medicare-covered service they are receiving or whether they are in Original Medicare or Medicare Advantage. Since many Medicare providers serve people with other forms of insurance bringing all Medicare providers under this rule will also help increase access to quality health care for underserved communities. This extension will have a direct impact on immigrant older adults who have arrived in the U.S. too recently to have accumulated the 40 quarters of Social Security earnings needed to qualify for premium-free Medicare and need the same health care services as other similarly situated older adults.

Another critical step in properly implementing civil rights protections in healthcare under section 1557 is the Department's decision to recognize providers who received payments under Medicare Part B as recipients of Federal Financial Assistance [FFA]. The past exclusion of Medicare Part B from FFA designation has created confusion and opened the door to providers to refuse service not only to LGBTQI+ individuals but also to individuals on the basis of race and national origin. The harm this exclusion has caused historically to marginalized communities cannot be understated as we are pleased to see the step made by the Department to prevent future discrimination through this new FFA definition.

While [illegible] HHS's assessment about the impact that this proposed change will have on Part B providers who do not receive other FFA we believe any impacts will be minimal and greatly outweighed by the benefits of ensuring people with Medicare are protected by this rule. First few Medicare providers are not already covered entities under this rule. We agree with HHS's proposal in the cost analysis discussion to adopt the 2016 rule's finding that almost all practicing physicians were likely covered by the rule because they accept FFA from sources other than Medicare Part B. This finding is bolstered by the continued growth of MA which now serves 48% of Medicare enrollees compared to 31% in 2016. [Footnote 2: Kaiser Family Found. Medicare Advantage in 2022: Enrollment Update and Key Trends (Aug. 25 2022) www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/; growth of Medicare Advantage] because providers who contract with an MA plan are already covered under this rule

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Coalition of State Rheumatology Organizations (CSRO)

Attorneys General of California, New York Massachusetts, and nineteen other States

The Colorado Health Foundation

Wisconsin Primary Health Care Association

U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Howard Brown Health

Center for American Progress

National Immigration Law Center

38 Members of Congress

Justice in Aging

(b)(5)

[Bold: MNACHC also strongly supports OCR's proposal to treat Medicare Part B payments as federal financial assistance [FFA] and Part B providers and suppliers as recipients under 1557 Title VI, Title IX Section 504 and the Age Act.] This change in interpretation is well- supported by how the Part B program has evolved the fact that most Part B providers are already receiving other forms of FFA and the clear intent of the § 1557 statute. Will eliminate confusion for older adults and people with disabilities and help ensure that people with Medicare have the same protections and rights regardless of the Medicare provider they choose the Medicare-covered service they are receiving or whether they are in Original Medicare or Medicare Advantage. Bringing all Medicare providers under this rule will also help increase access to quality health care for underserved communities who face the most discrimination and barriers as many Medicare providers serve people with other forms of insurance.

NAHU members also would appreciate clarification on compliance deadlines for entities that newly become covered entities according to the scope of the rule. Should an entity realize that it is newly subject to the rule how long does it have to develop compliance procedures and implement the complicated provisions of this rule? It occurs to us that entities could need to become compliant the minute they begin accepting any type of funding that directly or indirectly flows from HHS. However, such entities may not realize their compliance obligations right away and they will need time to implement appropriate procedures. Accordingly, we request a safe harbor compliance window of at least six months for newly covered entities to be included in any final rule.

HHS seeks comment on the time Part B providers should be allowed to come into compliance with these civil rights statutes and the implementing regulations and what resources it can provide to assist newly covered entities. We urge HHS to ensure Part B providers' compliance with these rules along the same timelines as all other covered entities. First there are few providers who have not already been covered by these rules due to receipt of other FFA. Second the burden for these entities to comply with the new requirements of Sec. 1557 is not particularly different from entities that are currently covered. The materials HHS is already preparing such as sample notices that are translated should help these entities as well.

[Bold: F. HHS should use its statutory authorities to expressly enumerate and enforce nondiscrimination protections in CMS and other health program specific regulations – including on the basis of sex characteristics.] We support the proposal to restore the enumeration of prohibitions on sexual orientation and gender identity in several CMS program regulations and to extend to them to some additional program rules. HHS correctly explains why CMS has clear authority and strong policy reasons to set forth these express enumerated protections in its program rules separate and apart from Section 1557 and its implementing rules. CMS program rules provide different compliance mechanisms – including prospective as well as complaint-based mechanisms – that complement Section 1557's fundamental but essentially backward-looking complaint-based enforcement scheme. In many contexts CMS program regulations are also more visible to some providers patients patient advocates and other stakeholders and are more readily translated into institutional policy training and patient awareness. For the same reasons HHS should expressly enumerate discrimination on sex characteristics [including intersex traits] in these CMS program rules. HHS should also extend enumerated SOGISC inclusive nondiscrimination provisions similarly to other CMS and HHS program regulations. In particular CMS should adopt parallel regulations throughout its Conditions of Participation rules.

As further explained below we also urge HHS to (1) work with other agencies with Section 1557-covered programs to adopt a Section 1557 Common Rule, (2) expressly enumerate nondiscrimination protections in CMS and other health program specific regulations; and (3) use its existing statutory authorities to extend clarify and enforce nondiscrimination protections in its human services programs.

CMS Amendments[The 2020 version of the regulations implementing section 1557 inexplicably removed protections against sexual orientation and gender identity discrimination from a number of regulations governing programs run by the Centers for Medicare and Medicaid Services (CMS). We are pleased to see those provisions restored and also included in additional CMS programs. We note however that the language around sex discrimination in these CMS "conforming amendments" does not match the proposed sex discrimination language in 1557 itself. We encourage HHS and CMS to adopt identical language to avoid confusion and ensure consistency of implementation.

[Bold: CMS Amendments]The 2020 version of the regulations implementing section 1557 inexplicably removed protections against sexual orientation and gender identity discrimination from a number of regulations governing programs run by the Centers for Medicare and Medicaid Services (CMS). We are pleased to see those provisions restored and also included in additional CMS programs. We note however that the language around sex discrimination in these CMS "conforming amendments" does not match the proposed sex discrimination language in 1557 itself. We encourage HHS and CMS to adopt identical language to avoid confusion and ensure consistency of implementation.

[Bold and Italics: Medicare Specific Interpretations and Centers for Medicare & Medicaid Services [CMS] Amendments]The AAMC supports the Department proposals to promote consistency across HHS programs regarding policies and requirements that prohibit discrimination including proposals for CMS to amend regulations to apply these protections to all its programs including fee-for-service and managed care programs.

Finally we support the Department's proposed amendments to the Centers for Medicare and Medicaid Services (CMS) regulations to prohibit discrimination on the basis of sexual orientation and gender identity for programs including Medicaid Children's Health Insurance Plan (CHIP) Program of All-Inclusive Care for the Elderly [PACE] the Exchange and Qualified Health Plans [Footnote 25, Id. at 47891]. Additionally the prohibition of insurers from marketing practices and benefit designs that discriminate in part on, or would be deterministic practices such as insurers charging people with HIV/AIDS higher costs or placing their medications in higher cost tiers [Footnote 26, Id. at 47868 47938 (Proposed § 92 207), Jane Perkins and Wayne Turner NHeLP and the AIDS Institute Complaint re HHS re HIV/AIDS discrimination by FL NATIONAL HEALTH LAW PROGRAM (May 28 2014) https://healthlaw.org/resource/nhelp-and-the-aids-institute-complaint-to-hhs-re-hiv-aids-discrimination-by-fl/]. We request that the Department's changes to CMS regulations are consistent with the language in the proposed rule section 92.101(a)(2). [Footnote 27 87 Fed. Reg. at 47916 (Proposed § 92.101(a)(2))]

Centers for Medicare and Medicaid Services (CMS) Amendments]The Trump administration's 2020 version of Section 1557 implemented regulations inexplicably removed protections against sexual orientation and gender identity discrimination from a number of regulations that govern programs run by the Centers for Medicare and Medicaid Services (CMS). We are in favour of the reinstatement of these provisions and we are pleased that they are being extended to additional CMS programs. However we would like to note that the language around sex discrimination in these CMS "conforming amendments" does not match the proposed sex discrimination language in Section 1557 itself. As such we strongly encourage HHS and CMS to adopt identical language which will help 1) to avoid confusion 2) to ensure a more consistent implementation for this important rule and 3) to protect greater access to culturally humble healthcare for LGBTQIA+ people across the country.

We also strongly support the provisions reinstating prohibitions of discrimination based on sexual orientation and gender identity in Programs for All-Inclusive Care for the Elderly [PACE] Medicaid and the Children's Health Insurance Program (including managed care entities and the 1115 contracts). PACE programs and Medicaid are vital sources of coverage and care for low-income older adults who are dually eligible for Medicare and Medicaid including LGBTQIA+ older adults. Therefore it is critical to ensure these programs, including Medicaid managed care plans are subject to strong and consistent nondiscrimination rules. To provide greater clarity for compliance and enforcement we urge HHS to harmonize the regulatory protections in these programs with the inclusive language proposed in Sec. 92.101(b).

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Minnesota Association of Community Health Centers

National Association of Health Underwriters

National Center for Lesbian Rights

InterACT Advocates for Intersex Youth

InterACT Advocates for Intersex Youth

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Eating Disorders Coalition for Research, Policy & Action

Association of American Medical Colleges [AAMC]

Senate Democrats

Equitas Health

Center for Elder Law & Justice

(b)(5)

[Bo d. CMS Amendments] The 2020 version of the regulations implementing Section 1557 inexplicably removed protections against sexual orientation and gender identity discrimination from a number of regulations governing programs run by the Centers for Medicare and Medicaid Services (CMS). We are pleased to see these provisions restored and also include in additional CMS programs. We note however that the language around sex discrimination in these CMS "conforming amendments" does not match the proposed sex discrimination language in 1557 itself. We encourage HHS and CMS to adopt identical language to avoid confusion and ensure consistency of implementation

Discrimination in Medicaid & PACE] We strongly support the reinstatement of prohibitions against discrimination based on sexual orientation and gender identity in Medicaid including managed care entities and their contractors] and Programs for All-Inclusive Care for the Elderly [PACE]. To improve compliance and enforcement however [Bo d. we urge HHS to harmonize the protections for these programs with the language proposed in Sec § 92.101[b][2][ii] [i.e. to include sex stereotypes sex characteristics including intersex traits pregnancy or related conditions sexual orientation and gender identity including transgender status. PACE and Medicaid provide vital coverage for many older adults with low incomes a significant number of whom are LGBTQI+. The estimated 12 million people dually eligible for Medicare and Medicaid are disproportionately low-income people of color disabled and in poorer health. [Footnote 26: CMS Medicare-Medicaid Coordination Office Fact Sheet: People Dually Eligible for Medicare & Medicaid (Mar. 2020) https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMCO_Factsheet.pdf, Kaiser Family Found. Racial and Ethnic Health Inequities and Medicare (Feb. 16 2021) https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.] Further as noted above a disproportionate share of LGBTQI+ older adults live in poverty compared to the general population. Both PACE and Medicaid cover LTSS that Medicare does not making LTSS one of the most common reasons an individual is enrolled in Medicaid. Because of the often daily and intimate nature of the services provided under these programs—including the fact that the services are sometimes provided in the beneficiary's own home—it is essential for the person receiving services that they have Sec. 1557's protections. As examples in our discussion above with respect to LGBTQI+ discrimination illustrate individuals receiving Medicaid-funded LTSS are

The Department has no basis to amend CMS Medicaid CHIP and PACE rules. The Department's basis for amending the CMS rules for Medicaid CHIP and PACE is even more flimsy than its reliance on Bostock. The Department bases these proposed rules on general provisions of the Social Security Act requiring that health assistance be provided in an "effective and efficient manner" in the "best interest of beneficiaries" [for Medicaid and CHIP programs] and to "ensure the health and safety of individuals enrolled in a PACE program" [Footnote 10: See NPRM at 47891-47895.] Nowhere in the statutes cited by the Department does Congress indicate that these provisions are related to prohibiting discrimination or in any way require that recipients of federal funds provide gender affirming treatment in order to be "effective and efficient." It is not likely that Congress ever contemplated such a specious interpretation.

[NAME?

[Italic: Reversal of adverse "conforming amendments" from the Trump administration in various CMS programs]We are delighted to see previous conforming amendments from the 2016 rule restored to CMS programs including the Children's Health Insurance Program [CHIP] Programs of All-Inclusive Care for the Elderly [PACE], and qualified health plan [QHP] issuers. For programs such as PACE the importance of reinstating the strong nondiscrimination protections cannot be understated. Older LGBTQI+ adults face many barriers to accessing and receiving healthcare and experience specific health needs and disparities including higher rates of poor physical health and disability more difficulty managing an HIV status and higher rates of isolation and psychological distress [Footnote 9: Emma Charles A. "Social Economic and Health Disparities among LGBT Older Adults." Generations (San Francisco Calif.) U.S. National Library of Medicine 2016 www.ncbi.nlm.nih.gov/pmc/articles/PMC5481896/.] As such LGBTQI+ older adults could greatly benefit from PACE program services that may may have otherwise avoided if strong nondiscrimination protections were not in place. The language around sex discrimination in these CMS "conforming amendments" does not match the proposed sex discrimination language in 1557 itself. We encourage HHS and CMS to adopt identical language to avoid confusion and ensure consistency of implementation.

As proposed CMS should also amend its own regulations in order to apply the protections to Medicaid fee-for-service [FFS] programs and managed care programs. It will promote consistency across the Department's programs of policies and requirements that prohibit discrimination based on sexual orientation or gender identity.

Bold: b. Transitioning treatments inflict irreversible harm on children.] The Proposed Rule makes no distinction regarding the provision of gender affirming care to minors versus adults. In fact the Rule applies its expansive definition of Sex" to include "gender identity" to regulations governing the Children's Health Insurance Program (CHIP) [Footnote 176: 87 Fed. Reg. 47824 47828-29, 47831.] as the Obama administration had done previously in its 2016 regulations [Footnote 177: 87 Fed. Reg. 47892] and specifically mentions "children" as negatively affected by discrimination in healthcare. [Footnote 178: 87 Fed. Reg. 47831.] The Rule states "The proposed amendments to 42 CFR 438.3(c)(4) 438.206(c)(2) 440.262 and 457.495(e) would explicitly prohibit discrimination on the basis of sexual orientation and gender identity in addition to the existing prohibitions imposed on Medicaid and CHIP issuers Section 1557." [Footnote 179: 87 Fed. Reg. 47892.] In addition the Proposed Rule claims the authority to define Essential Health Benefits that pertain to among others children. "Section 1302(b) of the ACA also gives CMS the statutory authority to prohibit discrimination in the small group and individual markets pursuant to the authority to define EHB at section 1302(b) of the ACA. The statute specifies that in defining EHB the Secretary must take into account the health care needs of diverse segments of the population including women children persons with disabilities and other groups. [Footnote 180: 87 Fed. Reg. 47898.]

Finally we support the Department's proposed amendments to the Centers for Medicare and Medicaid Services (CMS) regulations to prohibit discrimination on the basis of sexual orientation and gender identity for programs including Medicaid Children's Health Insurance Plan (CHIP) Programs of All-Inclusive Care for the Elderly (PACE) the Exchange and Qualified Health Plans. [Footnote 25: Id. at 47891]. Additionally the prohibition of insurers from marketing practices and benefit designs that discriminate in particular would help deter discriminatory practices such as insurers charging people with HIV/AIDS higher costs or placing their medications in higher cost tiers. [Footnote 26: Id. at 47868 47916 (Proposed § 92.207); Jane Perkins and Wayne Turner NHELP and the AIDS Institute Joint Letter to HHS re HIV/AIDS discrimination by HL NATIONAL HEALTH LAW PROGRAM (May 28 2014) https://healthlaw.org/resource/nhelp-and-the-aids-institute-comment-re-to-hhs-re-hiv-aids-discrimination-by-pcp/.] We request that the Department's changes to CMS regulations are consistent with the language in the proposed rule section 92.101(a)(2) [Footnote 27: 87 Fed. Reg. at 47916 (Proposed § 92.101(a)(2))]

We also strongly support the provisions reinstating prohibitions of discrimination based on sexual orientation and gender identity in Programs for All-Inclusive Care for the Elderly [PACE] Medicaid and the Children's Health Insurance Program including managed care entities and their contractors. PACE programs and Medicaid are vital sources of coverage and care for low-income older adults who are dually eligible for Medicare and Medicaid including LGBTQI+ older adults. It is therefore critical to ensure these programs including Medicaid managed care plans are subject to strong and consistent nondiscrimination rules. To provide greater clarity for compliance and enforcement we urge HHS to harmonize the regulatory protections in these programs with the inclusive language proposed in Sec. 92.101(b).

(b)(5)

SIECUS: Sexuality Information and Education Council of the United States

Justice in Aging

Arkansas Department of Human Services
California Department of Health Care Services

(b)(5)

Howard Brown Health

Tribal Technical Advisory Group to CMS (TTAG)

Ethics & Public Policy Center

Senate Democrats

Center for Elder Law & Justice

(b)(5)

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The Department has no basis to amend CMS Medicaid CHIP and PACE rules.The Department's basis for amending the CMS rules for Medicaid CHIP and PACE is ever more flimsy than its reliance on Bostock. The Department bases these proposed rules on general provisions of the Social Security Act requiring that health assistance be provided in an "effective and efficient manner" in the best interest of beneficiaries. [for Medicaid and CHIP programs] and to "ensure the health and safety of individuals enrolled in a PACE program" [Footnote 10: See NPRM at 47891 47895. Nowhere in the statutes cited by the Department does Congress indicate that these provisions are related to prohibiting discrimination or in any less require that recipients of federal funds provide gender affirming treatment in order to be "effective and efficient." It is not likely that Congress ever contemplated such a specious interpretation.

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SIECUS: Sexuality Information and Education Council for the United States

Sexuality Education for Social Change

Justice in Aging

Arkansas Department of Human Services

Howard Brown Health

(b)(5)

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INSURANCE MARKETS, ENFORCEABILITY AND STATE AUTHORITY[In explaining its reasons for not relying on Section 1557 as authority for support of a proposed amendment regarding guaranteed issue of coverage (Sec on 147.104) HHS states "Because states would not have authority to enforce Section 1557 CMS is of the view that partial reliance on Section 1557 could unnecessarily complicate enforcement efforts." 87 Fed. Reg. at 47898. While the States do not dispute that HHS is the lead enforcement agency for Section 1557 we assume that HHS did not intend to express that States can never enforce Section 1557 only that states do not have the same primary enforcement authority with respect to Section 1557 comparable to states' responsibilities as a whole state insurance markets or the specific statutory provisions or accession to federal grant making agencies in 42 U.S.C. § 2000d-1. In practice state agencies often play a role in oversight and enforcement of federal non-discrimination laws against subgrantees and other federal funds recipients in circumstances where there is dual federal/state administrative responsibility. And state Attorneys General generally have broad independent authority to enforce consumer protection laws both state and federal when taking action to protect consumers within their own states against unlawful conduct, including discriminatory conduct. [Italics: See e.g. New York by Schneiderman v. United City Sch. Dist. | 177 F. Supp. 3d 739 747 48 | N.D.N.Y. 2016] [holding that New York Attorney General had authority to enforce Title VI to protect quasi-sovereign interests]. [Italics: see also Munsey v. Del Taco Inc. | 46 Cal.4th 661 676 (2009) | noting that under California's Unfair Competition Law or UCL federal law violations may serve as a predicate for a state UCL claim).Although the administrative procedures specified in the Section 1557 regulation itself would not be enforced or applied by states the States may utilize their independent enforcement authorities that allow them to seek redress for violations of law including federal laws by entities within their jurisdictions. In the absence of the individual mandate penalty many more people will be able to afford health coverage without being subjected to discrimination We applaud HHS's commitment to ensuring that all individuals are able to access health care coverage without being subject to discrimination on the basis of race color national origin sex age or disability. We strongly support the application of Section 1557's regulatory requirements to the Federally-facilitated Exchanges [FFEs] the State-based Exchanges [SBEs] and to all health insurance issuers that receive federal financial assistance consistent with the statute's intent. We also appreciate HHS's clarification that covered health programs or activities include all products sold by health insurance issuers even grandmothered or grandfathered plans short-term limited duration insurance plans and excepted benefits plans.

Comments associated with this issue are recorded in the subsections below

No comments are associated with this issue

SIECUS: Sexuality Information and Education Council for the United States

Sexuality Education for Social Change

Attorneys General of California, New York, Massachusetts, and nineteen other States

U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

(b)(5)

[Underline: Weaponizes abortion and the gender ideology against small businesses families and faith-based providers and empowers government actors to override conscience protections]The Department claims that the economic impact to small business will not be significant. How can you adequately calculate this when the obligations for care under this Rule are limitless in scope because they are self determined and without objective definition as described above? Asserting that the Rule clears the 3% "significant impact" and 5% "substantial number" thresholds for small entities is unjustifiable by the scant incomplete analysis provided. Where is the Family Policymaking Assessment required under Public Law 105-277?

General Government Appropriations Act 1999 [Pub. L. 105-277] federal agencies are required to assess the impact of proposed regulations on families. Officially known as the "Family Policymaking Assessment" agencies are required to assess their actions "before implementing policies and regulations that may affect family well-being." [Footnote 23: Section 654 of the Treasury and General Government Appropriations Act 1999 [Pub. L. 105-277) https://www.govinfo.gov/content/pkg/PLAW-105pub277/pdf/PLAW-105pub277.pdf]Given the sensitive nature of Section 1557's proposed regulation we humbly request that HHS conduct an assessment on the impact of this proposed rule on family well-being. The seven categories that qualify for assessment are: (1) the action strengthens or erodes the stability or safety of the family and particularly the marital commitment;(2) the action strengthens or erodes the authority and rights of parents in the education nurture and supervision of the children; (3) the action helps the family perform its functions or substitutes governmental activity for the function; (4) the action increases or decreases disposable income or poverty of families and children; (5) the proposed benefits of the action justify the financial impact on the family; (6) the action may be carried out by State or local government or by the family; and(7) the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society. We are interested in the department addressing how the Section 1557 proposed regulation "increases or decreases disposable income or poverty of families and children" and how the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society." [Footnote 24: Ibid. 523.] Given the department's failure to conduct an analysis of how the additional cost of new surgeries will impact those who are insured, insurers and so on it is reasonable to be concerned that the

Herein lies the trap the Department has laid for itself and every affected entity by expanding the meaning of sex without defining what it actually means. The massive unarticulated costs and liabilities of this wrongheaded Rule to entities providers individuals and the American taxpayer must be calculated. The Department must be able to fully account for the broad and deep impact and consequence of the mandate it prescribes.

[Underline: Weaponizes abortion and the gender ideology against small businesses families and faith-based providers and empowers government actors to override conscience protections]The Department claims that the economic impact to small business will not be significant. How can you adequately calculate this when the obligations for care under this Rule are limitless in scope because they are self determined and without objective definition as described above? Asserting that the Rule clears the 3% "significant impact" and 5% "substantial number" thresholds for small entities is unjustifiable by the scant incomplete analysis provided. Where is the Family Policymaking Assessment required under Public Law 105-277?

Finally, cost of proposed regulations. Given the regulatory flexibility act which requires an analysis of the costs and harms associated with a given rule HHS must adequately address the potential costs/harms of its proposed Section 1557 regulation. If the department does not do so it will open for the door for lawsuits. In addition before a rule is finalized the department must provide an analysis of how much insurance will cost for insurers employers small businesses states and the insured. Which procedures will now be covered? What are the costs associated with these approved procedures? Given the Biden Administration's stated interest in promoting "equity" especially among minorities as failure to account for these costs will disproportionately harm rural hospitals and those living in poorer areas. The department has failed to answer these questions or provide the essential reports for how it will impact the insured and medical providers alike.

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Government Appropriations Act 1999 [Pub. L. 105-277] federal agencies are required to assess the impact of proposed regulations on families. Officially known as the "Family Policymaking Assessment" agencies are required to assess their actions "before implementing policies and regulations that may affect family well-being." Of the seven categories provided we are particularly interested in the department assessing the impact of the second category. It assesses whether "the action strengthens or erodes the authority and rights of parents in the education nurture and supervision of their children." As it relates to K-12 schools and the rights of parents in their child's education nurture and effective supervision the department fails to clarify the rights of parents as it relates to abortion or education access and/or assistance in achieving an abortion. Does the department consider it a form of discrimination to notify parents about a minor child receiving an abortion or "termination of pregnancy" via a referral from a school administrator counselor or nurse? What if the nurse suspects the chemical abortion pills and "oversees" the abortion for a minor? Does the department ensure that a minor's parents will be adequately informed prior to this? If a parents' sincerely held religious beliefs told that abortion is a preborn child and not merely another aspect of "pregnancy" will parents be informed in advance about school curriculum or trainings that teach abortion contrary to their beliefs? Additionally what impact will the addition of in loco parentis have on parental notification?To adequately clarify the department's standard and provide an adequate assessment in line with the 654 of the Treasury and General Government Appropriations Act the department should clarify the impact of this rule as it relates to "a non majority" in medical emergencies and parental notification laws. Given this we request that the department immediately assess how the proposed rule will impact families particularly considering whether "the action strengthens or erodes the authority and rights of parents in the education

[Bold: The Negative Impacts of Abortion] Women who undergo an abortion [surgical or chemical] experience high rates of anxiety depression substance and alcohol abuse and thoughts of suicide. For some this takes the form of Post-Abortion Syndrome (PAS) or After Abortion Grief. This syndrome refers to the myriad of emotional and psychological challenges women experience following an induced elective abortion. It is not uncommon for women to experience sustained feelings of regret and loss. Since abortions cost less and require fewer accommodations than pregnancy childbirth and lactation we are concerned that some may view abortion to be the "cheap and easy" option in high performance high stress environments. The department's proposed rule has failed to consider the physical emotional or mental harm a student may suffer when faced with an abortion. Since the rule includes abortion as a "related condition" of pregnancy the department must provide an analysis of how many young women will be at risk for these adverse effects under their new rule. How will schools provide the necessary resources for students considering an abortion or recovery thereof?

No comments are associated with this issue

Finally, cost of proposed regulations. Given the regulatory flexibility act which requires an analysis of the costs and harms associated with a given rule HHS must adequately address the potential costs/harms of its proposed Section 1557 regulation. If the department does not do so it will open for the door for lawsuits. In addition before a rule is finalized the department must provide an analysis of how much insurance will cost for insurers employers small businesses states and the insured. Which procedures will now be covered? What are the costs associated with these approved procedures? Given the Biden Administration's stated interest in promoting "equity" especially among minorities as failure to account for these costs will disproportionately harm rural hospitals and those living in poorer areas. The department has failed to answer these questions or provide the essential reports for how it will impact the insured and medical providers alike.
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(b)(5) Concerned Women for America

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General Government Appropriations Act 1999 (Pub. L. 105-277) federal agencies are required to assess the impact of proposed regulations on families. Officially known as the "Family Policymaking Assessment" agencies are required to assess their actions "before implementing policies and regulations that may affect family well-being. (Footnote 23: Section 654 of the Treasury and General Government Appropriations Act 1999 (Pub. L. 105-277). https://www.govinfo.gov/content/pkg/PLAW-105publ277/pdf/PLAW-105publ277.pdf)Given the sensitive nature of Section 1557's proposed regulation we humbly request that HHS conduct an assessment on the impact of this proposed rule on family well-being. The seven categories that qualify for assessment are: (1) the action strengthens or erodes the stability or safety of the family and particularly the marital commitment;(2) the action strengthens or erodes the authority and rights of parents in the education, nurture and supervision of their children;(3) the action helps the family perform its functions or substitutes governmental activity for the function;(4) the action increases or decreases disposable income or poverty of families and children;(5) the proposed benefits of the action justify the financial impact on the family;(6) the action may be carried out by State or local government or by the family; and(7) the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society. We are interested in the department addressing how the Section 1557 proposed regulation "increases or decreases disposable income or poverty of families and children" and how "the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society." (Footnote 24: Ibid. 523.) Given the department's failure to conduct an analysis of how the additional cost of new surgeries will impact those who are insured, insurers and society is reasonable to be concerned that the

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Where is the Regulatory Impact Analysis for declaring a class of treatment based on "presumptive" and "discrimination" and the costs required to undergo treatment to reverse a regretted transition or to treat associated bodily damage from sex reassignment treatments? Chemical and surgical interventions for gender transition have become big business lacking any oversight or associated liability. Why should an insurer be required to cover the removal of a young man's testicles within three months of him declaring a decision to change "genders"? This would be required as "gender affirming care" under this Rule. Any determination to "discriminate" against elective treatment that mutilates the body even if it increases serious health risks could be challenged as discriminatory.

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Comments associated with this issue are included in the subsections below.

No comments are associated with this issue.

over compliance requirements and rights of people to be free from discriminat or un protected bases:]We recommend revising the indicated language in Section § 92.206 (b)(4) as a provider could engage in a discriminatory denial of care even if a claimant cannot show that the care in quest or was on other occasions provided for other purposes. For example there are certain procedures that trans people seek for medically necessary gender affirming care that may typically be seen as cosmetic procedures for the general population. This can sometimes cause denial of care for trans people trying to access these services with the current regulatory language. These suggested changes would be reflected in 92.206 as follows "In providing access to health programs and activities a covered entity must not (1) Deny or limit health services including those that are offered exclusively to individuals of one sex to an individual based upon the individual's sex assigned at birth gender identity or gender otherwise recorded;(2) Deny or limit a health care professional's ability to provide health services on the basis of an individual's sex assigned at birth gender identity or gender otherwise recorded if such denial or limitation has the effect of excluding individuals from participation in denying them the benefits of or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity (3) Deny or limit health services sought for purposes of gender transition or other gender affirming care if the denial or limitation is based on a patient's sex assigned at birth gender identity including transgender status or gender otherwise recorded.||Italic Unaddressed discrimination on the basis of race color national origin (including limited English proficiency and primary language) sex (including pregnancy sexual orientation gender identity and sex characteristics) age and disability as applied to State and Federally-facilitated Exchanges with any detailed supporting informat on facts surveys and sources or reports |The addition of intersectional discrimination is much

No comments are associated with this issue.

No comments are associated with this issue.

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The Heritage Foundation

Concerned Women for America

Howard Brown Health

Coalition appreciates Section VII in the proposed rule and its invitation to comment on the importance of adopting the Access Board's [underlined/bold/blue 2017 Medical Diagnostic Equipment Accessibility Standards] into enforceable regulation. We now have had almost six years to see what individual health providers and facilities health care systems hospitals health insurers and federal and state health care agencies would voluntarily do with the detailed thorough consensus standards developed by the Access Board. We find that not much has been done. The U.S. Department of [bold/blue/underlined: Veterans' Affairs adopted the Standards] soon after their completion and applies them to the agency's new equipment acquisitions. However this example was not followed by others. In those five years people with mobility developmental and strength and balance disabilities across a range of ages different races/ethnicity and LGBTQ+ status have continued to be denied access to the most basic medical procedures like physical exam and an accurate measure of weight. As noted by the National Council on Disability "In its 2021 letter on [italics/blue Enforceable Accessible Medical Equipment Standards – A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities][Bold/italics: The harsh and discriminatory reality is that people with mobility disabilities will continue to receive unequal health care until there is a regulation.] It's means that we described unavailability of weight adjustable examination tables accessible mammography equipment accessible weight scales and lifting equipment to facilitate transfers among other accessible medical and diagnostic equipment we mentioned in the status quo. They will continue to be less likely to receive preventive health care services— like cervical cancer screening; colorectal cancer screening; obesity screening, and breast cancer screening. Tragically lack of accurate diagnosis and access to timely treatments will result in preventable deaths. Patients with disabilities who are unfamiliar with their

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Tennessee Disability Coalition

Brief: C. The NPRM's proposed provisions for access to facilities and proposed integration provision are essential protections for people with disabilities.]We support § 92.205 and § 92.205 which preserve prior existing requirements for structural accessibility and the provision of reasonable modifications to ensure access to facilities for people with disabilities. However we strongly recommend that the final rule incorporate existing standards relating to accessible medical and diagnostic equipment that were developed by the U.S. Access Board and finalized in 2017. "Footnote 120: US ACCESS BOARD Medical Diagnostic Equipment Accessibility Standards https://www.access-board.gov/mde/ [Last visited Oct. 3, 2022] | For some people with disabilities equipment accessibility is as necessary to equally effective health care as the accessibility of buildings and facilities and is equally directed to requests for reasonable modifications in a covered entity's policies and procedures.

Center for Reproductive Rights

equipment|The MRET Center endorses the expectation that covered entities have accessible medical diagnostic equipment available and that it is an enforceable standard[ ]n the absence of such diagnostic equipment how can appropriate and nondiscriminatory medical care be provided?We wish to provide three further comments for consideration.a. It is unclear why the Rule limits the expected standard to diagnostic equipment rather than the more general expectation of medical equipment [including therapeutic and preventive] in addition to diagnostic equipment. We suggest deleting the word "diagnostic" and clarifying the intention that accessible medical equipment should be available and enforceable expectation.b. As is clear to OCR there are two meanings of the word [italic accessible]. First that the piece of equipment is in a physical location that is accessible to people with disabilities (see b.) that follows). The second is that the piece of equipment is accessible in its design (e.g. the example of screening mammography exams designed such that they do not require the patient to stand). Clarification that both interpretations of accessibility are embodied by the Rule would be beneficial. For purposes of clarity additional examples would also be helpful. It is true that many types of highly specialized medical equipment exist and that it may be an unreasonable expectation that every covered entity be expected to have every piece of equipment on site. We believe it would be sufficient for the covered entity to have such access to such medical equipment if and only if the covered entity provides access [e.g. transportation] to the specialized medical equipment and only if the delay in provision would not negatively influence the health outcome.In guidance that follows the publication of the Rule we advocate that OCR publish guidance to help covered entities determine which diagnostic therapeutic and other medical equipment be maintained on site and which can be available through other means (e.g. contracted entities or services). Such	(b)(5)	Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard [MRCT Center]
We believe that lack of access to accessible medical diagnostic equipment [MDE] requires enforceable standards. We agree with the National Council on Disability that HHS OCR should issue a regulation requiring covered healthcare providers to acquire accessible equipment that complies with the MDE Standards as well as develop a technical assistance document on Accessible MDE [illegible] it is important to adopt the Access Board's 2017 Medical Diagnostic Equipment Accessibility Standards so they become enforceable regulations. Since the development of the standards we have had almost six years to see that no individual health providers facilities health care systems hospitals health insurers or federal and state healthcare agencies have voluntarily adopted the standards. While the U.S. Department of Veterans' Affairs adopted the standards soon after their completion and applies them to the agency's new equipment acquisitions no others have followed. People with mobility developmental and strength and balance disabilities across a range of ages different races/ethnicity and LGBTQ+ status have to be denied access to the most basic medical procedures a physical exam and an accurate measure of weight. As noted by the National Council on Disability in its 2021 letter on [italics] Enforceable Accessible Medical Equipment Standards - A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities:] Without a regulation we see widespread unavailability of height adjustable examination tables accessible mammography equipment accessible weight scales and lift equipment to facilitate transfers among other accessible medical and diagnostic equipment we remain in the status quo. People with mobility disabilities will remain less likely to receive preventive health care services—like cervical cancer screening; colorectal cancer screening, obesity screening; and breast cancer screening.Inaccessible equipment is not a matter of mere inconvenience. Even if a disabled person has a family member or friend who might be able to accompany them to an appointment and provide transfer assistance the consequences of doing so are burdensome disproportionally by low-income individuals and families of color who are least able to afford time off. An aging partner should not be expected to provide transfer assistance but is likely to feel pressured to do so. Patients with disabilities who are unfamiliar with disability norms or already uncomfortable with English are less likely to press for a full exam	(b)(5)	Alliance of Multicultural Physicians
11. Investigations of Discriminatory Benefit Design (Preamble) The Preamble discusses how HHS will approach investigations related to allegedly discriminatory benefit design. Specifically the proposed rule newly addresses how a third-party administrator may be liable under this part when it is responsible for an underlying discriminatory plan design feature that is adopted by a group health plan. Recommendation: BCBSA recommends that the Final Rule clarify that purely administrative actions such as document development or preparing policy booklets for a client will not create a liability for the third party administrator when the discriminatory terms of the group health plan originated with the plan sponsor rather than the third-party administrator. Rationale: As the Preamble notes "the Employee Retirement Income Security Act of 1974 (ERISA) requires group health plans to be administered consistent with their terms and therefore third party administrators are unable to change any discriminatory design features in the self-insured plans they administer to comply with Section 1557's requirements." Thus consistent with the 2016 rule third-party administrators should not be held responsible for the benefit designs of the self insured group health plans they administer when the responsibility for the decision or alleged discriminatory actions lies with the plansponsor	(b)(5)	Disability Rights Maine
	(b)(5)	Blue Cross Blue Shield Association
Meaningful access to facilities and equipment by people with disabilities is paramount in delivering necessary preventative care and treatment. The issue of inaccessible diagnostic treatment is a double edged sword for a rural state like North Dakota. Because of the limited number of medical facilities and the varied needs of people with disabilities having accessible equipment used to diagnose conditions is critical. Yet this can be a financial burden to small rural providers. We recommend an approach like that of the Americans with Disabilities Act 2010 standards which would require updating the equipment as it is replaced. Or in the alternative creating grant opportunities to allow smaller providers opportunities to fund the purchase of new accessible diagnostic equipment.	(b)(5)	ND Protection & Advocacy Project
[Bold: Website Accessibility Requirements] The proposed rule solicits comments as to whether a covered entity's website should be subject to accessibility requirements. NAHU members are concerned about the cost of such of a requirement so we would not support its application. At minimum we would request an exemption for all businesses and industries classified as small businesses by the federal Small Business Administration.		National Association of Health Underwriters
In response to OCR's request for comments on whether the Section 1557 rule should require covered entities to comply with specific accessibility standards we recommend requiring covered entities to comply over time with the latest WCAG guidelines as they are updated by the Web Accessibility Initiative. As noted in the preamble to the proposed rule vital health and healthcare information is now commonly communicated via websites including notices of civil rights and how to request language support and auxiliary aids and services. Covered entities must undertake periodic assessments of their websites to both maintain existing accessibility and keep up with evolving accessibility standards since there is little point to having a notice that is featured prominently on a website that is unused by people with disabilities due to absent or inconsistent real life accessibility. A requirement to keep up with the latest standards could offer a range of time so that larger entities with more resources will have a shorter period to comply with a newly published WCAG standard while smaller entities with fewer resources will have more time to do so. Regarding whether the Section 1557 rule should require covered entities to comply with specific accessibility standards we highly recommend requiring covered entities to comply with the latest WCAG guidelines as they are updated by the Web Accessibility Initiative. So much is done online these days and it is critical that people with disabilities can access the information and navigate the health care websites with as much ease as people without disabilities. There are many resources and tools that exist that can help health care providers to ensure that the websites are accessible. And only we know that this requires ongoing monitoring and evaluation of websites. It is not a "once and done" activity. As changes are made accessibility needs to be one of the many factors considering any updates.		Disability Rights Maine
		Tennessee Disability Coalition

b. The MRCT Center supports the inclusion in Section 1557 of a provision requiring covered entities to comply with accessibility standards for web content and we advocate that the most recent edition of the selected published standard is adopted. While we are familiar with Web Content Accessibility Guidelines and the WCAG 2.1 standards (which are the prevailing standards and touted for example by the Department of Justice in its guidance) we defer to others that have greater expertise as to the options. Whatever standard is chosen regardless of whether the standard is set out in the Rule or by guidance OCR should require covered entities comply with the most recent standard available with the minimum timeline for adoption and no greater than a year. Shorter timelines might be appropriate depending on the complexity of the updates in the future and can be decided at the time. We also suggest that the Rule be specific in requiring compliance with accessibility standards for web content for all languages in which the provider is providing language assistance services and auxiliary aids. We suggest that in addition to accessibility standards for web content that the Rule require health literacy standards at the 6th grade level or lower (easy read) to help people with intellectual disability be able to understand the information. This will also assist translation and interpreter services.

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Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

[Bold: Language-Access ibility Requirements.] The proposed rule also asks for comments from stakeholders about how HHS could be of assistance in helping covered entities in meeting the proposed rule's language-accessibility requirements. Our association members believe that when HHS finalizes the rule the best thing it can do is to provide clear sub-regulatory compliance guidance including templates for required notifications.

No comments are associated with this issue.

[Italic. Whether covered entities seek guidance on best practices for compliance with Section 1557 and on what topics.] We believe that many covered entities will likely seek guidance on best practices for LGBTQI+ cultural competence/responsiveness. A recent study found that medical students who received more LGBTQI+ education reported being more effective in increasing comfort knowledge and confidence when providing care for LGBTQI+ patients. [Footnote 17: Nowaskie Dustin Z. and Anuj U. Patel. "How Much Is Needed? Patient Exposure and Curricular Content on Medical Students' LGBTQ+ Cultural Competency." BMC Medical Education." BioMed Central. BioMed Central, 7 June 2022. bmcmeded.biomedcentral.com/articles/10.1186/s12909-020-02251-1.] There are a number of existing resources that provide guidance and best practices for providing culturally responsive and affirming care to LGBTQI+ patients that will be a with Lumpkin while with Section 1557:

- Howard Brown Health – LGBTQI+ cultural competency trainings: https://howardbrown.org/area/education/curriculum/
- The Fenway Institute – Education and Trainings: https://fenwayhealth.org/the-fenway-institute/education/ [Providing affirming and nondiscriminatory healthcare is at the heart of everything that we do at Howard Brown. We know firsthand that there are still far too many instances of LGBTQI+ patients being refused care harassed and discriminated against in healthcare. This proposed rule would go a long way in establishing and strengthening nondiscrimination protections in healthcare for LGBTQI+ patients. As the country sees more and more anti-LGBTQI+ legislation specifically aimed at criminalizing affirming healthcare it is more important now than ever to finalize and enforce these nondiscrimination protections in the proposed Section 1557 rule. Healthcare is a human right and a people deserve to be able to access necessary and vital healthcare regardless of how they identify.

Howard Brown Health

[Bold: Compliance Guidelines.] HHS inquired whether covered entities seek guidance on best practices for compliance with Section 1557 and if so on which topics. NAHU members always believe that sub-regulatory guidance that provides covered entities with best practices for compliance is desirable action. Regarding this proposed rule our membership would appreciate compliance guidelines on the applicability of these requirements specifically to group health plans third-party administrators and health insurance carriers including the interplay and examples of how each of these entities may qualify as covered health programs. Additionally our association would like more detail about how this regulation applies to health insurance agents and brokers both independently and in their roles as appointed agents of a particular health insurance issuer that qualifies as a covered health program. Another area where NAHU members believe more guidance is warranted is what constitutes a covered funding stream. More examples of direct and indirect sources of funding and how they affect applicability of this regulation would be very helpful. Finally the proposed rule includes notification requirements as well as specifications that certain covered entities develop written compliance policies and procedures as well as a grievance process. NAHU members always believe that templates and sample notices are helpful tools to encourage appropriate compliance.

National Association of Health Underwriters

6. The MRCT Center strongly endorses the position that the revised Rule clarifying Section 1557 should establish that one standard of nondiscrimination applies and that standard is the most protective of those who have been or are subject to discrimination on the bases of race color national origin disability age or sex. It should clarify that one standard exists for health care for all categories and no one class that one disadvantaged group is afforded preference or rights above another. That disparate impact beyond and inclusive of disparate treatment is a standard that should be the single applicable standard. In addition the Rule should clarify that reasonable accommodations are an expectation and must be provided to demonstrate compliance with the Rule.

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Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

The final rule should further clarify that private litigants can bring a separate impact claims based on any form of discrimination prohibited by Section 1557 and its implementing regulations. As noted above Congress intended Section 1557 to remedy both "invidious discrimination and the stark disparities in outcomes in our health care system." [Footnote 53: 156 Cong. Rec. S1842 (daily ed. Mar. 23 2010) (statement of Sen. Leahy).] In order to improve health outcomes for Black Americans and other people of color we must address practices that even if not explicitly motivated by race have a clear disparate impact. Disparate impact claims are also essential to addressing the discriminatory outcomes which may arise from the use of clinical algorithms which as the Proposed Rule notes "may result in discriminatory outcomes when variables are used as a proxy for a protected basis and may also result from correlations between a variable and a protected basis" not just when they intend to discriminate. [Footnote 54: Nondiscrimination in Health Programs and Activities 87 Fed. Reg. at 47882.] The final rule should clearly assert what the Court held in Rumble v. Fairview Health Services that Section 1557 creates a "health-specific anti-discrimination cause of action that is subject to a singular standard regardless of a plaintiff's protected class status". [Footnote 55: Rumble v. Fairview Health Servs. No. 14-CV-2037 SRN/FLN 2015 WL 1197415 *11 (D. Minn. Mar. 16 2015) (citation omitted).] and that this "includes a private right of action for disparate impact claims. Even if the underlying statute does not detail the specific form of discrimination the rule would allow for individuals to seek relief for discrimination in provision of healthcare. [Footnote 56: Timothy Jost HHS Issues Health Equity Final Rule (HEALTH AFFAIRS May 14 2016) https://www.healthaffairs.org/do/10.1377/forefront.20160514.054868/.]

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NAACP Legal Defense and Education Fund, Inc.

recognize disparate impact theories of discrimination, a similar statute enforcement actions] for three key reasons. First, recognizing disparate impact will create a more effective remedy for discrimination in healthcare as the nature of discrimination has evolved. Second, other parts of the rule already appear to embrace a disparate impact theory of discrimination. For example, proposed § 92.210 regarding the use of clinical algorithms in decision making recognizes the ways in which use of clinical algorithms in healthcare may result in discrimination prohibited under Sec. 1557 and that a covered entity may be found liable even if such discriminatory impact was not intended. Finally, recognizing disparate impact would advance other goals in the NPRM, specifically a private right of action as recognized in [Italics: Cummings v. Premier Rehab Keller, P.L.L.C.] [Footnote 64: Cummings v. Premier Rehab Keller, P.L.L.C., 64 F.4th 125, 130 (5th Cir. 2023), 2023 U.S. App. LEXIS 1562, 2023 WL 372569, 70 (2022) ("it is 'beyond dispute that private individuals may sue to enforce' [section 504 and Section 1557's] and in the preamble. [Footnote 65: 87 FR 47855.] Without disparate impact, a private right of action would ring hollow for older adults of color and other individuals who face systemic discrimination in healthcare. As legal experts have noted "the ways in which racial discrimination manifests in the health care context has changed in the nearly 60 years since Title VI was enacted. In many (but certainly not all) ways once blatant racism in both policies and practice gave way to more subtle seemingly neutral policies that disproportionately impact people of color. Current de facto segregation perpetuates the very disparities created by an era of de jure segregation." [Footnote 66: Jamille Fiecas Allsbrook & Kate Keith, ACA Section 1557 As A Tool For Anti-Racist Health Care Health Affairs (Dec. 8, 2021) https://www.healthaffairs.org/do/10.1377/forefront.20211207.962085/full/] [For example, during COVID-19, Justice in Aging filed multiple complaints with OCR regarding CSCs that unlawfully discriminated against older adults and people with

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Comments associated with this issue are included in the subsections below.

No comments are associated with this issue.

The proposed rule would radically remake American healthcare by replacing science-based medicine with ideology-driven mandates. As proposed, the rule is arbitrary and capricious, exceeds statutory authority, and is unlawful and unconstitutional. The primary proposed changes are unsupported by substantial evidence. The Proposed Rule contradicts long-standing scientific understandings of human biology and thereby endangers public health. The Proposed Rule turns the clock back on girls' and women's rights, tramples parental rights, harms children's interests, dismantles sex-based patient protections, and violates religious freedom and conscience rights of medical professionals, hospitals, and religious institutions. The Proposed Rule subverts our civil rights laws and should be withdrawn and abandoned.

We have included citations to supporting research, including direct links to the research. We direct OCR to each of the materials we have cited and made available through active links and we request that the full text of each of the studies and articles cited along with the full text of our comment be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If OCR is not planning to consider these materials as part of the record as we have requested here, we ask that you notify us and provide us an opportunity to submit copies of the studies and articles into the record.

When it comes to saying who is entitled to be treated as a man or a woman, nothing can be more arbitrary and capricious than the Proposed Rule's Humpty Dumpty abuse of language. [Footnote 25: "'When I use a word,' Humpty Dumpty said, in rather a scornful tone, 'it means just what I choose it to mean — neither more nor less.' 'The question is,' said Alice, 'whether you can make words mean so many different things.' 'The question is,' said Humpty Dumpty, 'which is to be master — that's all.'" Lewis Carroll, Through the Looking-Glass and What Alice Found There (1871).]

HHS has not and cannot demonstrate need and a substantial evidentiary basis for such a self-contradictory and unnecessary Proposed Rule. This is nothing more than arbitrary and capricious rulemaking by the Department driven by an unscientific ideology that will permanently disfigure the practice of medicine if finalized.

[Bold.] HHS appears to have acted outside the public rulemaking process. [Both the Obama and Trump administrations followed the legally required public comment and rulemaking process in issuing their Section 1557 regulations in 2016 and 2020, respectively. Yet on May 10, 2021, HHS unilaterally issued a "notification of interpretation and enforcement," stating: "Consistent with the Supreme Court's decision in [Italics: Bostock] and Title IX jurisprudence, OCR will interpret and enforce Section 1557's prohibition on discrimination on the basis of sex to include: '(1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity.'" [Footnote 26: U.S. Dep't. Health & Human Servs., Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, 3 (May 10, 2021) (https://www.hhs.gov/sites/default/files/publication-bostock-nprm-not-final-or-pdf.)] First, as discussed below, [Italics: Bostock] did not apply to Title IX or Section 1557 and the Supreme Court made clear in its [Italics: Bostock] decision that it was not deciding any issue outside the hiring/firing context under Title VII. [Footnote 27: 140 S. Ct. 1731, 1753 (2020).] Second, while the Department of Education (ED) has proposed it has not yet issued new Title IX regulations interpreting Title IX's prohibition against sex discrimination to cover gender identity through the public notice and comment process. Third, HHS (as well as ED and the Department of Justice (DOJ)) cannot issue such commands outside the public rulemaking process. Indeed, one judge ruled HHS' notification an act of "administrative fiat." [Footnote 28: Franciscan Alliance, Inc. v. Becerra, No. 7:16-cv-00108, at 8 (N.D. Tex. Aug. 9, 2021).]

Further, HHS issued an additional "guidance" document on March 2, 2022 in which it reiterated that OCR is investigating and enforcing Section 1557 cases involving purported discrimination on the basis of sexual orientation and gender identity. [Footnote 29: Office for Civ. Rights, U.S. Dep't. Health & Hum. Servs., HHS Notice and Guidance on Gender Affirming Care, Civil Rights and Patient Privacy, 1 (Mar. 2, 2022), https://www.hhs.gov/sites/default/files/hhs-ocr-notice-and-guidance-gender-affirming-care.pdf.] The document stated: "Categorically refusing to provide treatment to an individual based on their gender identity is prohibited discrimination. Similarly, federally-funded covered entities restricting an individual's ability to receive medically necessary care, including gender affirming care, from their healthcare provider solely on the basis of their sex assigned at birth or gender identity, likely violates Section 1557." [Footnote 30: Id. at 2.] By unilaterally issuing these documents outside the public rulemaking process, it appears HHS has already pre-judged the outcome; it appears that the Agency will not seriously consider contrary views and is not interested in public input. Indeed, a federal district court just ruled on October 1, 2022 that the March 2 guidance is "unlawful" and "vacated and set aside." [Footnote 31: Texas v. Equal Emp't. Opportunity Comm'n, No. 2:21-cv-194, at *32 (N.D. Tex. Oct. 1, 2022).] The court ruled the guidance is "arbitrary and capricious" and it violated the APA for failing to follow notice and comment rulemaking requirements and to be published in the federal register as required by FOIA. [Footnote 32: Id. at *17-*18, *24-*25.] As such, the March 2 guidance cannot be the impetus for this rulemaking.

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Justice in Aging

Ethics & Public Policy Center

National Asian Pacific American Women's Forum

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of sex" under Section 1557 is arbitrary and capricious and contrary to law. Statutory language logic and medical history support the view that "sex" means "biological sex" under Title IX and by extension Section 1557 not "gender identity."|Bold: A. Sex Under Section 1557 means biological sex. Section 1557 guarantees that no individual can be denied benefits in a federally run or federally funded health program or activity based "on the grounds prohibited under" and the enforcement mechanisms from four existing federal civil rights laws: Title VI of the Civil Rights Act of 1964 (race color national origin) Title IX of the Education Amendments of 1972 (sex) the Age Discrimination Act of 1975 (age) and Section 504 of the Rehabilitation Act of 1973 (disability). [Footnote 44 42 U.S.C. § 18116.] As now FPPC President Ryan Anderson and now FPPC Senior Fellow Roger Severino noted in 2016 "Section 1557 of the ACA does not create special privileges for new classes of people or require insurers and physicians to cover or provide specific procedures or treatments." [Footnote 45: Roger Severino & Ryan T. Anderson Proposed Obamacare Gender Identity Mandate Threatens Freedom of Conscience and the Independence of Physicians Heritage Found. Backgrounder No. 3089 2 (Jan. 8 2016) https://www.heritage.org/health-care-reform/report/proposed-obamacare-gender-identity-mandate-threatens-freedom-conscience.' Looking to the statutory text and congressional intent it is clear that Section 1557 did not extend to sexual orientation or gender identity. Regarding sexual orientation the ACA makes one reference to the term in a provision related to grant programs. [Footnote 35: See 42 U.S.C. § 294e-1(b)(2) ("participation in the institutions' programs of individuals and groups from different racial ethnic cultural geographic religious linguistic and class backgrounds and different genders and sexual orientations").] If Congress wanted to prohibit LGBTQ discrimination it would have used the term as it did here. Regarding gender identity the ACA was passed by Congress in March 2010 and at

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Proposing unprecedented changes to federal law through such an arbitrary and capricious process lacks any degree of legitimacy. The requirements of administrative rulemaking are meant to prevent this type of abuses of power. This Rule hinges on an insubstantial circular "justification" created out of whole cloth increasing novel meanings and sweeping expansions never authorized by Congress and federal courts have acknowledged that. Even worse this Rule seeks to mandate an oppressive health care regime through Section 1557 of the ACA and other federal programs serving vulnerable women and children that rejects the humanity of babies in the womb the human dignity of the female sex and the human rights of children who have become pawns in an exploitative for-profit enterprise of "gender affirming care" that deforms young bodies and sterilizes youth in Kafkaesque-style deception.

Concerned Women for America

The Proposed Rule states "Since [Italics: Bostock] two Federal courts of appeals have held that the plain language of Title IX's prohibition on sex discrimination must be read similarly." [Footnote 74: 87 Fed. Reg. 47829.] In support HHS cites to a Ninth Circuit and Fourth Circuit case. [Footnote 75: 87 Fed. Reg. 47829.] This is a far cry from consensus. HHS further mentions DOJ has taken the same position in Title IX litigation. [Footnote 76: 87 Fed. Reg. 47829.] While citing to a brief DOJ filed in an Eleventh Circuit case it fails to acknowledge that court rejected DOJ's position. In [Italics: Adams v. School Board of St. Johns County] the Eleventh Circuit granted rehearing [Italics: en banc] and vacated the panel's 2-1 decision that aligns with the Department's interpretation. [Footnote 77: Adams v. Sch. Bd. of St. Johns Cnty. No. 18-13592 (11th Cir. Aug. 23 2021).] The vacated panel majority had held that [Italics: Bostock]'s reasoning that Title VII with its "sparsely broad terms" "forbids discriminating against transgender people "applies with the same force to Title IX's equally broad prohibition on sex discrimination." [Footnote 78: Adams v. Sch. Bd. of St. Johns Cnty. 968 F.3d 1286 1305 (11th Cir. 2020) vacated No. 18-13592 (11th Cir. Aug. 23 2021).] Given that the [Italics: en banc] Eleventh Circuit has not issued its opinion [Footnote 79: Oral argument was held February 22 2022.] it would be arbitrary and capricious for HHS to ignore the controlling decision and rely on its partisan litigation position over the court's actions. To the extent HHS is relying on [Italics: Bostock] as the legal impetus for its rulemaking that basis is deficient. [Italics: Bostock] requires no such regulatory action. It is arbitrary and capricious and contrary to law for HHS to claim that [Italics: Bostock] requires HHS's expansion of sex discrimination under Section 1557 and provides grounds to support its rulemaking.

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[Bold: D. The Proposed Rule arbitrarily ignores that a person's sex is defined by biology.] Even the decision in [Italics: Bostock v. Clayton County] on which the Proposed Rule heavily relies explicitly assumed that "sex" referred "only to biological distinctions between male and female." [Footnote 80: Bostock 140 S. Ct. at 1739 (2020).] It is arbitrary and capricious for the proposed rule to avoid specifying precisely what sex in medicine and science means and how it relates to medical necessity with respect to gender dysphoria treatments. The concept of gender dysphoria is meaningless without sex just as transgender transition as a procedure medically necessary or is meaningless. What would a person be transitioning to and from exactly? If the agency cannot answer such a basic question with any semblance of scientific and medical rigor it has no basis to mandate coverage of such "transition" treatments and procedures in any context and certainly not as an essential health benefit. Moreover not only [Italics: must] the agency answer the question of what sex is in medicine it must answer it correctly and in accordance with logic and science.

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As Congress did not intend to include "gender identity" and "sexual orientation" in the Affordable Care Act the Department does not have authority to promulgate the proposed rules. The Department cannot legislate in the place of Congress through administrative rulemaking. By doing so in this NPRM the Department has proposed rules that are arbitrary and capricious. Even if Bostock applies to Section 1557 (and Arkansas DHS does not concede that it does) the holding is very limited and does not support the Department's expansive application in the proposed rules. It is a very long stretch between Bostock's prohibition against firing an individual based on sexual orientation and gender identity and the Department's explanation requirement for coverage for gender-affirming treatment. The Department's proposed regulations reach into nearly every aspect of healthcare in the United States and well beyond any prohibition against discrimination based in the holding of Bostock.

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Arkansas Department of Human Services

[Bold: G. The HHS interpretation of "sex" to include "gender identity" arbitrarily expands the scope of protection afforded under Section 1557 to a set of undefined poorly defined or open-ended categories.] Similar to FDA's expansion of "sex" to include "gender identity" protections under Title IX HHS proposes to expand Section 1557's sex discrimination protections to "gender identity." In addition it injects additional undefined or poorly defined terms into the Rule signaling its intent to afford anti-discrimination protections to these new categories. As described below HHS's expansive actions gives these new categories protected status. However given the undefined or poorly defined definition of these new categories it is nearly impossible to determine the exact scope of the Proposed Rules rendering it arbitrary and capricious to extend anti-discrimination protections to undefined and novel categories. Healthcare entities insurers and providers have a right to be given notice and clarification of the extent of their legal obligations and the HHS actions deprives them of this right.

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HHS claims the Proposed Rule is necessary "to better align the Section 1557 regulation with the statutory text … to reflect recent developments in civil rights case law to address unnecessary confusion in compliance and enforcement resulting from the 2020 Rule and to better address issues of discrimination that contribute to negative health interactions and outcomes." [Footnote 7: 87 Fed. Reg. 47823.] It also claims its proposed regulations are "consistent with the statutory text of Section 1557 and Congress's intent." [Footnote 8: 87 Fed. Reg. 47824.] As explained in more detail below the Proposed Rule contradicts 1557's statutory text and the text of Title IX which it incorporates by reference furthers the polar opposite of Congressional intent ignores relevant case law adds unnecessary confusion in compliance and enforcement and arbitrarily capriciously and dangerously meddles in the practice of medicine and expands the scope of discrimination under 1557 beyond reasonable bounds. Indeed the Proposed Rule fails to point to any legislative history indicating Congress ever contemplated application of sexual orientation gender identity or transgender status under Section 1557 in the Affordable Care Act (ACA).

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HHS claims that the 2020 Rule "ensure[s] the Department's mission of pursuing health equity and protecting public health." [Footnote 9: 87 Fed. Reg. 47823.] Indeed, on September 30 2022 Vice President Harris stated in an interview about "disparities" and climate events "her belief that "our lowest income communities and our communities of color [] are the most impacted by these extreme conditions . . . so we have to address this in a way that is about [taking] giving resources based on equity[]" and "making sure that the bad actors pay a price for what they do that is directly harming [those] communities in terms of their health and well being." [Footnote 10: Privanka Chopra Junas Interview of Kamala Harris before the Democratic National Committee's Women's Leadership Forum in Washington D.C. (Sept. 30 2022) https://youtu.be/o9SDaVB79Hk.] But the mission of HHS is to "enhance the health and well-being of [] all Americans by providing for effective health and human services and by fostering sound sustained advances in the sciences underlying medicine public health and social services." [Footnote 11: U.S. Dep't Health & Human Servs. Introduction About HHS https://www.hhs.gov/about/strategic-plan/2022-2026/introduction/index.html#:~:text=mission%20is%20to%20enhance%20the,sciences%20underlying%20medicine%20public%20health%20and%20social%20services." [Footnote 12: U.S. Dep't Health & Human Servs. Introduction About HHS https://www.hhs.gov/about/strategic-plan/2022-2026/introduction/index.html#:~:text=mission%20is%20to%20enhance%20the,sciences%20underlying%20medicine%20public%20health%20and%20social%20services. (emphasis added)] | There is nothing in HHS's mission statement about "health equity." [Footnote 12: For example several states employed discriminatory racial set asides for their federally funded COVID-19 vaccine distribution to promote "health equity." EPPC along with Boyden Gray & Associates filed a complaint on behalf of a New Hampshire resident whom the state prohibited from receiving a COVID-19 vaccine solely because of his race. Cf. EPPC and Boyden Gray & Associates Demand HHS Hold New Hampshire Accountable for Unlawful Racial Set Asides in COVID-19 Vaccine Distribution https://eppc.org/news/eppc-and-boyden-gray-associates-demand-hhs-hold-new-hampshire-accountable-for-unlawful-racial-set-asides-in-covid-19-vaccine-distribution/. Despite the clear obligations of Section 1557 and Title VI of the Civil

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Although the Rule's "gender identity" language is clearly intended to apply to children in the context of health care and the Rule also attempts to establish "gender affirming care" as the standard of care for non-discriminatory treatment of gender dysphoria the Rule's failure to address the growing controversy over the provision of "gender affirming care" to minors including medical and surgical interventions that carry permanent consequences is shocking. HHS instead glosses over the growing international backlash against the use of permanent or life-altering medical and surgical interventions—styled as "gender affirming care"—with minors. HHS's reliance on the discredited WPATH standards is another indicator of the arbitrary and capricious nature of the Proposed Rule. [Footnote 181: Coleman E. Standards of Care for the Health of Transgender and Gender Diverse People Version 8. International Journal of Transgender Health Vol. 23 Issue 1 (2022): CORRECTION Statement of Removal. International Journal of Transgender Health 23(sup1):p S259 | especially in light of the recent WPATH action eliminating all minimum age recommendations for medical and surgical "gender affirming" treatments for minors. [Footnote 182: Lane B. Not Up to Standard Gender Clinic News September 28 2022 https://genderclinicnews.substack.com/p/not-up-to-standard.] Detransitioners are the tragic victims of the "dangerous medicine" that masquerades as "gender-affirming care." They are predominantly young people who after being hurried down the "gender affirming" path of permanent body alterations eventually realized the harm wrought by the pursuit of the "gender identity" mirage. Their testimonies are compelling and deserve to be heard. In refusing to hear the testimony of de-transitioners HHS betrays its bias and demonstrates once again the arbitrary and capricious nature of the Proposed Rule.

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As a textual barrier applying sex discrimination prohibitions to a religious institution to the extent it "would not be consistent with the religious tenets of such organization" is not a ground prohibited under Title IX. Further Title IX's prohibition against sex discrimination is in 20 U.S.C. § 1681(a) as is the religious exemption (§ 1681(a)(3)). Title IX's sex discrimination prohibition cannot be read separate and apart from the exemptions—especially those in the same section! To say otherwise would be arbitrary and capricious and contrary to law.

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The Proposed Rule states that "the application of the Title IX exception for religious control or religious organizations in particular could raise distinctive concerns in the health care context that are not typically present in education programs and activities." [Footnote 203: 87 Fed. Reg. 47841.] The Department gives several examples such as "the ability of affected parties to choose or avoid a certain religiously affiliated health care institution and the urgency of the need for services provided by the covered entities." [Footnote 204: Id.] It alleges that "patients seeking health care are much more likely to be driven by considerations of availability convenience and urgency geography cost insurance network restrictions and other factors unrelated to the question of whether the health care provider is controlled by or affiliated with a religious organization." HHS fails to provide support for this statement making its reasoning arbitrary and capricious. Countless patients including the undersigned seek health care specifically from a provider that shares their religious beliefs even if such a provider is less convenient further away or costs more. HHS states that in many communities patients may have no other option than to seek health care from religious affiliated providers indicating that patients do have preferences regarding the religious nature of the health care provider and do make care decisions based on such affiliation. HHS cannot disregard the statutory protections of the Section 1557 of the ACA and its obligations under the First Amendment RFRA and federal conscience and religious freedom protection laws to promote the ACA's general principal objective of increasing access to health care." [Footnote 205: 87 Fed. Reg. 47843.]

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HHS also claims that the 2020 Rule "caused confusion in compliance by failing to provide clear procedural requirements." [Footnote 14: 87 Fed. Reg. 47830.] This is mere speculation. HHS fails to cite to any entity complaint or enforcement action that demonstrates such confusion exists. Making such a claim without substantive concrete evidence is arbitrary and capricious.

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We have included numerous citations to supporting research including direct links to the research. We direct HHS to each of the materials we have cited and made available through active links and we request that the full text of each of the studies and articles cited along with the full text of our comment be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If HHS is not planning to consider these materials part of the record as we have requested here we ask that you notify us and provide us an opportunity to submit copies of the studies and articles into the record.

Just cause in Aging

The Proposed Rule arbitrarily and capriciously fails to recognize the biological reality that only females can get pregnant and give birth—a reality that is recognized in the ACA itself. [Footnote 235: See e.g. ACA Section 2301 ("pregnant women"); Section 2951 ("a woman who is pregnant"); Section 1943 ("pregnant women"); Section 2303 ("pregnant women"), Section 2801 ("pregnant women"); Section 511 ("pregnant women"); Section 2952 (relative mental health consequences for women of resolving a pregnancy); Section 10213 ("pregnant and parenting women"), see also Section 3021 ("women's unique health care needs").] The Proposed Rule states that "transgender man or nonbinary person assigned female at birth" can give birth. [Footnote 236: 87 Fed. Reg. 47865.] No one is "assigned female at birth", a person is [or is not] a female and that biological reality is recognized at birth. Second men cannot get pregnant or give birth and to imply otherwise is insulting and degrading to women. HHS as a federal health organization should not continue perpetuating unscientific fallacies and misinformation when it comes to human reproduction. Proposed § 92.2(d)(b) [Should not use the nonsense and unclear phrase "sex assigned at birth." There is a more precise word that should be used—sex.

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It is arbitrary and capricious for HHS to rely on Title IX regulations to prohibit discrimination based on pregnancy related conditions [and marital parental and family status] while ignoring and refusing to rely on Title IX's statutory abortion neutrality provision and religious exemption. 45 CFR 92.6(b) should not be repealed.

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deny or limit services based on "gender identity." Is there any claim for service that could be denied? At any age? The Department must answer whether "gender affirming care" is for any claim related to one's identity and it must provide the specific objective criteria that defines the limits of such treatments. If the Department is unable to clearly delineate the areas or services required, it is further proof that this Rule is arbitrary and capricious. The Department must answer these questions: What specific exclusive list of treatments and procedures constitute "gender affirming care?" Does it cover any cosmetic plastic surgery for any individual to change body appearance, reshape body parts and alter sexual function? Does it include coverage for breast binders for youth, mastectomies and hysterectomies for teenage girls, cosmetic surgeries for lightening or masculinizing characteristics, prosthetic penises or breast augmentation for male bodies and female bodies? Without an exhaustive list of procedures and the objective enforceable criteria for when these procedures are indicated under the Rule's "gender affirming care" mandate, this Rule is arbitrary and capricious. Because the Rule is entirely vague, it is necessary for the Department to establish clearly whether "gender affirming care" includes all manner of health care treatments, behavioral, mental and physical that might affirm an individual's actual sex, including reassigning with that sex in addition to any desired features, functions, thoughts and appearance of sex. To deny coverage, services and procedures designed to assist an individual to align with his or her bodily sex and function would be sex discrimination. The requirement for nondiscriminatory care carries with it the obligation that covered entities for any health service or procedure that he is an individual conforms to his or her natural sex and sexual function. To be nondiscriminatory, it must also include any desired appearance that is consistent with a person's sex. Nothing can be denied, including all cosmetic surgeries and elective procedures.

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Concerned Women for America

Fortunately, there are effective ways to bolster this outrageous attempt to impose an extreme agenda on the United States. Legal challenges can give judges an opportunity to strike rule or to enjoin HHS from implementing it. Where immediately everyone has the right to contribute public comments on the rule. Here for a 60-day period ending in October. These comments must be taken into consideration by HHS and because HHS must respond to them, could even delay the process. If there is sufficiently large number of comments. I encourage individuals and institutions to join The National Catholic Bioethics Center and many other groups who will be fighting the good fight on this.

5. We suggest that either the preamble to the Rule the Rule or accompanying guidance give further examples of discrimination on the basis of disability. Specific illustrations would be helpful.

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

As further explained below, we also urge HHS to (1) work with other agencies with Section 1557-covered programs to adopt a Section 1557 Common Rule, (2) expressly enumerate nondiscriminatory protections in CMS and other health program-specific regulations; and (3) use its existing statutory authorities to extend, clarify and enforce nondiscriminatory protections in its human services programs.

InterACT: Advocates for Intersex Youth

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Advocates for Intersex Youth

expanding coverage under the ACA to include critically important sexual and reproductive health services such as gender affirming care. This care can include a range of medical services for example hormone replacement therapy that seek to assist an individual in affirming their gender identity. Additionally it is also a matter of significance especially in the wake of the Dobbs v. Jackson [embedded hyperlink text (https://www.supremecourt.gov/opinions/21pdf/19-1392_6j37.pdf)] decision for the Affordable Care Act to extend coverage to all pregnancy-related services including abortion care. Access to abortion care is already fraught with obstacles for individuals who can become pregnant but even more so for LGBTQIA+ individuals. A 2019 study [embedded hyperlink text (https://sexrepbmj.com/content/familyplanning/48/2/122.full.pdf)] found that 7% of transgender gender-nonconforming and non-binary individuals who became pregnant considered ending their own pregnancy without clinical supervision due to cost and lack of insurance. Further many studies have outlined that LGBTQIA+ people have a greater need for access to abortion care according to a medical guideline [embedded hyperlink text (https://www.glaad.org/blog/LGBTQAphorismatics)] developed by GLAAD. Ultimately it is also important for an understanding to be shared universally about the contribution of comprehensive sex education towards the destigmatization and increased knowledge of sexual and reproductive health services that include gender affirming care and abortion care. Comprehensive sex education teaches developmentally appropriate content surrounding sexual orientation and gender identity and is inclusive of LGBTQIA+ identities especially transgender gender non-conforming and/or non-binary individuals. This education also intends to affirm these identities and provide an inclusive understanding of healthy bodily development that can involve access to gender affirming care. Similarly comprehensive sex education also encompasses IV. [Bold: The final rule should explicitly prohibit intersectional discrimination.] As noted above Black women Black LGBTQ+ people and others may face discrimination simultaneously based on multiple protected characteristics creating distinct harms. While we appreciate HHS' discussion of intersectional discrimination in the preamble OCR should clearly state that Section 1557 protects against intersectional discrimination throughout the regulatory text. This approach would avoid inconsistent application of Section 1557 and ensure that Section 1557 provides adequate redress for those living at the intersection of multiple identities.

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SIECUS: Sex Ed for Social Change

NAACP Legal Defense and Education Fund, Inc.

clinical algorithms we recommend HHS both in this rulemaking and in future guidance take action to ensure equitable access to quality health care and LTSS for people of color. For example [Bold: HHS should issue guidance on affirmative obligations or prescriptive requirements to prevent discrimination based on race and color akin to its guidance on language access especially in LTSS.] There is growing evidence of race-based discrimination in the context of nursing facility admissions hospitalization of residents facility staffing levels and more. [Footnote 38: Justice in Aging Racial Disparities in Nursing Facilities—and How to Address Them (Sept. 2022) https://justiceinaging.org/wp-content/uploads/2022/09/Racial-Disparities-in-Nursing-Facilities.pdf.] In such guidance HHS should also explicitly account for the impact of industry changes such as the growth of Medicare Advantage or access to health care and insurance by people of color. For example in 2018 30% of Black and 34% of Hispanic people with Medicare were enrolled in a Medicare Advantage plan compared to only 16% of white enrollees. [Footnote 39: Kaiser Family Foundation Racial and Ethnic Health Inequities and Medicare (Feb. 16 2021) https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.] Yet there is little evidence that MA plans ever those intended to better coordinate Medicare and Medicaid are better alternatives for older adults of color. [Footnote 40: Eric T. Roberts & Jennifer Mellor Differences in Care Between Special Needs Plans And Other Medicare Coverage For Dual Eligibles Health Affairs (Sept. 2022) www.healthaffairs.org/doi/10.1377/hlthaff.2022.00464.] "Compared with non-Hispanic White dual eligibles dual eligibles of color [for example those identifying as Black or Hispanic] were less likely to report receiving better care in D-SNPs versus other Medicare coverage. These findings suggest that D-SNPs altogether have not provided consistently superior or more equitable care and they highlight areas where federal and state policy could strengthen incentives for D-SNPs to

Justice in Aging

internally.] Since the first transitioning surgeries were performed in the U.S. in adults in the mid-20th century to the present day there has been no medical consensus regarding the authoritative standard of care to treat gender dysphoria [previously "gender identity disorder"] in minors or to evaluate the risks and benefits of medically assisted "transitions." "Historically there have been uneven and at times competing trajectories in the development of therapeutic responses to gender dysphoria, diagnostic labels criteria and interventions have evolved significantly over a relatively short time. [Footnote 136: The APA's Diagnostic and Statistical Manual (DSM) changed terminology and diagnostic criteria as follows "transsexualism" (DSM-III) "gender identity disorder" (DSM-IV) and "gender dysphoria." Gender Dysphoria Diagnosis Am. Psychiatric Ass'n (2022) https://www.psychiatry.org/psychiatrists/diversity/education/transgender-and-gender-nonconforming-patients/gender-dysphoria-diagnosis.] The American Psychiatric Association [APA] defines gender dysphoria as "clinically significant distress or impairment related to a strong desire to be of another gender which may include desire to change primary and/or secondary sex characteristics." [Footnote 137: What Is Gender Dysphoria? Am. Psychiatric Ass'n (Nov. 2020) https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria.] An "inherently subjective phenomenon" gender dysphoria is variously classified as "a mental disorder" or "a condition related to sexual health." [Footnote 138: The APA classifies "gender dysphoria" under mental health disorders while the World Health Organization classifies "gender incongruence" under "sexual health." Kar Gerritse et al. Decision-Making Approaches in Transgender Healthcare: Conceptual Analysis and Ethical Implications 24 Med. Health Care & Phil. 687-686 (2021) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8557156/.] Until recently responding to a child's gender dysphoria with "watchful waiting" or family

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Children's Hospital in 2007 and used puberty suppression as a transitioning treatment for minors. With scant research available he viewed "stopping puberty" as "a diagnostic test." [Footnote 141: Pagan Kennedy Q & A with Norman Spack Boston.com (archives.boston.globe) (Mar. 30 2008) http://archive.boston.com/bostonglobe/ideas/articles/2008/03/30/q_a_with_norman_spack/?page=full.] If it brought relief the diagnosis was right. No professional medical society recommended medically treating gender dysphoria in minors until 2009. [Footnote 142: Edwards-Leeper & Norman P. Spack Psychological Evaluation and Medical Treatment of Transgender Youth in an Interdisciplinary "Gender Management Service" (GeMS) in a Major Pediatric Center 59 J. Homosexuality 321 323 (2012) https://pubmed.ncbi.nlm.nih.gov/22455323/.] When the Endocrine Society's then-newly-released Clinical Practice Guidelines supported puberty suppression and cross-sex hormones for minors—despite lacking "rigorous evaluation of the effectiveness and safety of endocrine protocols." [Footnote 143: Wylie C. Hembree et al. Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline 94 J. Clinical Endocrinology & Metabolism 3132 3134 (2009) https://academic.oup.com/jcem/article/94/9/3132/2597346.] In 2012 the World Professional Association for Transgender Health [WPATH] an advocacy group and early promoter of medical trans-identifying for minors noted that adoption of medical transitioning for minors "differs among countries and centers." Not all clinics offer puberty suppression ... The percentages of treated adolescents are likely influenced by the organization of health care insurance aspects cultural differences opinions of health professionals and diagnostic procedures offered in different settings." [Footnote 144: World Prof'l Ass'n for Transgender Health Standards of Care for the Health of Transsexual Transgender and Gender Nonconforming People Version 7 13 (2012) [hereinafter "WPATH SOC 7"].

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offering transitioning treatments for minors the number of minors seeking and receiving them has skyrocketed. So too has the number of gender clinics for minors growing from one in 2007 to over 60 today. [Footnote 152 Comprehensive Care Clinics | Human Rights Campaign Foundation https://www.thehrcfoundation.org/professional-resources/comprehensive-care-clinics.] But market expansion should not be mistaken for a medical consensus. The next chapter in treatment for gender dysphoria is still being written. Many countries that initially embraced transitioning treatments including for minors are now reconsidering. For example Sweden's National Board of Health and Welfare commissioned an extensive evidence review and concluded in 2022 "that the risks of early puberty and sex-confirming hormone treatment for those under 18 currently outweigh the possible benefits." [Footnote 153 Systematic Investigation and Hormone Treatment for Gender Incongruence in Children and Adolescents – Partial Update of Knowledge Support | 2022] https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-7-7774.pdf, see also Inga Nainggolan Hormonal Tx of Youth with Gender Dysphoria Stops in Sweden Medscape (2021) https://www.medscape.com/viewarticle/950960.] Finland likewise has reversed course. Following an extensive literature review the Finish Health Authority issued new guidelines that prioritize psychotherapy as the first line treatment for gender dysphoric minors. [Footnote 154 Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland) Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors |2020| available at https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf. COHERE Finland works in conjunction with the Ministry of Social Affairs and Health in the United Kingdom whistleblower complaints statement emphasizing mental health treatment for gender dysphoric minors rather than "gender affirmation." They stressed the importance of assessing the "psychological state and context in which gender dysphoria has arisen" before any treatment decisions are made. [Footnote 161: Position Statement The Royal Australian and New Zealand College of Psychiatrists Recognising and Addressing the Mental Health Needs of People Experiencing Gender Dysphoria/Gender Incongruence (Aug. 2021) https://www.ranzcp.org/news-policy/policy-documents-and-advocacy/position-statements/gender-dysphoria.] In February 2022 France's National Academy of Medicine warned medical professionals that the increase in young people seeking transitioning treatments may be due to social contagion and urged "great medical caution." [Footnote 162 Press Release French National Academy of Medicine Medicine and Gender Transidentity in Children and Adolescents (Feb. 25 2022) https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en. In short within the international medical community "gender affirming care" for minors in particular is not backed by a supportive consensus. This lack of consensus is also reflected among U.S. medical professionals. In the months leading up to its 2022 national conference the American Academy of Pediatrics [AAP] was accused by some of its own members of "censoring" concerns over the use of gender affirming medical and surgical interventions for minors amid a rising outcry from clinicians and parents. [Footnote 163 Abiga Anthony American Academy of Pediatrics Accused of Censoring Concerns about 'Gender-Affirming' Care National Review July 29 2022 https://www.nationalreview.com/2022/07/american-academy-of-pediatrics-accused-of-censoring-concerns-about-gender-affirmative-care/.] Parent organized protests at gender clinics across the U.S. including at Boston Children's Hospital's flagship program underscore the rising numbers of Americans who [illegible] consensus. [Despite the efforts under the current administration to push transitioning treatments for minors and notwithstanding the Proposed Rule the federal government has never formally determined that such treatments are the appropriate standard of care. As recently as June 2020 HHS regulators acknowledged that "there is no medical consensus to support one or another form of treatment for gender dysphoria." 85 Fed. Reg. 37160 37198. The Department explained that prior HHS regulations regarding gender transition surgeries "relied excessively on the conclusions of an advocacy group [WPATH] rather than on independent scientific fact-finding" such as the CMS factfinding for its most recent National Coverage Determination. After its factfinding CMS declined to issue a National Coverage Determination on gender transition surgeries for Medicare beneficiaries with gender dysphoria "because the clinical evidence is inconclusive." [Footnote 165 CMS Decision Memo for Gender Dysphoria and Gender Reassignment Surgery CAG–00446N (Aug. 30 2016) [hereinafter "CMS Decision Memo"] https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282.] "Based on an extensive assessment of the clinical evidence" CMS determined that "there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries [which include nursing home residents] with gender dysphoria and whether patients most likely to benefit from these types of surgical interventions can be identified prospectively." [Footnote 166 Id.] Similarly a 2018 Department of Defense [DOD] report on gender dysphoria found that there is "considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments such as cross-sex hormone therapy and sex reassignment surgery interventions which are unique in psychiatry and medicine remedy the multifaceted mental health problems associated with gender dysphoria." [illegible] the lack of medical consensus for the appropriate standard of care for gender dysphoria and transitioning interventions especially for minors. For instance several states have passed laws that prohibit providing minor children with transitioning treatments. [Footnote 169 See e.g. Ariz. S.B. 1138 (2022); Ark. H.B. 1570 [2021], Tenn. H.B. 0578 [2021]; Ala. S.B. 184 [2021].] Other states have and are considering similar bills. State executives also have weighed in on the issue. For example in February 2022 the Texas Attorney General issued an opinion either stating that sterilizing treatments and other permanent "sex-change procedures" including puberty suppressing cross-sex hormones and various surgeries "can constitute child abuse when performed on minor children." [Footnote 170: Tex. Att'y Gen. Op. Letter No. KP 0401 from Ken Paxton Attorney General to Matt Krause Chair House Committee on General Investigating Texas House of Representatives 1-2 [Feb. 18 2022] https://www.texasattorneygeneral.gov/sites/default/files/opinion-files/opinion/2022/kp-0401.pdf.] Texas's governor subsequently directed the Texas Department of Family and Protective Services to "conduct a prompt and thorough investigation of any reported instances of these abusive procedures in the State of Texas." [Footnote 171 Letter from Greg Abbott Governor State of Texas to Jaime Masters Commissioner Texas Department of Family and Protective Services [Feb. 22 2022] https://gov.texas.gov/uploads/files/press/Untitled_Masters_Jaime_2022222172358.pdf.] More recently Florida's Department of Health issued guidelines in response to an HHS document promoting "gender affirming care" for young people. Florida's DOH claimed that the treatment of gender dysphoria for children and adolescents should [italics: not] include social gender transition puberty blockers cross-sex hormones or transitioning surgeries because of "the lack of conclusive evidence and the potential for long-term irreversible effects." [Footnote 172 Office of the State Surgeon Gen. Fla. Dep't of Health

As discussed previously we appreciate HHS's recognition of intersectional discrimination and its unique harm for e.g. older adults of color and "individuals who experience both transphobia and racism." [Footnote 57 87 Fed. Reg. at 47870.] In addition to explicitly stating that Sec. 1557 prohibits intersectional discrimination under § 92.101 we urge HHS to recognize intersectional causes of action in the rule itself. The rule will be a stronger tool against intersectional discrimination if it clarifies that the multiple grounds on which individuals are protected against discrimination under Sec. 1557 are overlapping and additive and are not to be considered in isolation from each other.

[Bold: No Additional Reporting Requirements Without Funding. We also request that no reporting requirements be imposed unless it is supported by funding. As you know IHS Tribal facilities and UIDs are often understaffed and underfunded and therefore the burden on them is higher when it comes to designating reporting duties to staff. Tribal facilities also face unique difficulties hiring in remote and rural locations where many Tribal facilities are located. The IHS Tribal facilities and UIDs cannot be asked to even their scarce funding to comply with additional reporting requirements.

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Justice in Aging

Tribal Technical Advisory Group to CMS (TTAG)

|Italics Outreach and Education."We encourage HHS to consider pairing clear enforcement mechanisms with robust outreach and education outside of the administrative rulemaking process. Although the notices of availability and non-discrimination will help with properly apprising individuals about their rights, more must be done to ensure that older adults, people with disabilities, and their caregivers know about their options to enforce Sec. 1557. We believe that robust outreach and education (through e.g. [Redacted, pre-decisional] models such as coordinators in low-income housing care coordinators through health plans and social services case managers at community-based organizations) is key to ensuring that individuals are aware of their rights and empowered to fight back against discrimination. An education strategy that relies solely on the notices of availability and non-discrimination is insufficient.

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Justice in Aging

We further urge OCR to build on this landmark rule by implementing a strategic, comprehensive approach to advancing equity, addressing sex-based discrimination, and protecting patient privacy rights for LGBTQI+ patients. For example, OCR should open civil rights and privacy compliance reviews of medical institutions known to perform genital or sterilizing surgeries on infants or young children with intersex traits, and should ensure its public-facing materials unequivocally and discuss discrimination against all members of the LGBTQ+ community, including transgender, non-binary, and intersex people.

All Members of Congress

of sex (e.g., by having [male or female] permits and accommodates separate facilities for males and females (toileting, locker rooms, etc.) and certain kinds of sex-specific activities and athletic competitions | failure in fulfillment of its statutory intent to ensure equality between males and females. While advancing equality between the sexes, Title IX permits separation "on the basis of sex" specifically to take account of biological differences between males and females. At the time Title IX was passed and implemented (or more—but legislators, psychologists, or the average person—would have understood "sex" to mean "gender identity." Nor would prohibiting discrimination on the basis of sex have been understood to apply to "gender identity" (the term was largely unknown in 1972, beyond the fields of psychiatry and psychology, and connoted a psychological disconnect from one's sexed body). In contrast, the notion of "sex stereotypes" later included in Title IX analyses was a familiar concept integral to cultural and political discussions of sex discrimination. Efforts to shoehorn "gender identity" into Title IX's protections against "sex discrimination" undercut the very purpose of Title IX, which was intended to ensure female equality, opportunity, safety, and privacy. Redefining "sex" to mean "gender identity" completely erases those protections and disadvantages [Italics: females] who rely on sex-based (not "gender identity") based protections to ensure their safety, privacy, and educational opportunities [including athletic opportunities]. Title IX's aim to protect reasonable sex-based distinctions not obliterate them. Consequently redefining "sex" (a biological reality) to include "gender identity" (a contradictory self-perception) does violence to the express intent of Title IX, which expressly permits sex-based distinctions in particular circumstances. In practical terms, interpreting discrimination protections "on the basis of sex" to privilege "gender identity" effectively guts Title IX of meaningful protections for females and threatens to erase 50 years of women's sex-based rights under the law. Title IX's sex-based

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Title IX. [Section 1557 incorporates Title IX, which provides "No person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving federal financial assistance." Footnote 39: 20 U.S.C. § 1681(a).] As such, analysis of Section 1557's redefinition of "sex" starts with an analysis of "Sex." Under Title IX, in recently proposed Title IX regulations, ED declines to define the term "sex" because "I argues "sex has long been addressed by courts and because it is not necessary for the regulations to define the term for all circumstances." [Footnote 39: 87 Fed. Reg. 41534.] At the same time, however, "to clarify the scope of Title IX's prohibition on discrimination on the basis of sex," ED proposes that discrimination on the basis of sex be expanded to "include" ("at a minimum") discrimination on the basis of "sexual orientation; gender identity; sex stereotypes [i.e., "fixed or generalized expectations regarding a person's aptitudes, behavior, self-presentation, or other attributes based on sex"]; sex characteristics [including "a person's physiological sex characteristics and other inherently sex-based traits" and "intersex traits"]; and pregnancy or related conditions (defined as "(1) Pregnancy, childbirth, termination of pregnancy, or lactation; (2) Medical conditions related to pregnancy, childbirth, termination of pregnancy, or lactation; or (3) Recovery from pregnancy, childbirth, termination of pregnancy, lactation, or their related medical conditions"). [Footnote 40: 87 Fed. Reg. 41535.] ED does not define "gender identity" or "discrimination on the basis of pregnancy." ED's Title IX Proposed Rule states that discrimination on the basis of sex includes "discriminating against an individual because, for example, they are or are perceived to be male, female, or non-binary, transgender or cisgender, intersex, currently or previously pregnant, lesbian, gay, bisexual, queer, heterosexual or asexual, or gender-conforming or gender-nonconforming. All such classifications depend at least in part on consideration of a person's sex." [Footnote 41: 87 Fed. Reg. 41532.] ED attempts

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ED relies heavily on the Supreme Court's decision in [Italics: Bostock v. Clayton County,] [Footnote 61: 140 S. Ct. 1731 (2020).] The Proposed Rule explains that the Department's "prior position [is] that Title IX's prohibition on sex discrimination does not encompass discrimination based on sexual orientation and gender identity is at odds with Title IX's text and purpose and the reasoning of the [Italics: Bostock] Court and other courts to have considered the issue in recent years—both before and after [Italics: Bostock]." [Footnote 62: 87 Fed. Reg. 41550.] ED claims that its proposed definition is "consistent with Bostock and other Supreme Court precedent" because [Italics: Bostock], "makes clear that it is impossible to discriminate against a person on the basis of sexual orientation or gender identity without 'discriminating against that individual based on sex' even assuming that sex refers only to certain 'biological distinctions.'" [Footnote 63: See 87 Fed. Reg. 47865.] The Department proposes to not include the word "transgender" in this proposed provision. This approach recognizes that the form of discrimination discussed herein may impact a range of individuals including transgender people, individuals with intersex conditions or people who may need these services but do not identify as transgender."[. . .]. [discussing "discrimination experienced by transgender and gender non-conforming individuals."]

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Finally, incorporating the Section 504 integration provision into Section 1557 fulfills the Olmstead v. L.C. mandate by requiring that all covered entities ensure services and programs are provided in the most integrated setting appropriate to the needs of the qualified individual with a disability. P&A has seen a private insurer whose utilization management process identified a "high cost" case where a person with a paralytic condition who did not affect their cognitive function who had been receiving home nursing care was put at risk of institutionalization. Home health care coverage under this private insurer is arguably discriminatory in that home health care for a number of people with this same condition has been denied coverage to remain in their homes. Additionally, this requirement applies to all state Medicaid agencies and ideally would result in a benefit design reassessment to ensure that people with disabilities are not unnecessarily segregated or institutionalized and incentivizes home and community-based services. Medicaid Home and Community Based waivers often use a cost limit to say that the costs of HCBS services may not exceed institutional cost which should allow for the provision of comparable services at lower rates in the community as compared to institutional costs that are generally higher. However states often use assessments which look at a person with disability's needs and allot funding limits for those services. Assessing what kinds of services and supports a person needs to live successfully in their least restrictive community environment should not be dependent on how much money is in the pot. Ensuring that comparable integrated community based services and supports are available is essential to escape the institutional model. Utilize the expertise and advice of institutional providers to figure out how this can happen for states who have not achieved sufficient HCBS systems.

ND Protection & Advocacy Project

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Gender-Affirming Care and Youth

WHAT IS GENDER-AFFIRMING CARE?

Common Terms: (in alphabetical order):

Cisgender – Describes a person whose gender identity aligns with their sex assigned at birth

Gender diverse or expansive – An umbrella term for a person with a gender identity and/or expression broader than the male or female binary. Gender minority is also used interchangeably with this term.

Gender dysphoria – Clinically significant distress that a person may feel when sex or gender assigned at birth is not the same as their identity.

Gender identity – One's internal sense of self as man, woman, both or neither.

Nonbinary – Describes a person who does not identify with the man or woman gender binary.

Transgender – Describes a person whose gender identity and or expression is different from their sex assigned at birth, and societal and cultural expectations.

Gender-affirming care is a supportive form of health care that consists of an array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people.

For transgender and nonbinary children and adolescents, early gender-affirming care is crucial to overall health and well-being as it allows the child or adolescent to focus on social transitions and can increase their confidence while navigating the health care system.

Why Does it Matter?

Research demonstrates that gender-affirming care improves the mental health and overall well-being of gender diverse children and adolescents.[1] Because gender-affirming care encompasses many facets of healthcare needs and support, it has been shown to increase positive outcomes for transgender and nonbinary children and adolescents.[2] Gender-affirming care is patient-centered and treats individuals holistically, aligning their outward, physical traits with their gender identity.

Gender diverse adolescents, in particular, face significant health disparities compared to their cisgender peers. Transgender and gender nonbinary adolescents are at increased risk for mental health issues, substance use, and suicide.[3] The Trevor Project's 2021 *National Survey on LGBTQ Youth Mental Health* found that 52 percent of LGBTQ youth seriously considered attempting suicide in the past year.[4]

As with all children and adolescents, a safe and affirming healthcare environment is critical in fostering better outcomes for transgender, nonbinary, and other gender expansive children and adolescents. It is also important for families and schools to provide a supportive environment.[5]

Affirming Care	What is it	When is it used	Reversible or not
Social Affirmation	Adopting gender-affirming hairstyles, clothing, name, gender pronouns, and restrooms and other facilities	At any age or stage	Reversible
Puberty Blockers	Using certain types of hormones to pause pubertal development	During puberty	Reversible

Hormone Therapy	Testosterone hormones for those who were assigned female at birth Estrogen hormones for those who were assigned male at birth,	Early adolescence onward	Partially reversible
Gender-Affirming Surgeries	"Top" surgery – to create male-typical chest shape or enhance breasts "Bottom" surgery surgery on genitals or reproductive organs Facial feminization or other procedures	Typically used in adulthood or case-by-case in adolescence	Not reversible

ADDITIONAL INFORMATION

American Academy of Pediatrics
Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents

World Professional Association for Transgender Health
Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People

The Endocrine Society
Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline

RESOURCES:

Lesbian, Gay, Bisexual, and Transgender Health | Healthy People 2030
Discrimination on the Basis of Sex | HHS Office of Civil Rights
Lesbian, Gay, Bisexual, and Transgender Health: Health Services | Centers for Disease Control and Prevention
Gender-Affirming Care is Trauma-Informed Care | The National Child Traumatic Stress Network
Gender Identity | The Trevor Project
Gender-Affirming Care Saves Lives | Columbia University
Family Support: Resources for Families of Transgender & Gender Diverse Children | Movement Advancement Project
Health Care for Transgender and Gender Diverse Individuals | ACOG
Five Things to Know About Gender-Affirming Health Care | ACLU
Transgender and Gender Diverse Children and Adolescents | Endocrine Society
Glossary of Terms | Human Rights Campaign
Genderspectrum.org

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[4] Trevor Project, National Survey on LGBTQ Youth Mental Health 2021 (2021), https://www.thetrevorproject.org/survey-2021/.

[5] Ryan C, Russell ST, Huebner D, Diaz R, Sanchez J. Family Acceptance in Adolescence and the Health of LGBT Young Adults. Journal of Child and Adolescent Psychiatric Nursing. 2010;23(4), 205-213. https://doi.org/10.1016/j.jadohealth.2018.02.003.

OASH | Office of Population Affairs

Gender-Affirming Care and Young People

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A safe and affirming healthcare environment is critical in fostering better outcomes for transgender, nonbinary, and other gender expansive children and adolescents. Medical and psychosocial gender affirming healthcare practices have been demonstrated to yield lower rates of adverse mental health outcomes, build self-esteem, and improve overall quality of life for transgender and gender diverse youth.[5,6] Familial and peer support is also crucial in fostering similarly positive outcomes for these populations. Presence of affirming support networks is critical for facilitating and arranging gender affirming care for children and adolescents. Lack of such support can result in rejection, depression and suicide, homelessness, and other negative outcomes.[7,8,9]

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(in alphabetical order)

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Additional Information

- Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline
- Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents | American Academy of Pediatrics
- Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People | World Professional Association for Transgender Health

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Resources

- Discrimination on the Basis of Sex | HHS Office of Civil Rights
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- National Institutes of Health Sexual & Gender Minority Research Office
- Family Support: Resources for Families of Transgender & Gender Diverse Children | Movement Advancement Project
- Five Things to Know About Gender-Affirming Health Care | ACLU
- Gender-Affirming Care is Trauma-Informed Care | The National Child Traumatic Stress Network
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- Genderspectrum.org
- Glossary of Terms | Human Rights Campaign
- Health Care for Transgender and Gender Diverse Individuals | ACOG
- Transgender and Gender Diverse Children and Adolescents | Endocrine Society

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[4] Trevor Project. (2021). *National Survey on LGBTQ Youth Mental Health 2021*. Trevor Project. https://www.thetrevorproject.org/survey-2021/.

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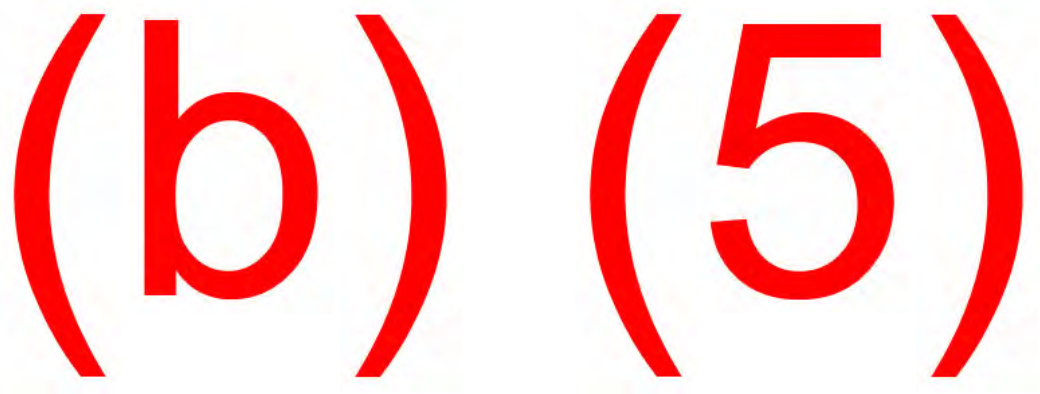
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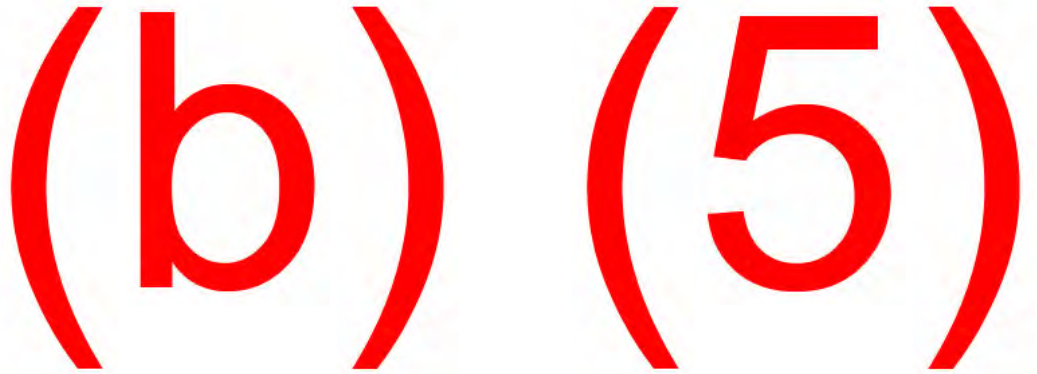
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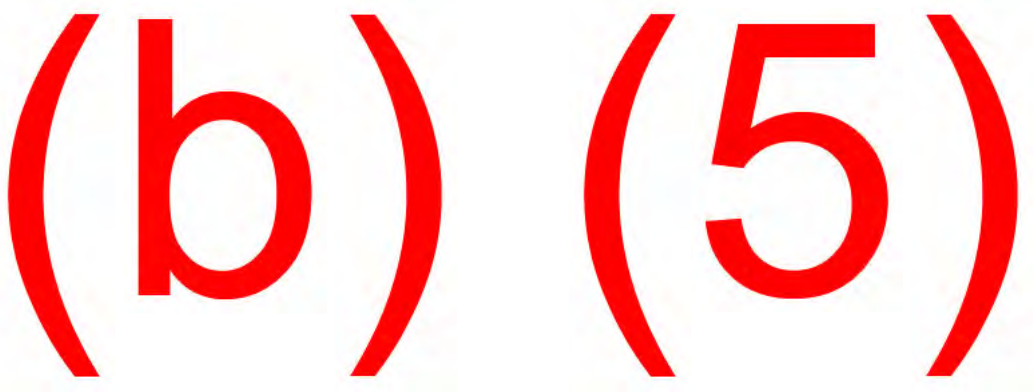
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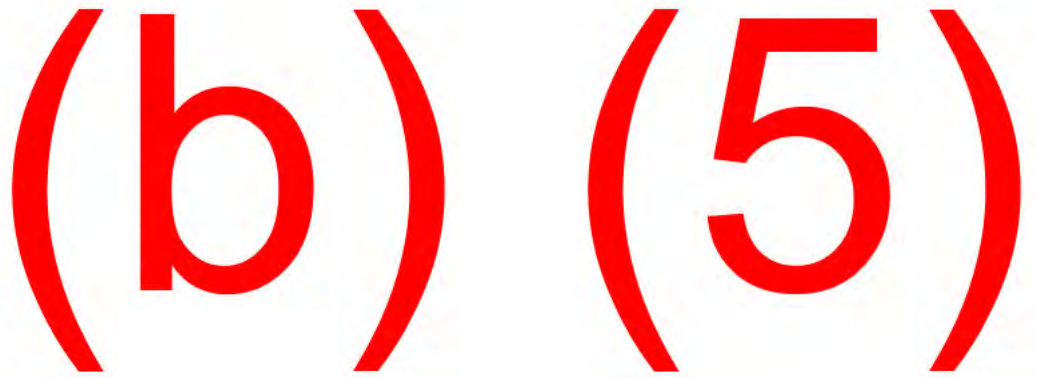

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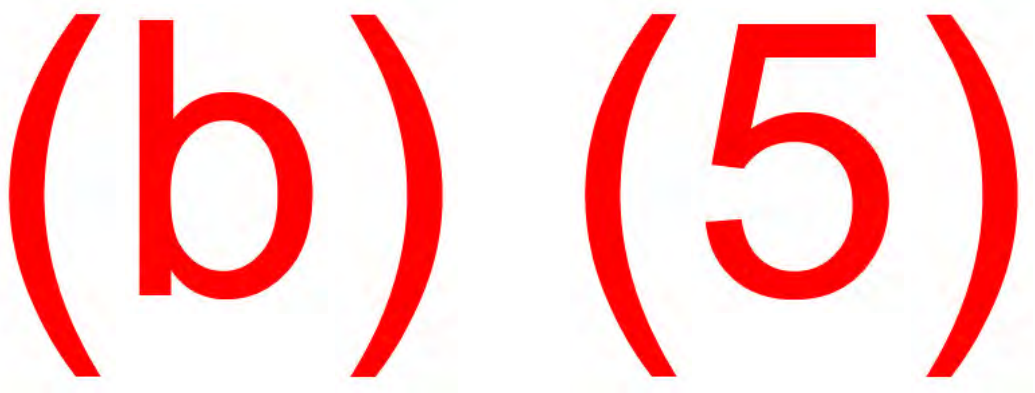
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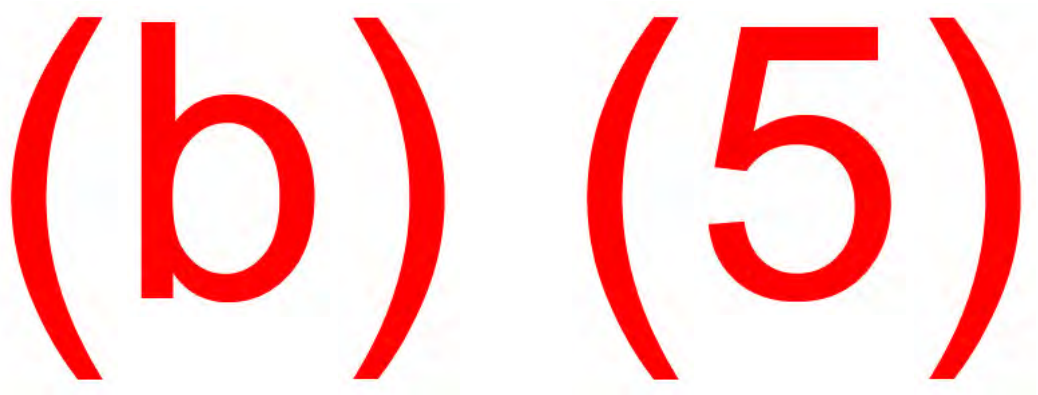

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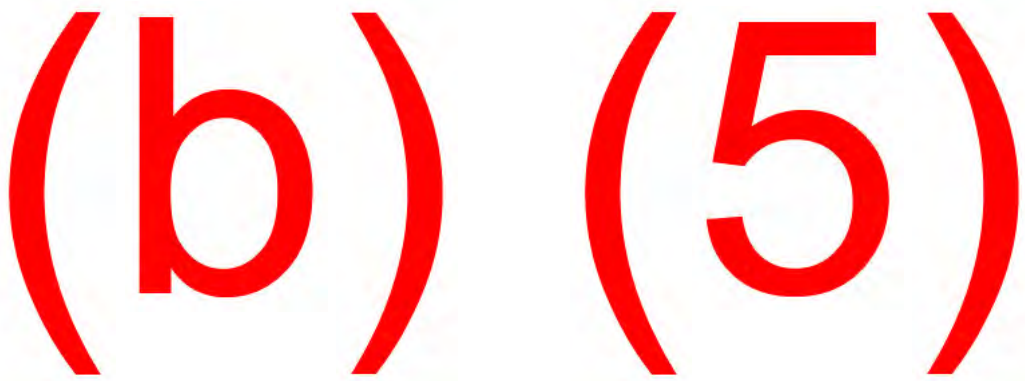
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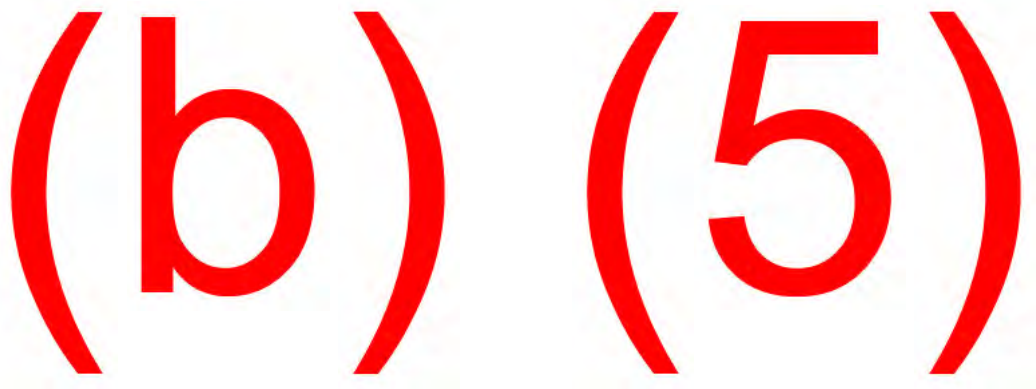
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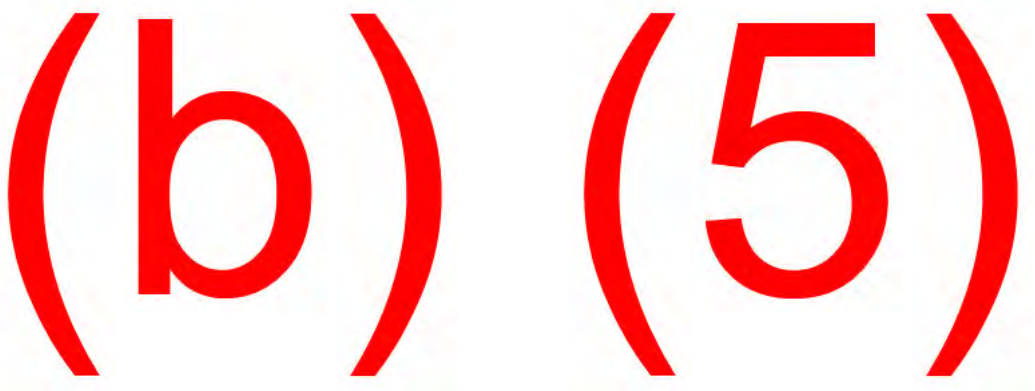

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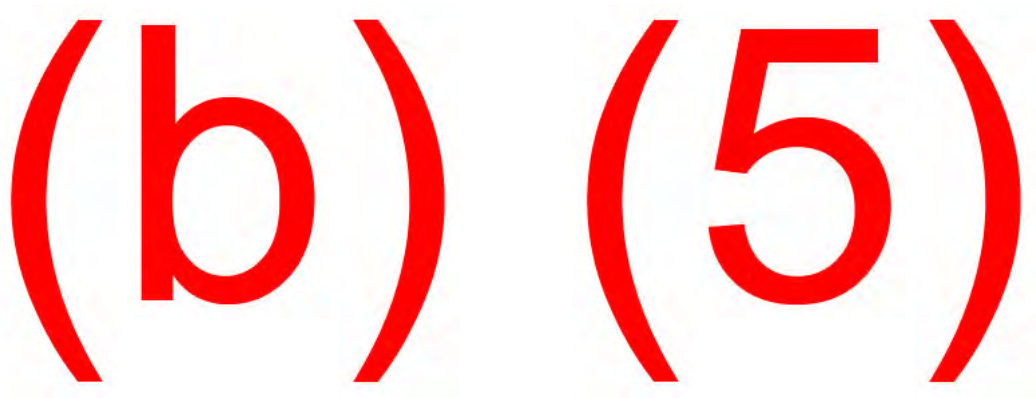
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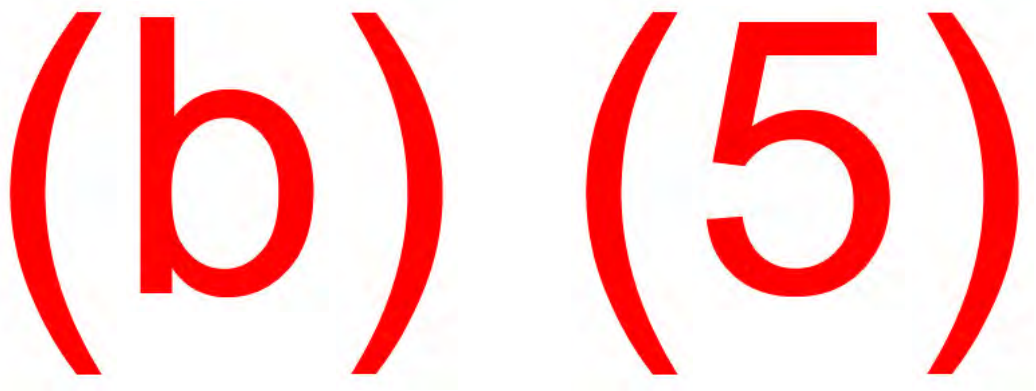

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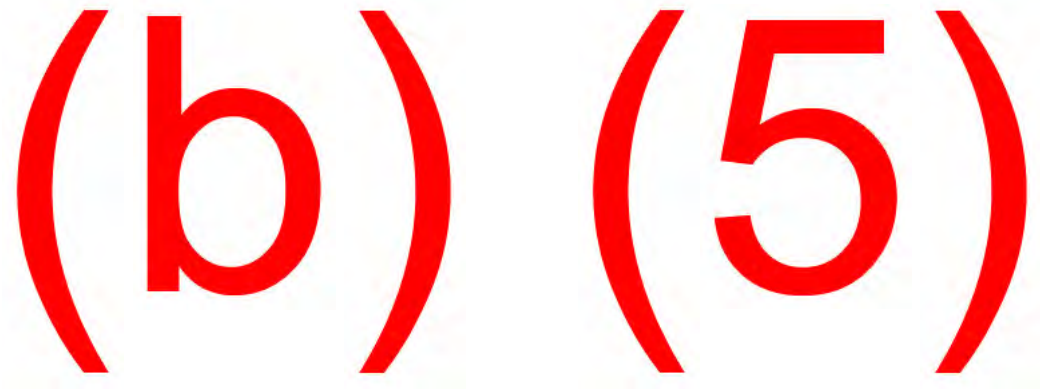

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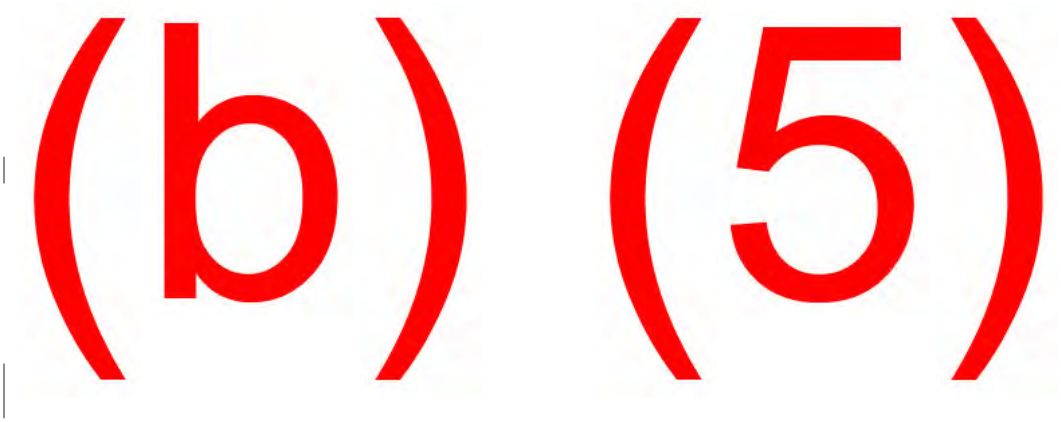
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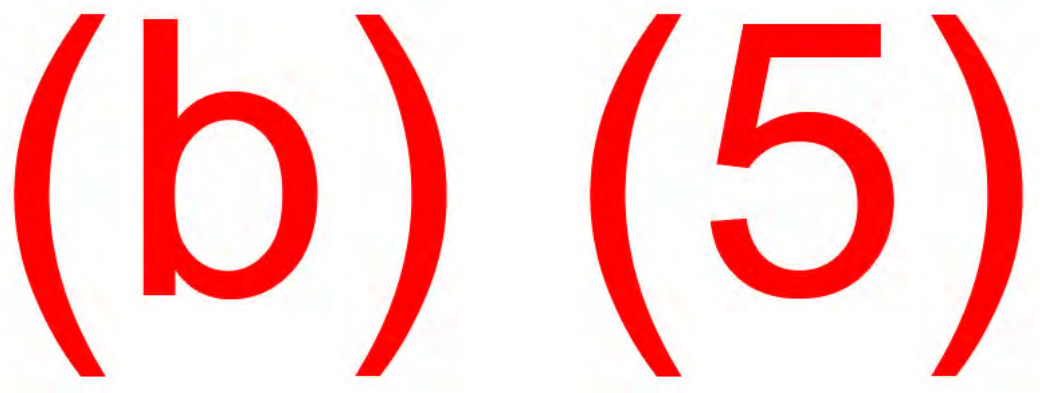
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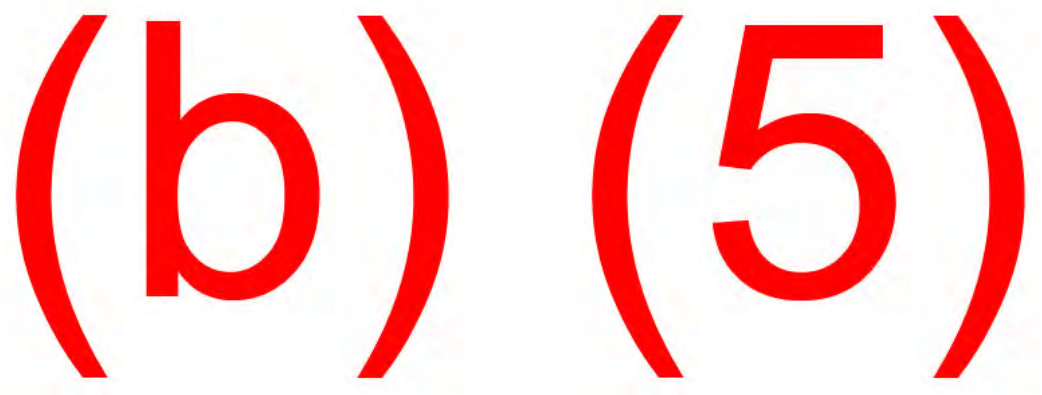

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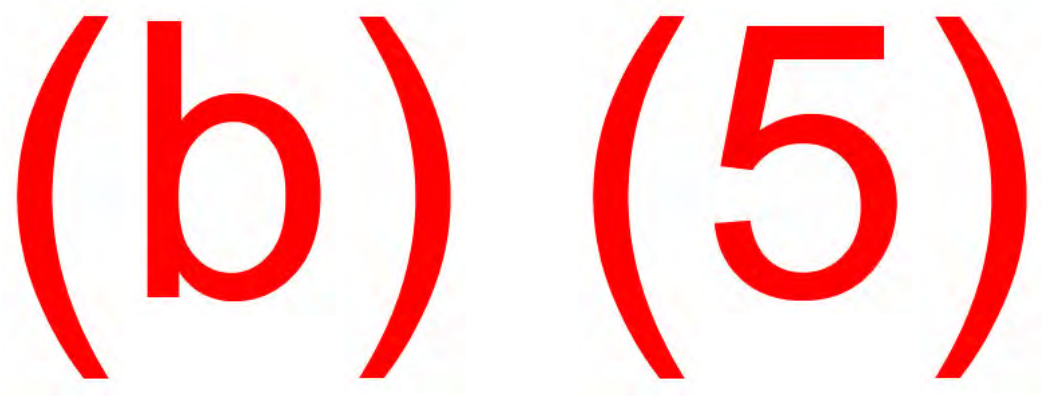
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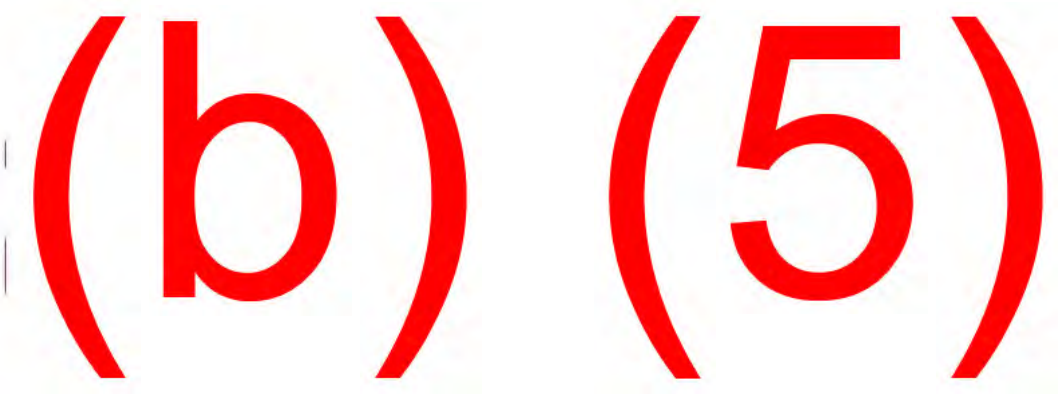
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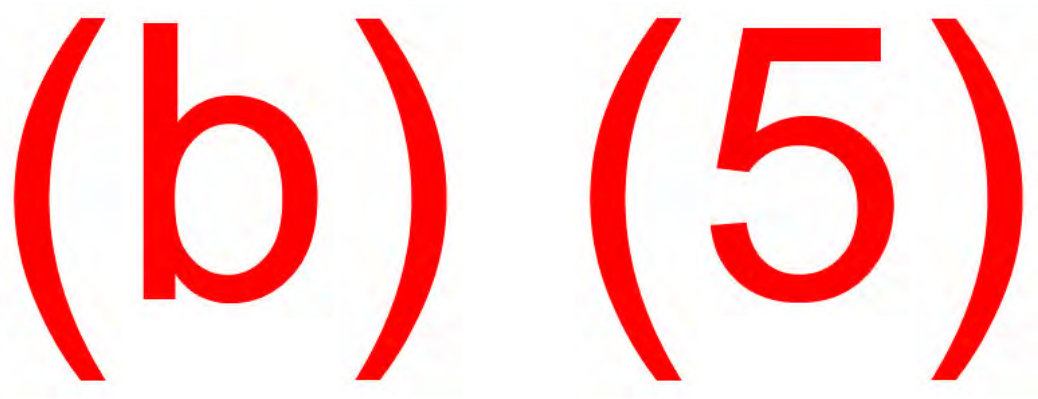
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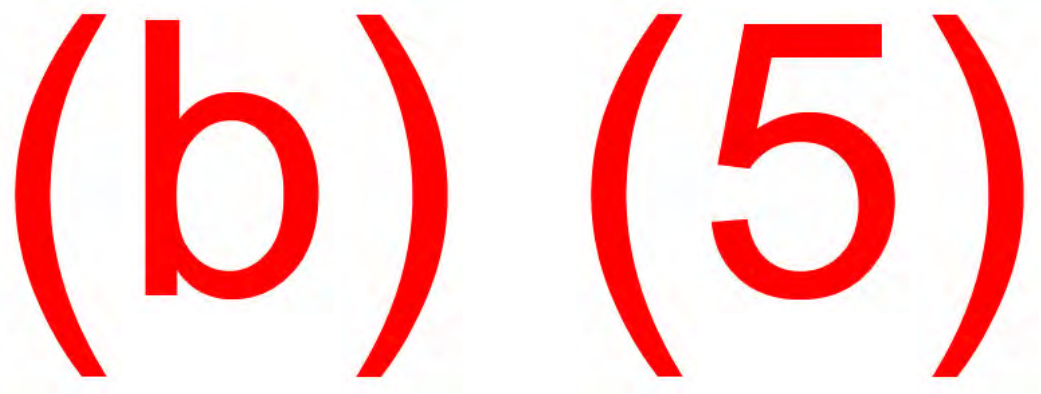
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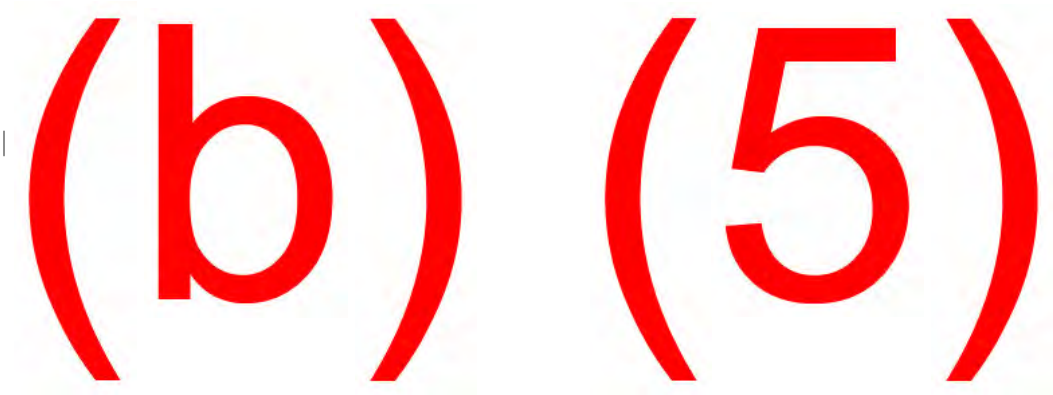
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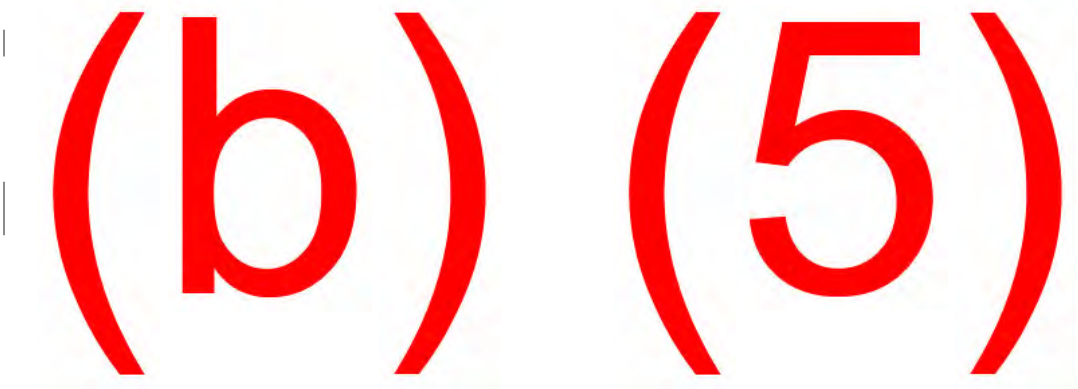
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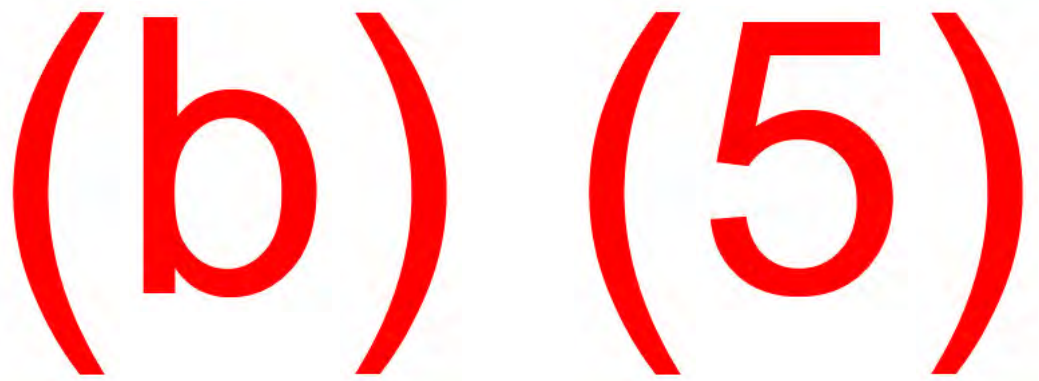

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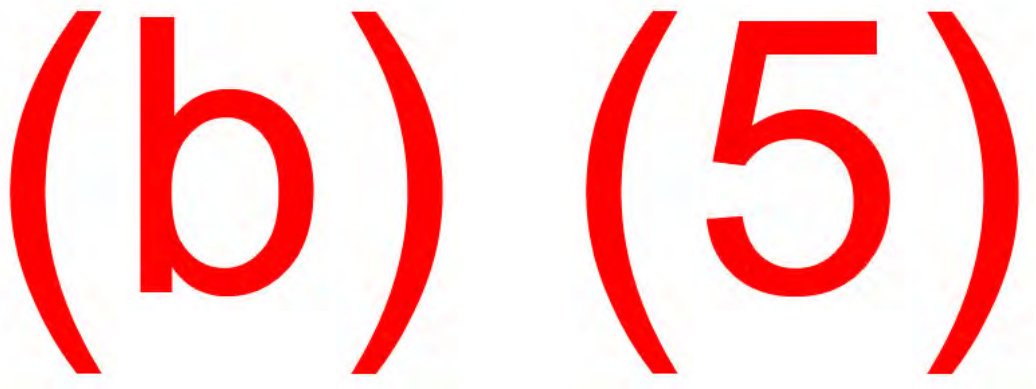

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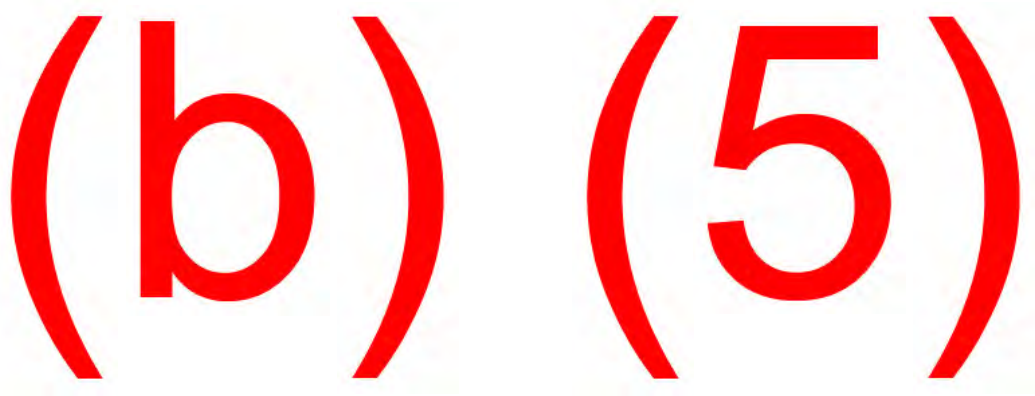
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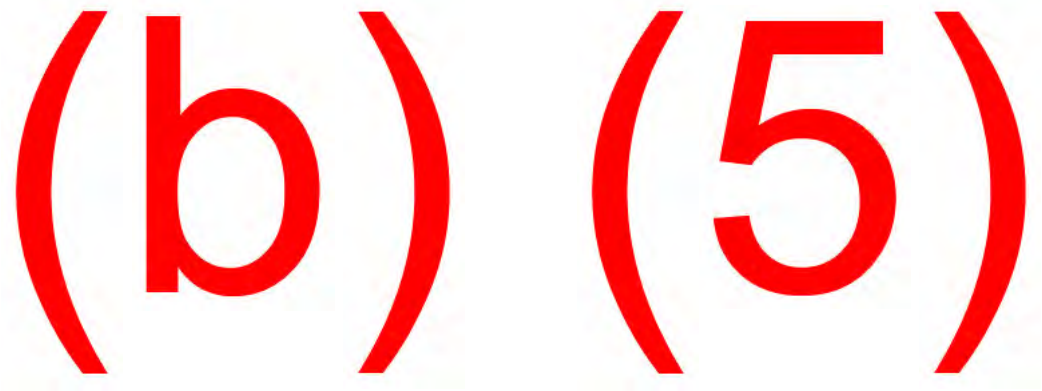
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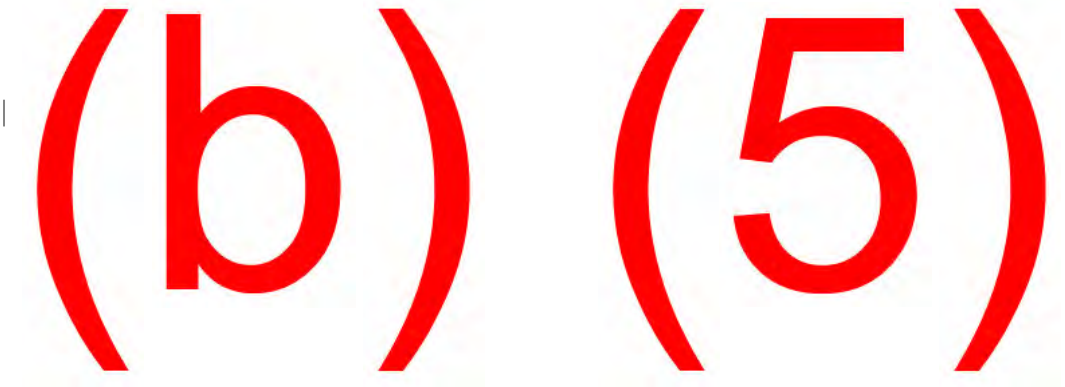
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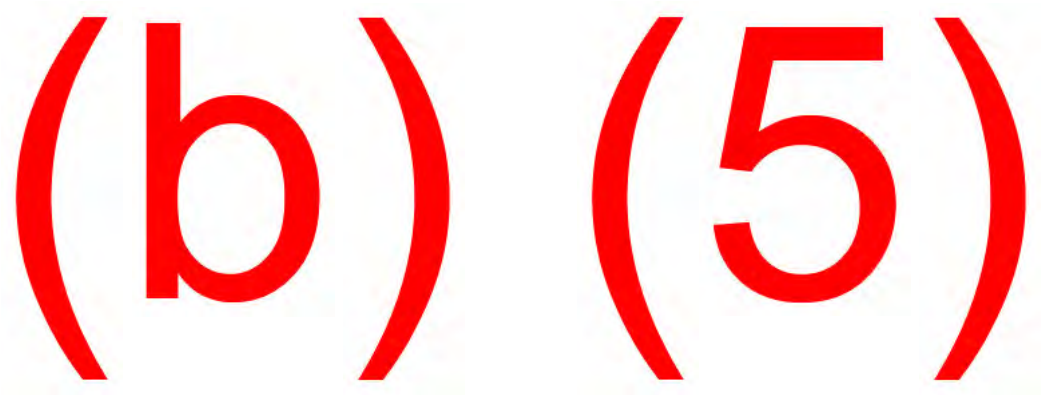

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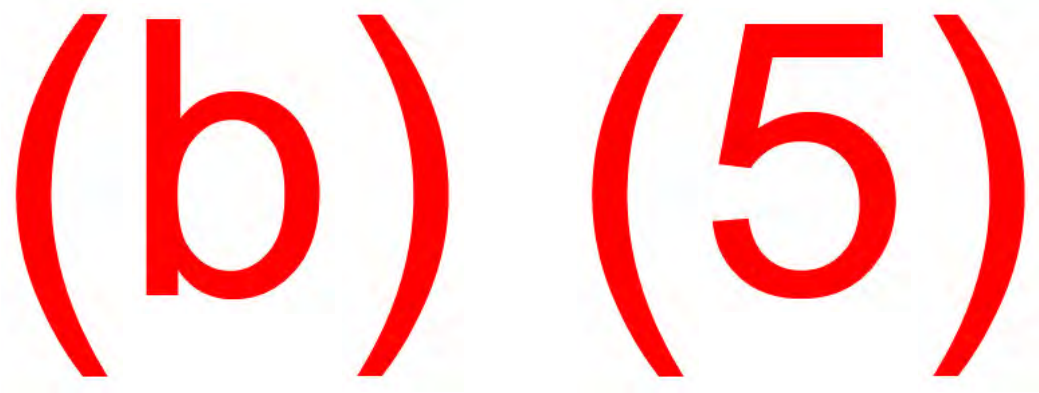

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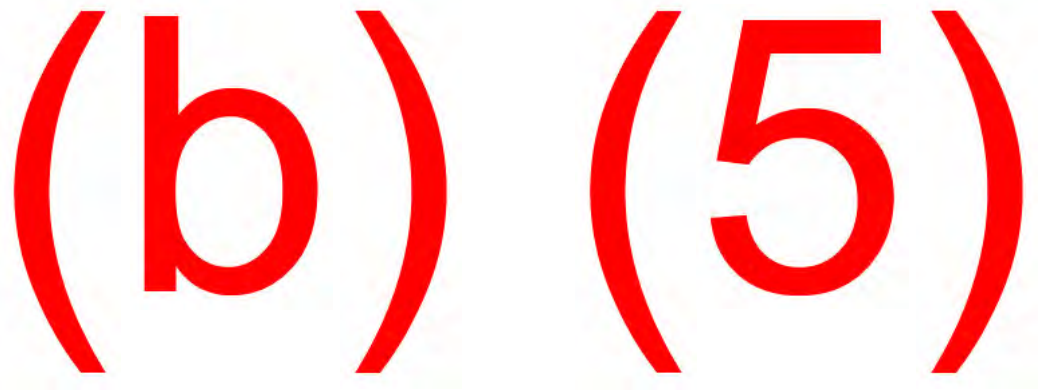
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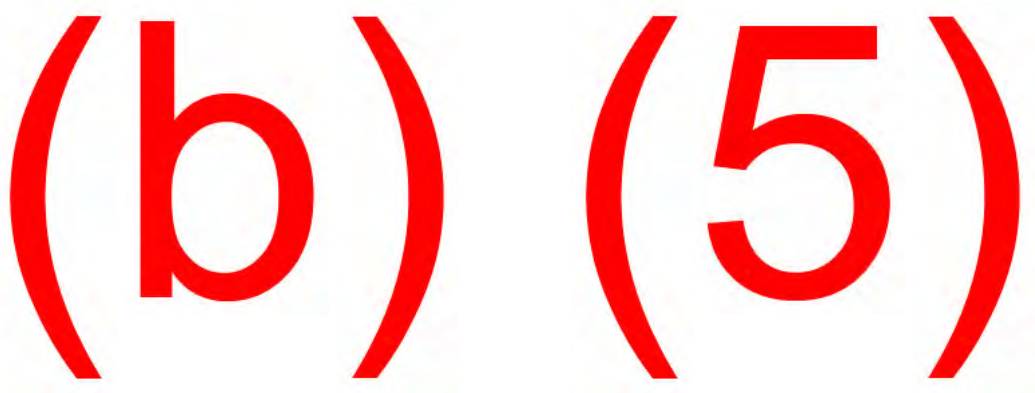
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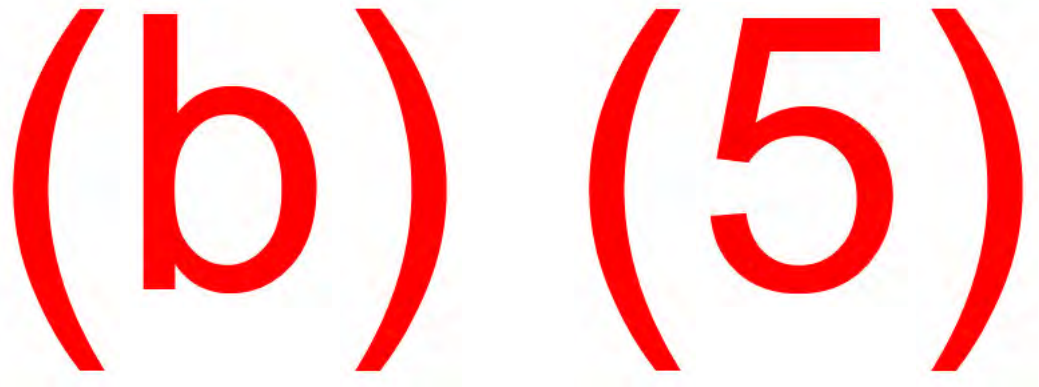

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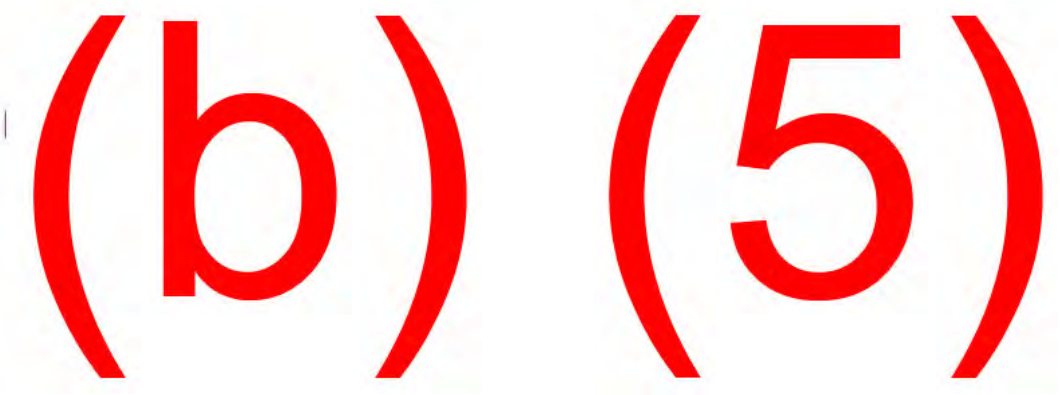

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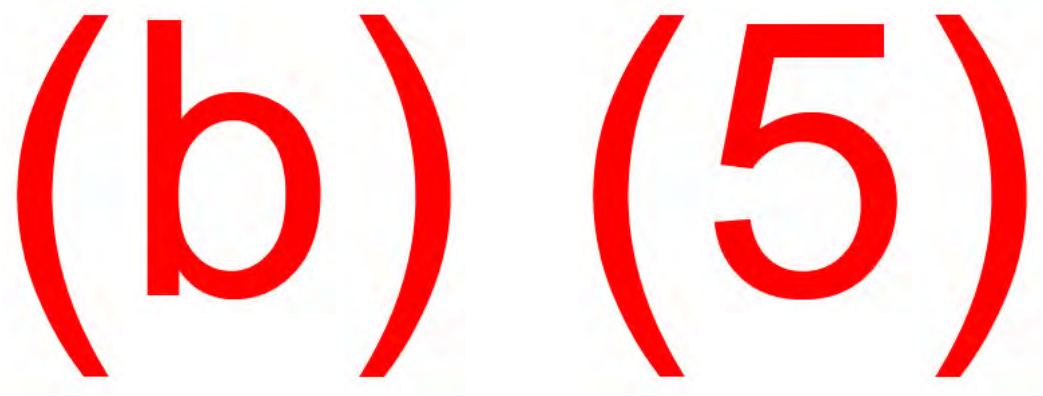

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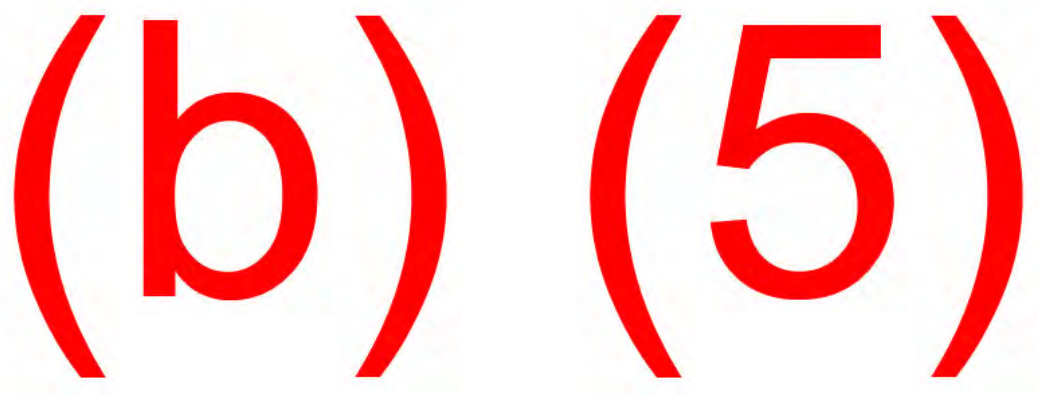
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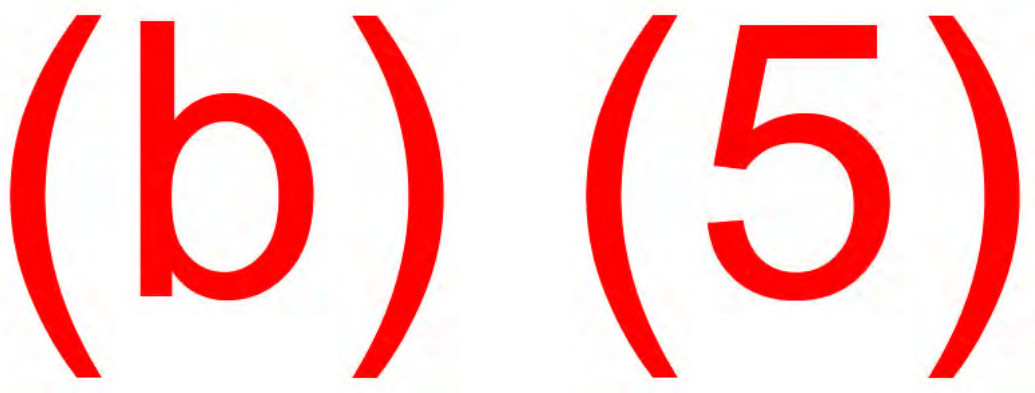

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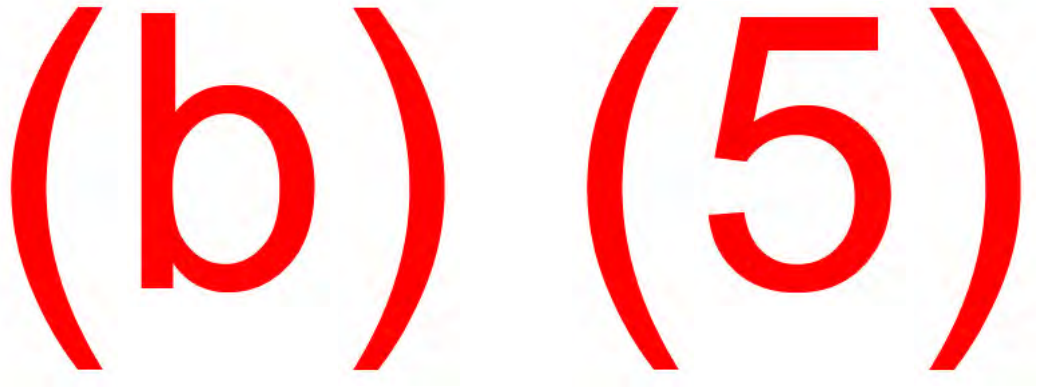

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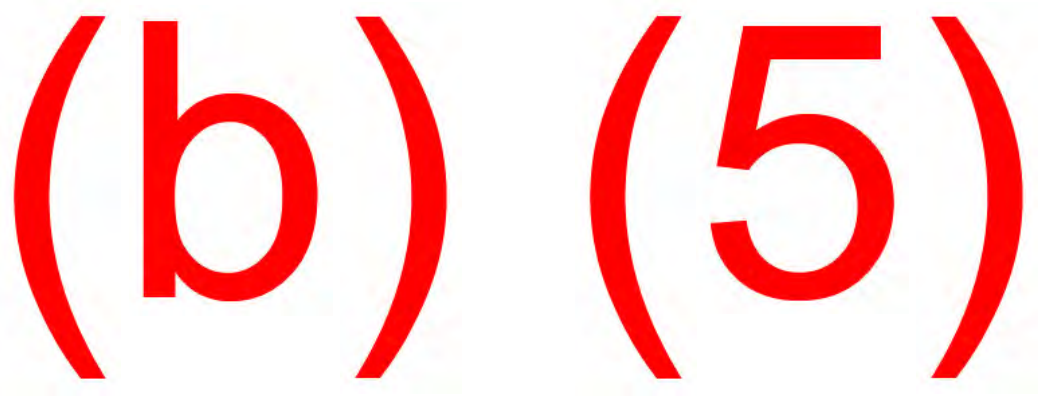

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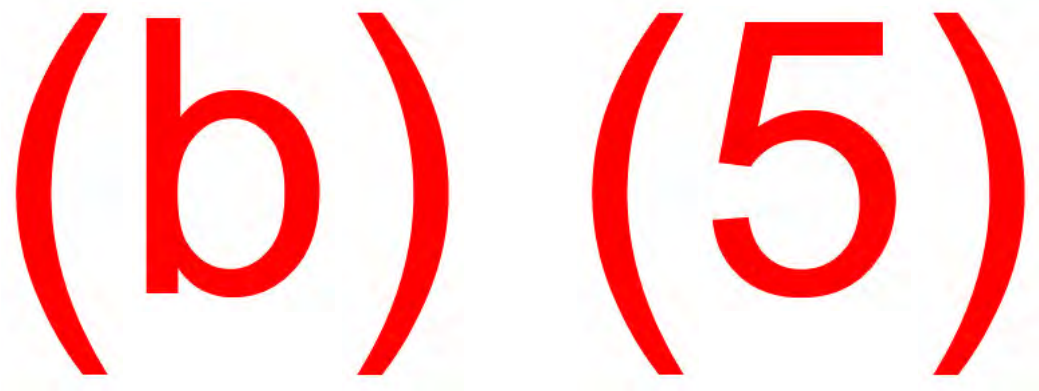

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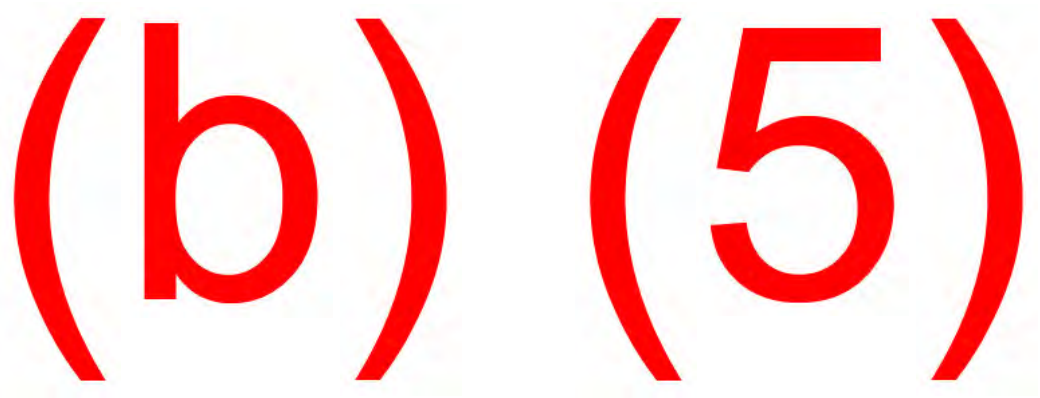

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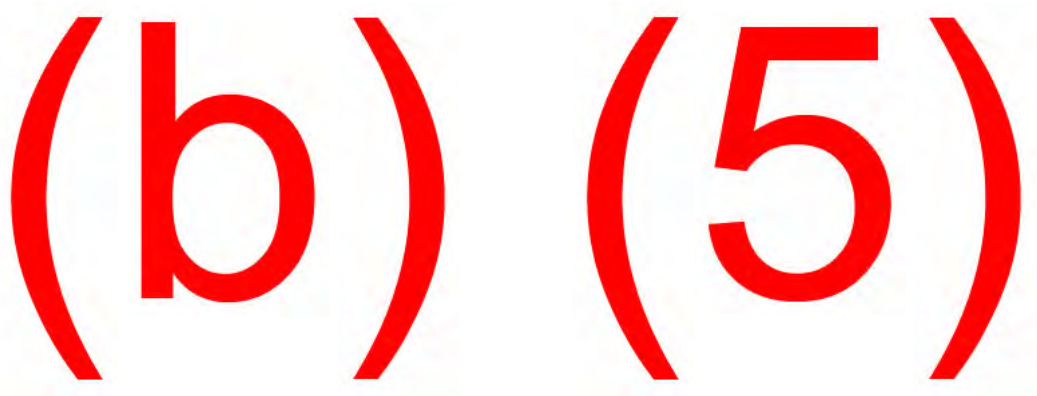

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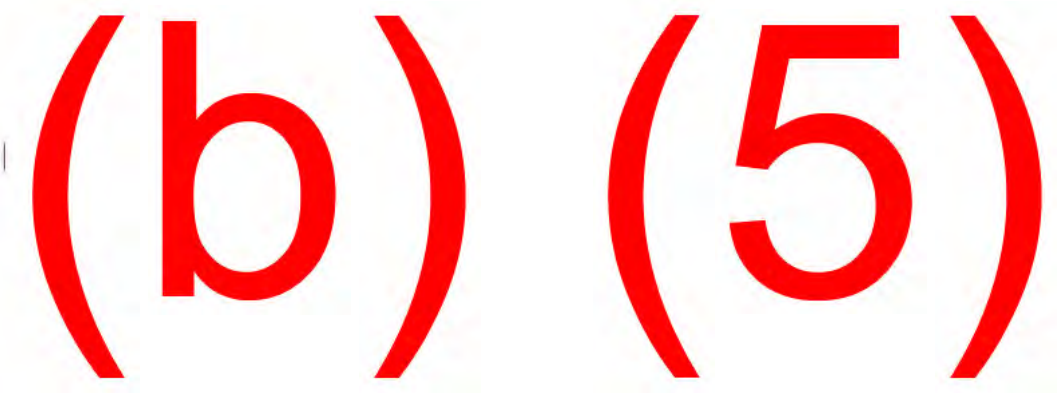

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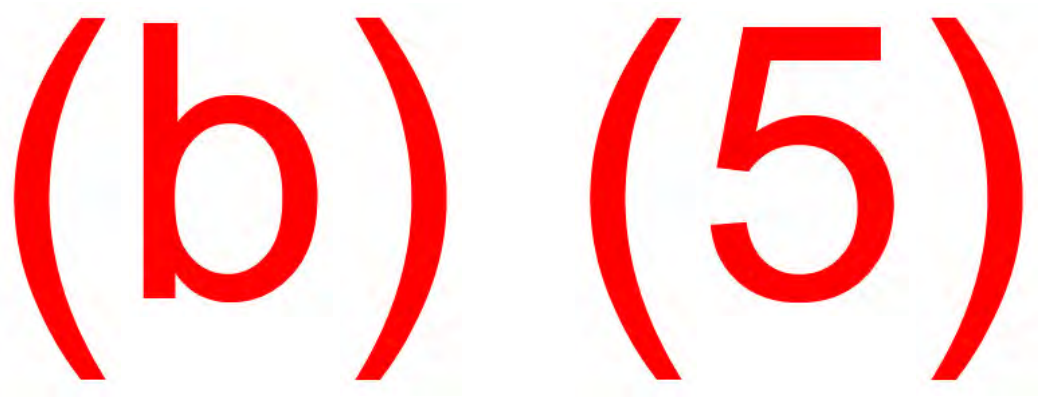
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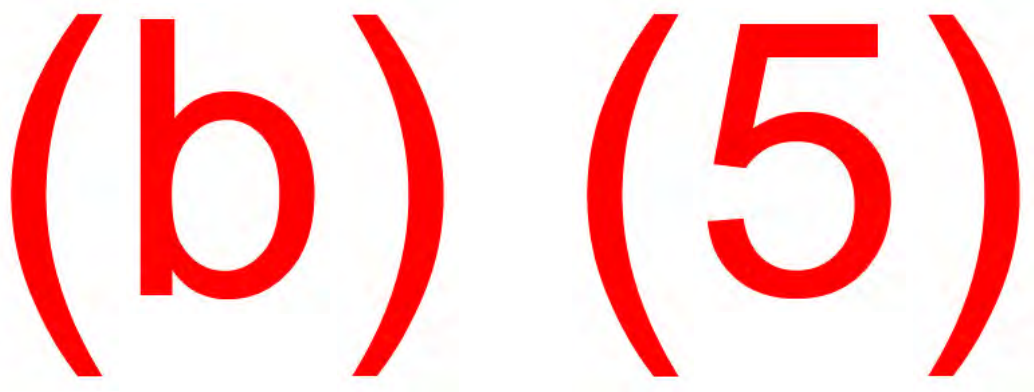

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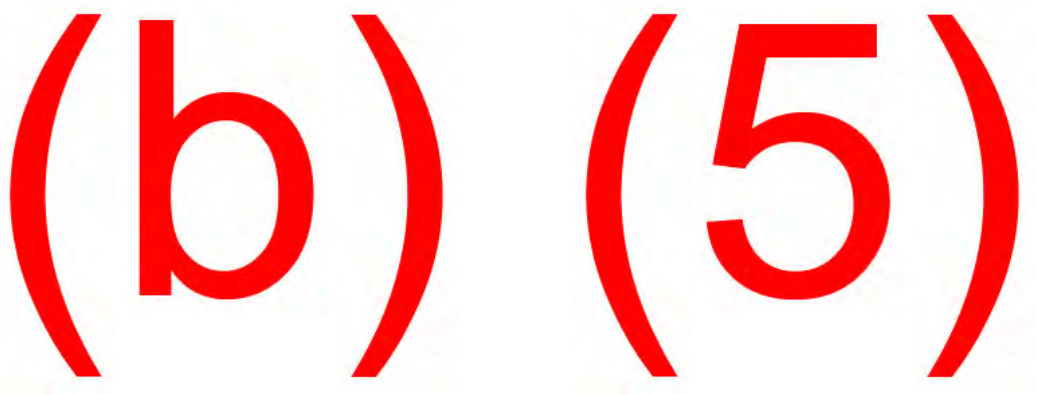

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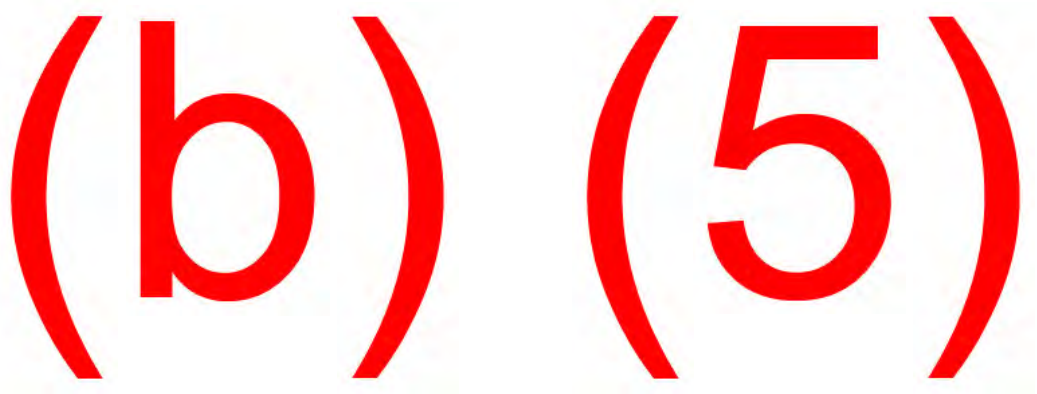
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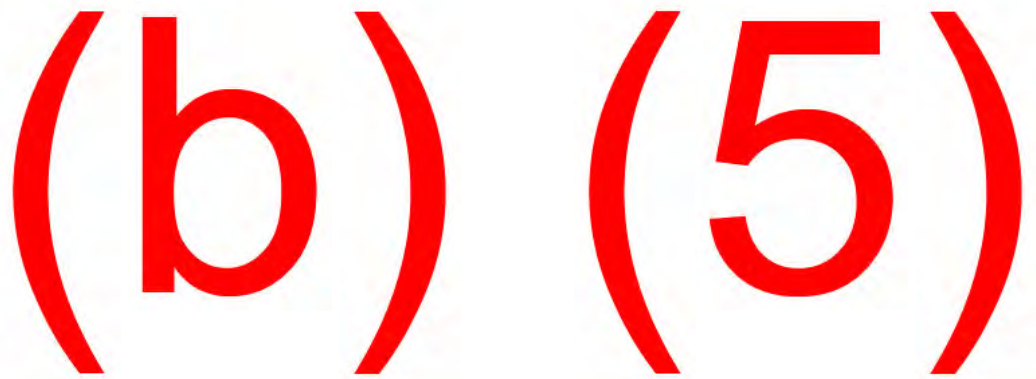

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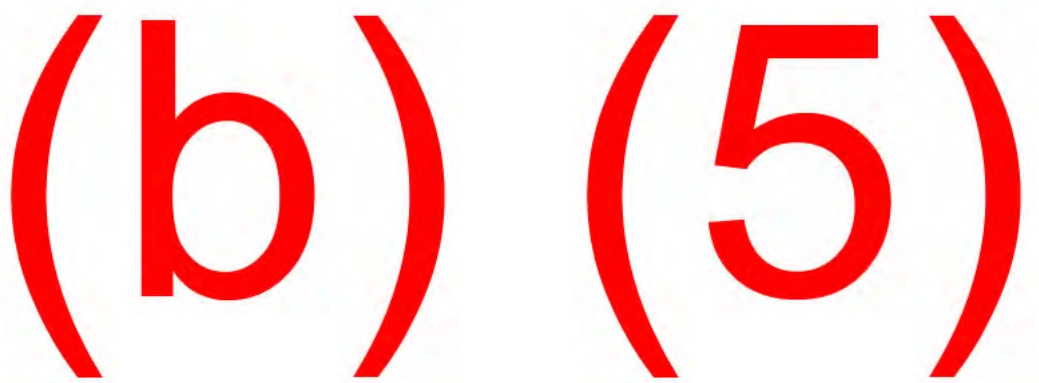

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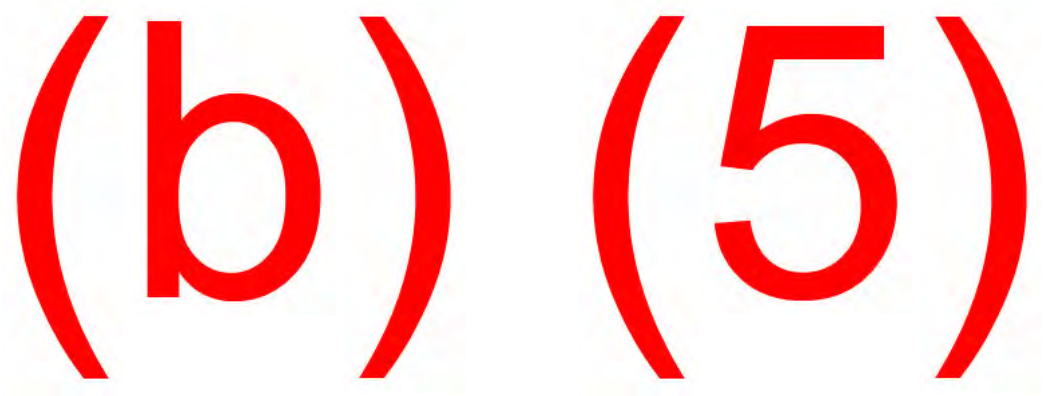

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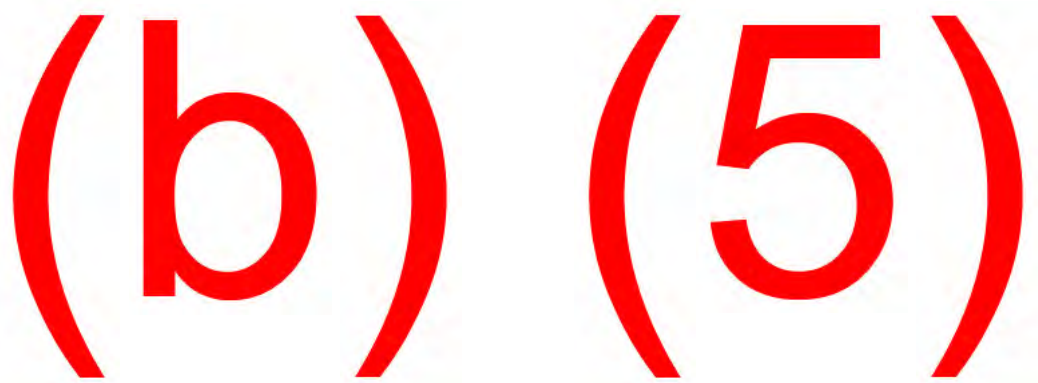
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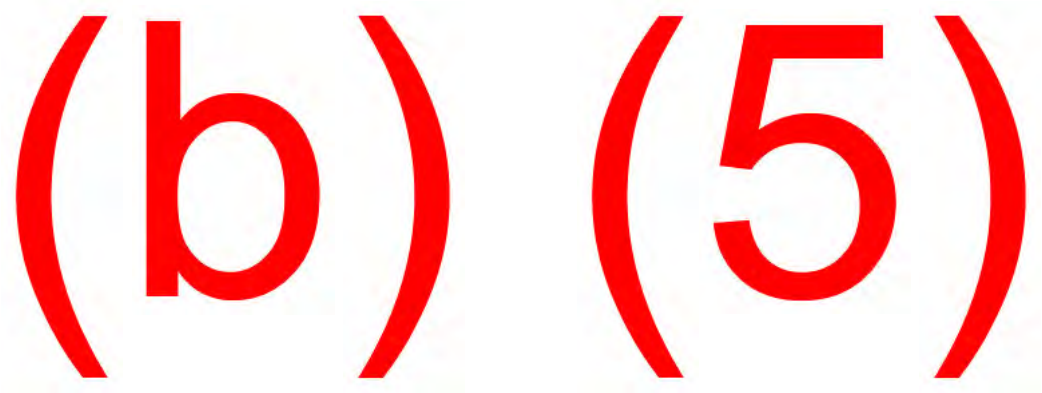
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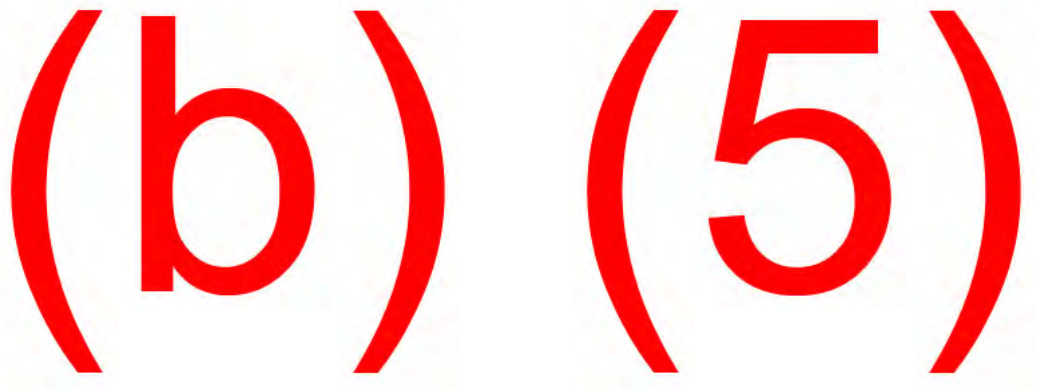

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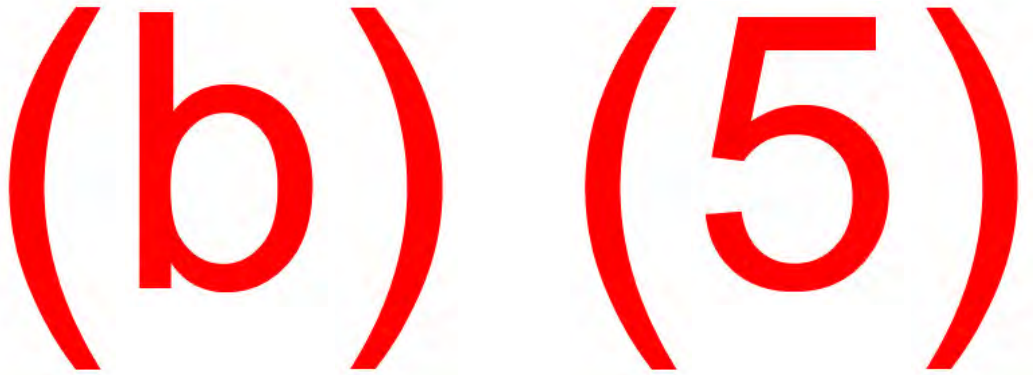

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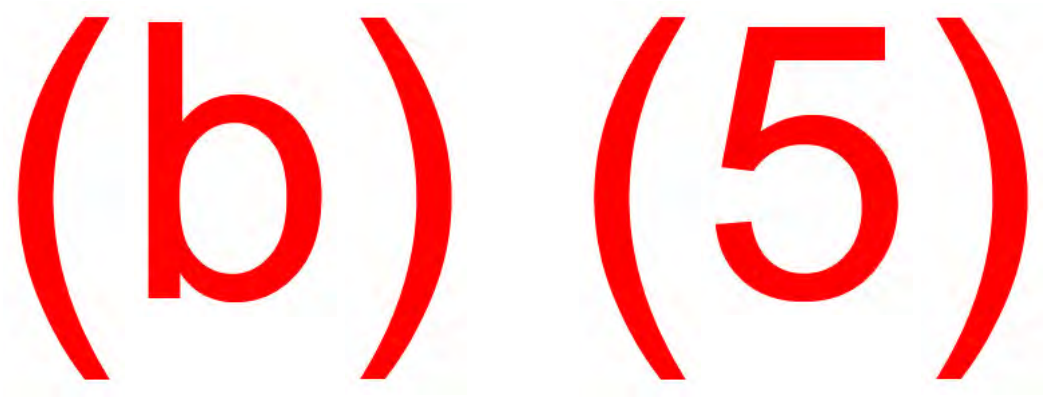

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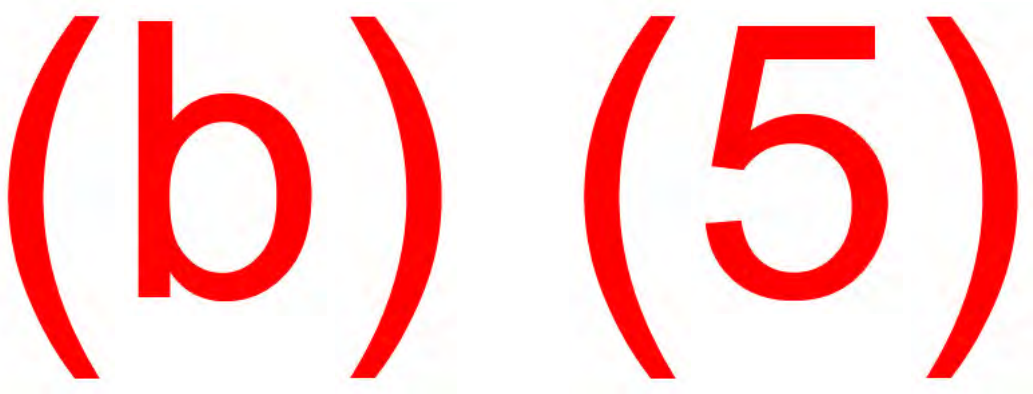
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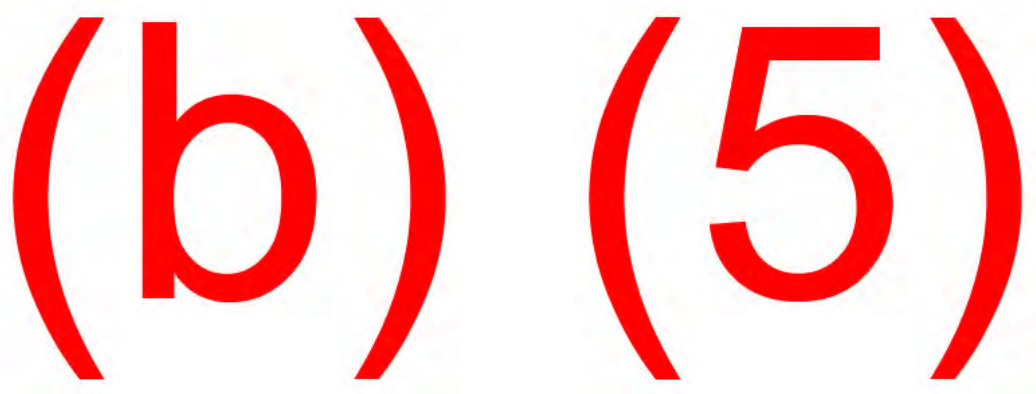

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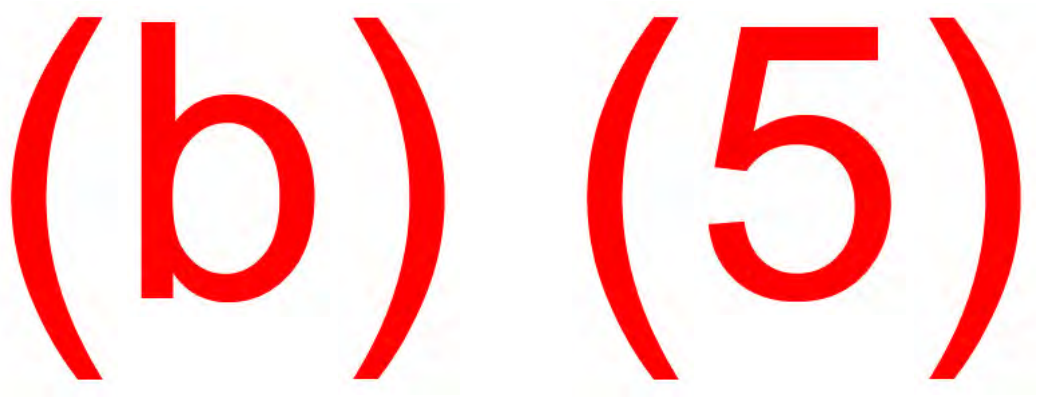

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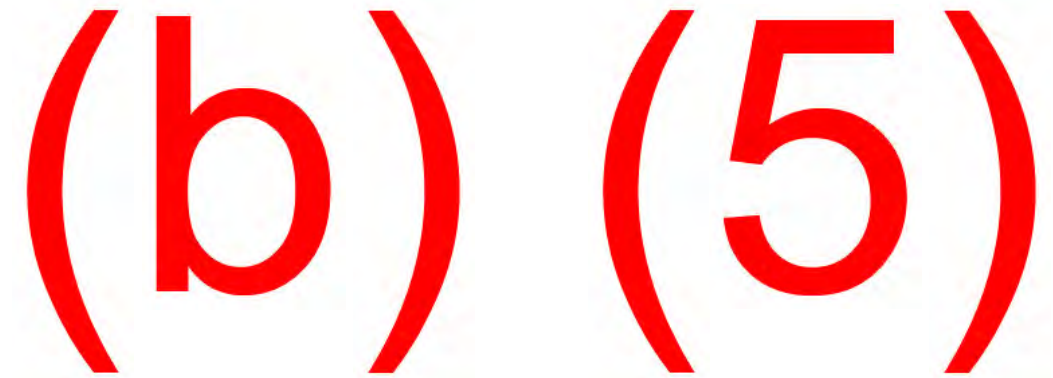

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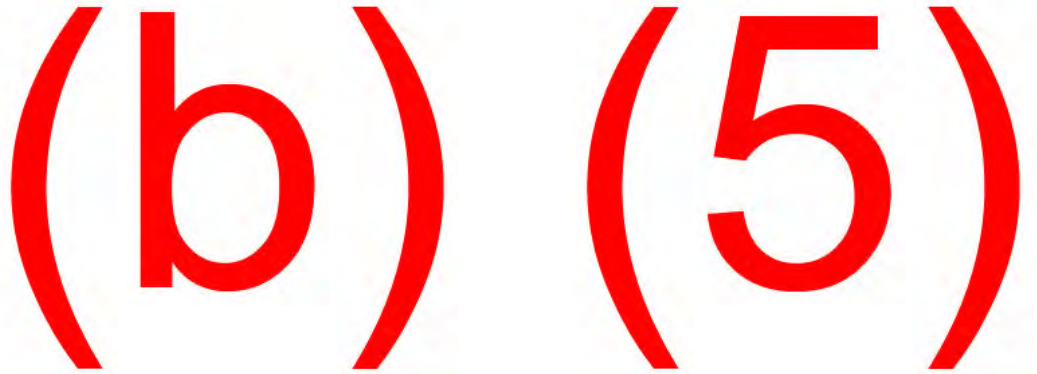
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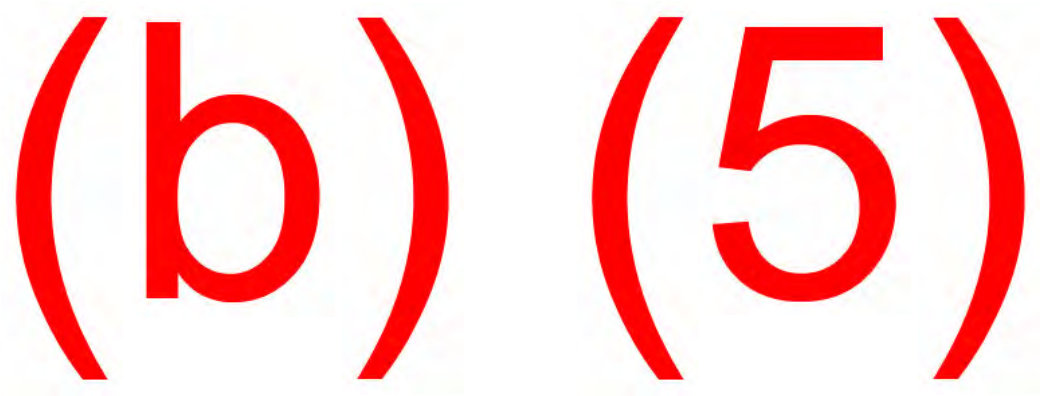
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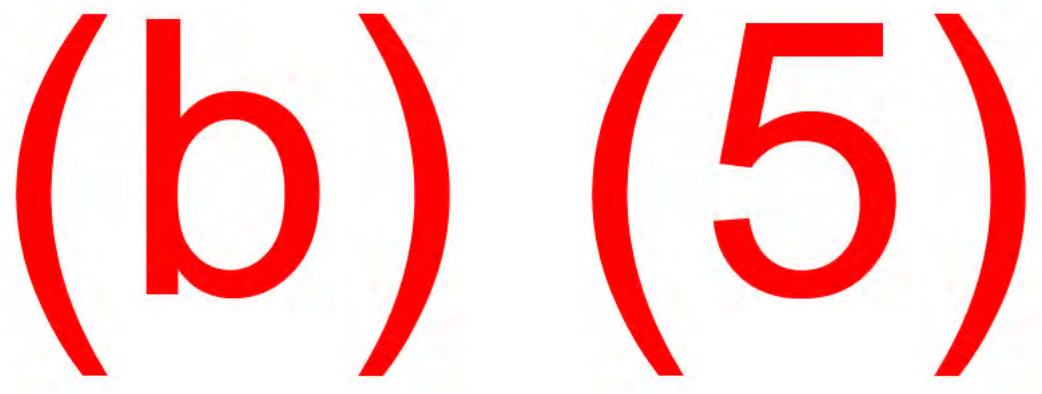

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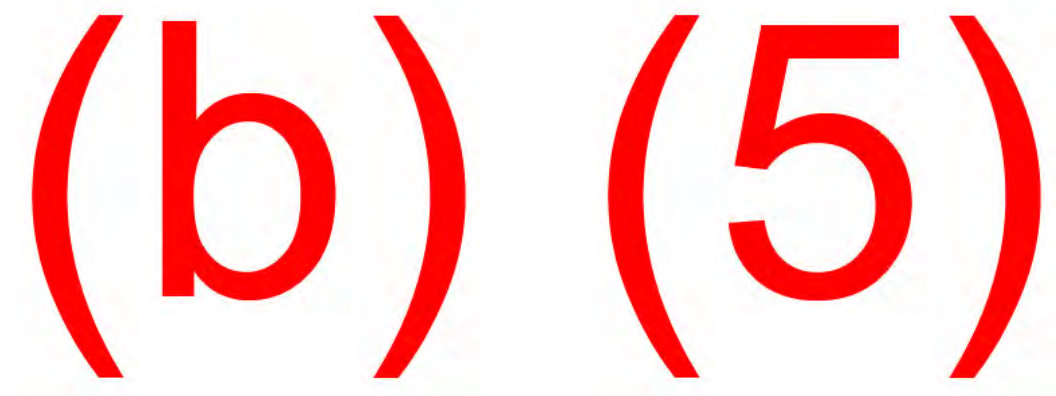

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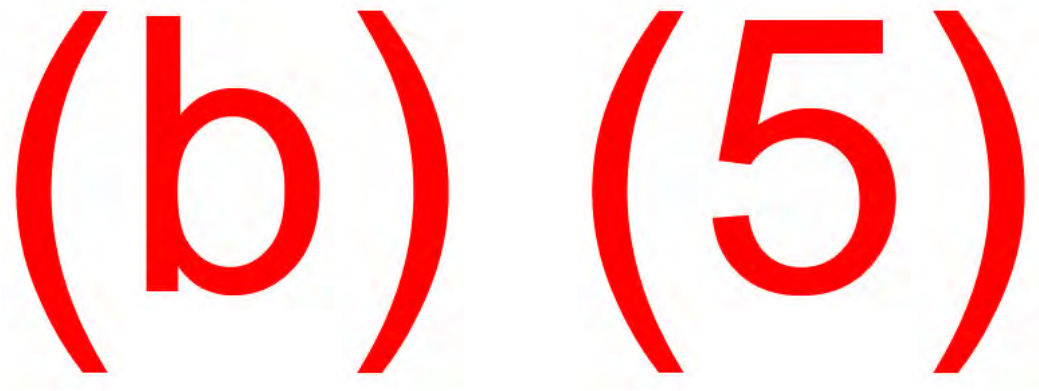

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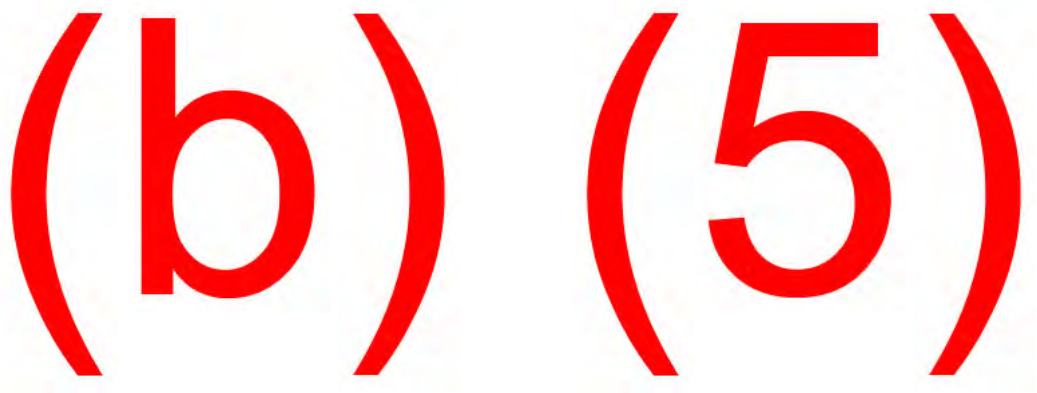
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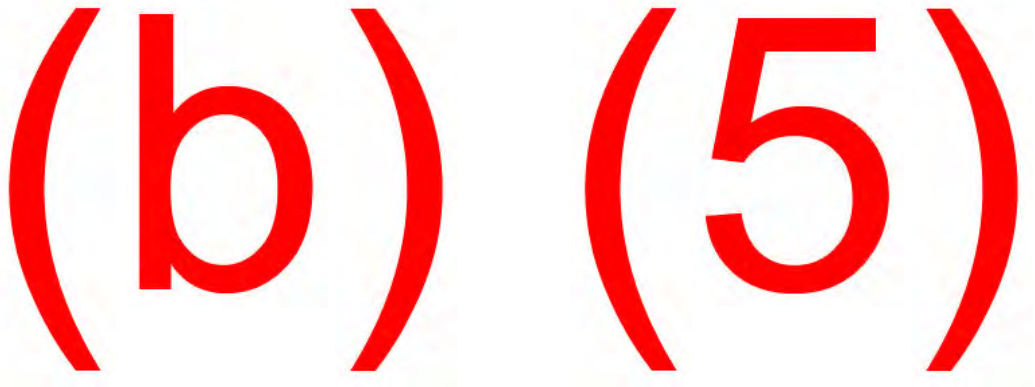
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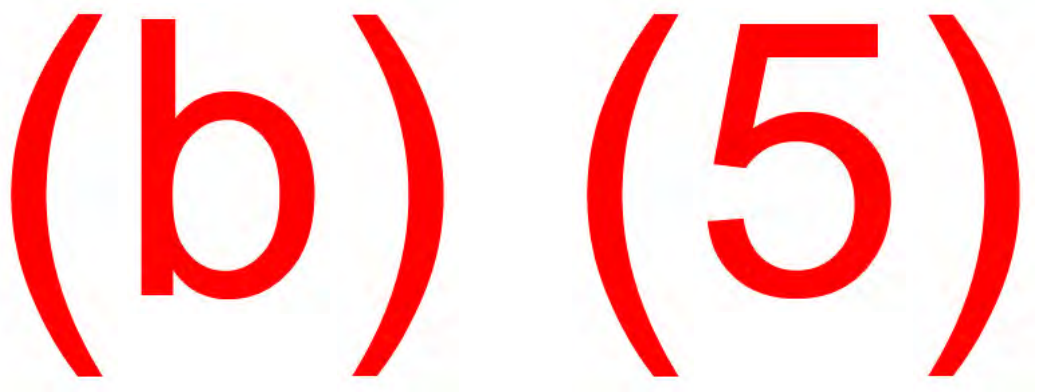
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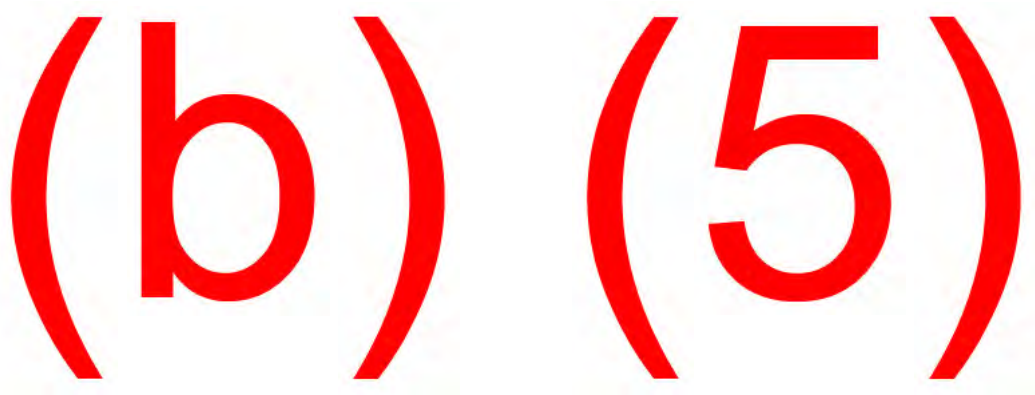

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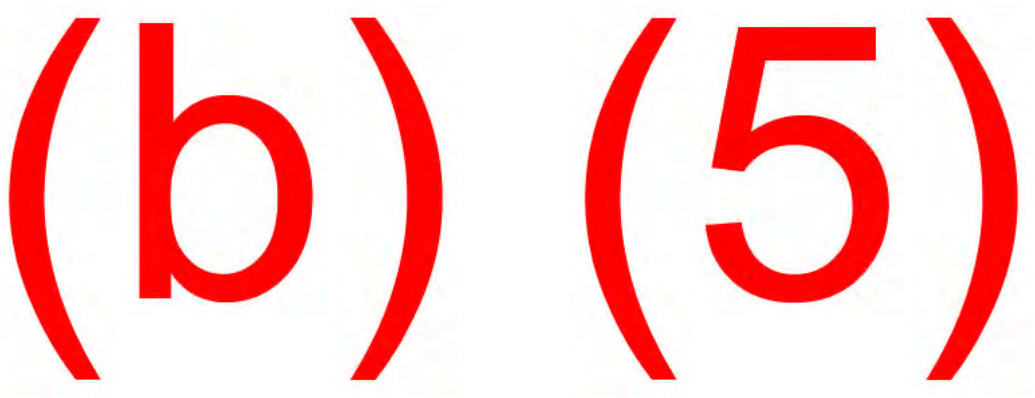
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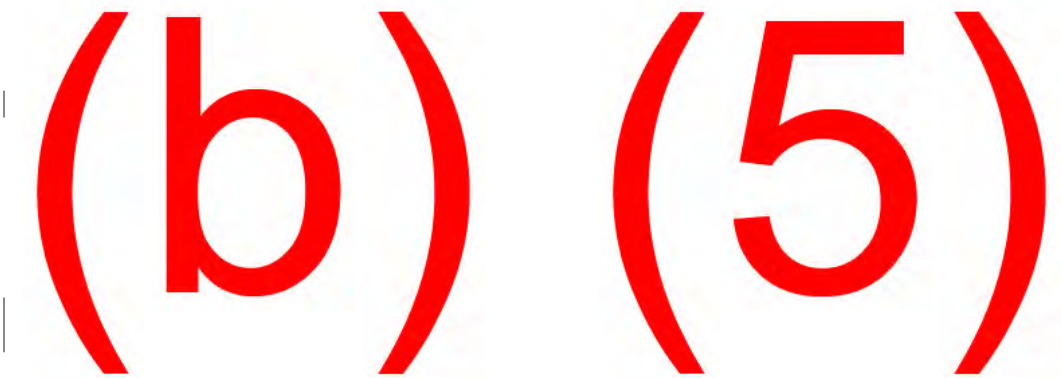

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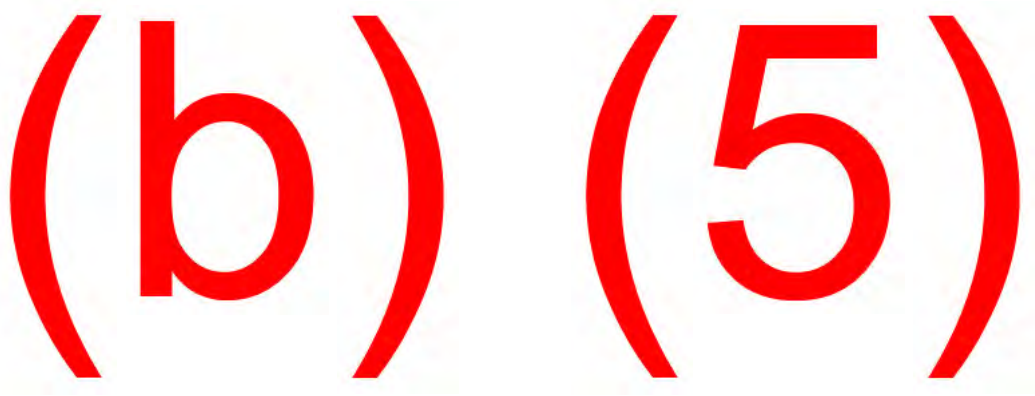
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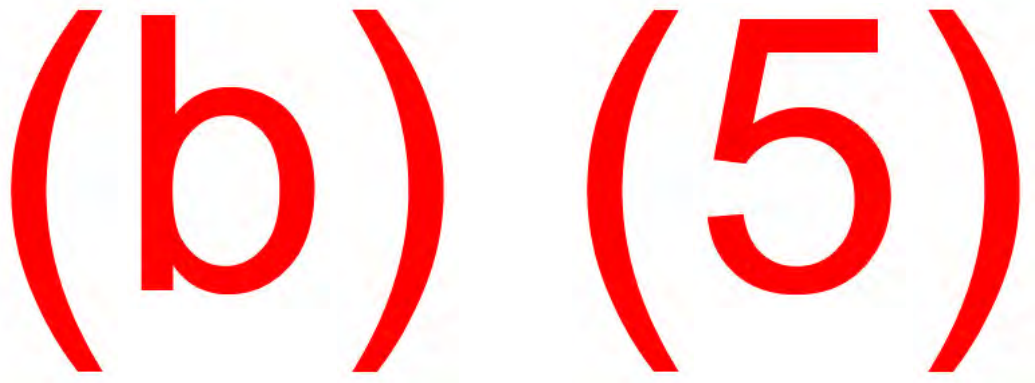

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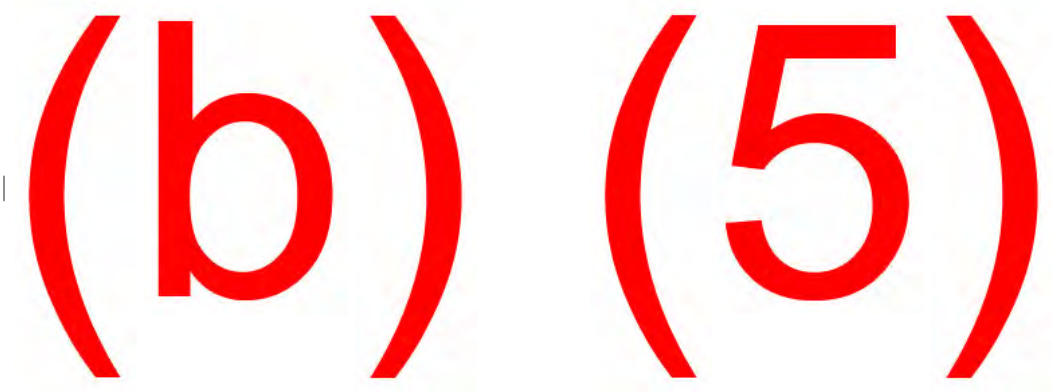

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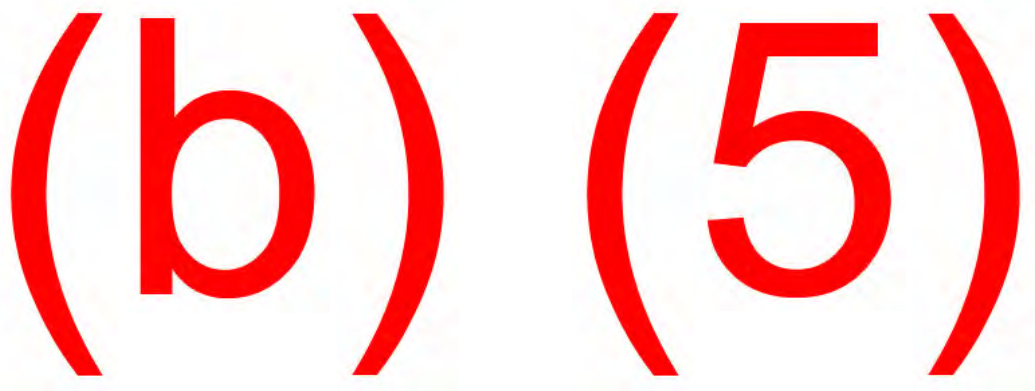
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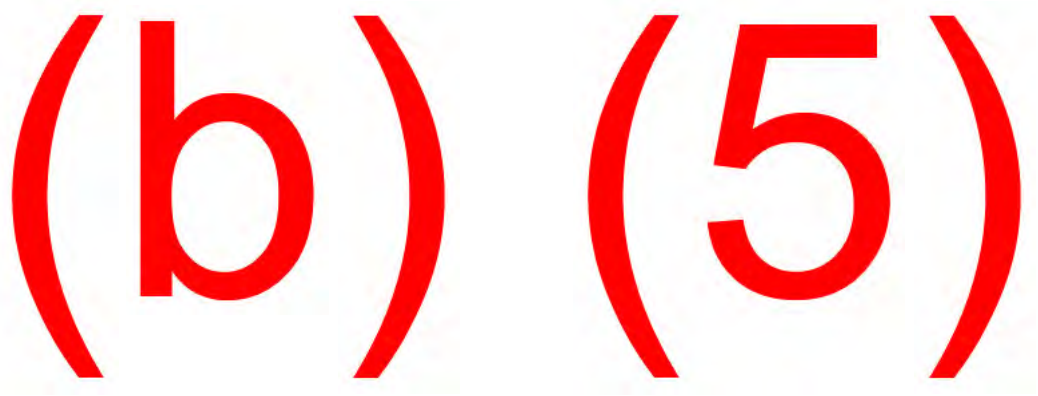
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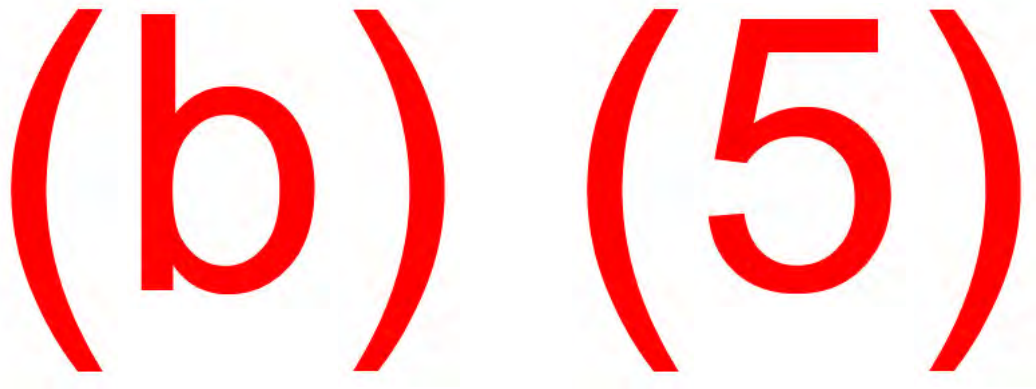

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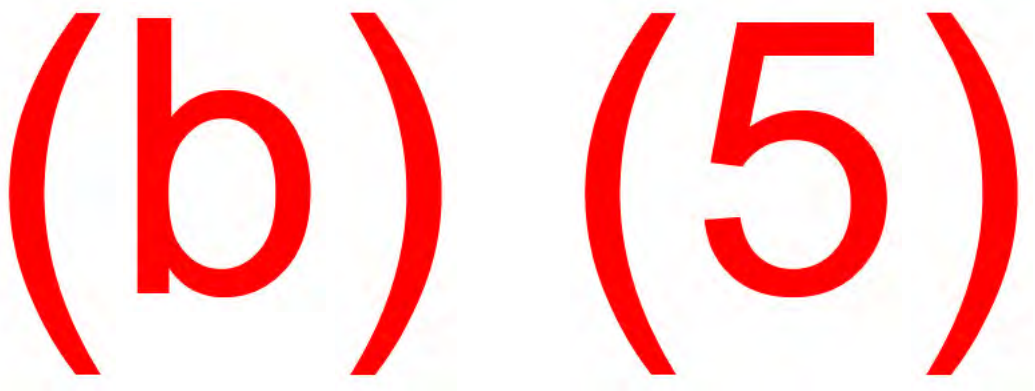
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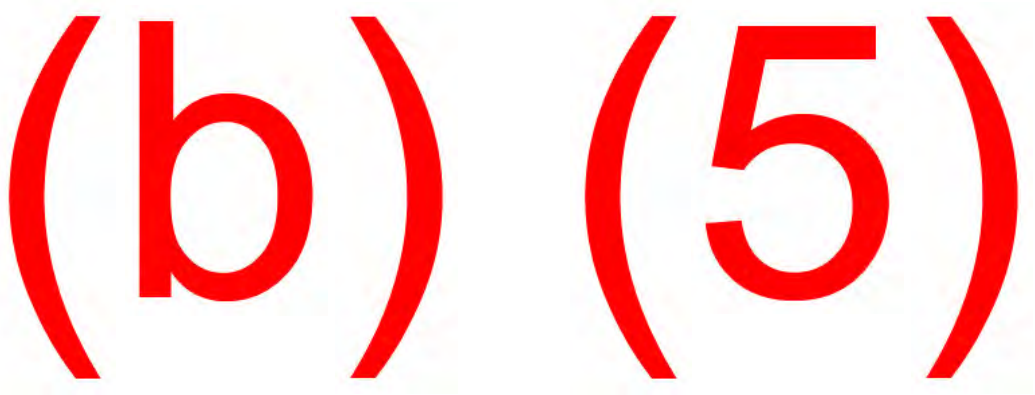

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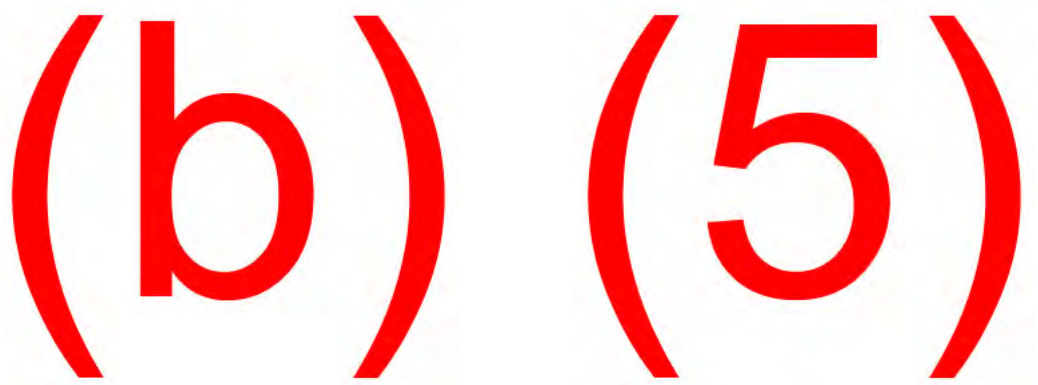

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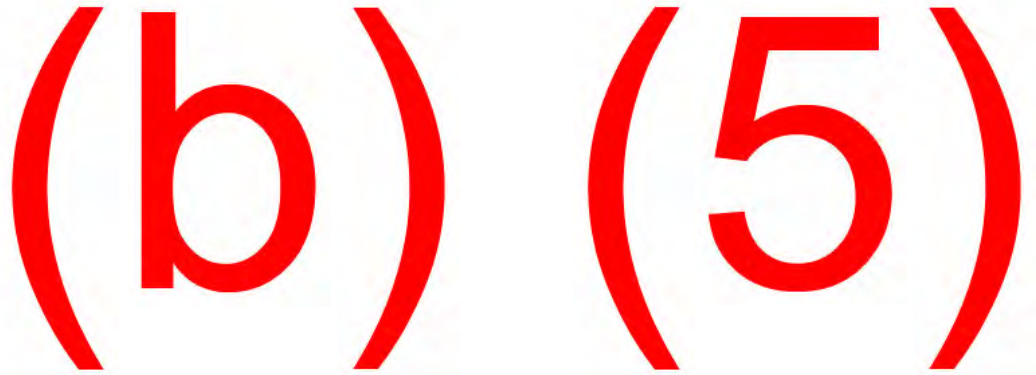

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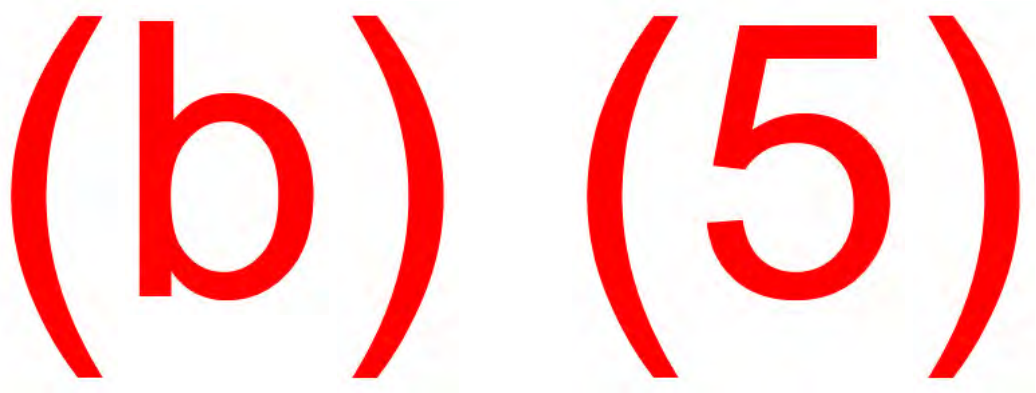
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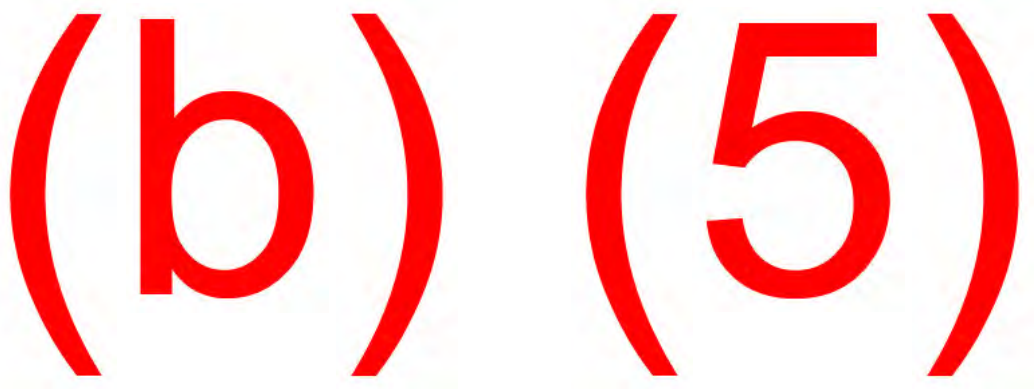

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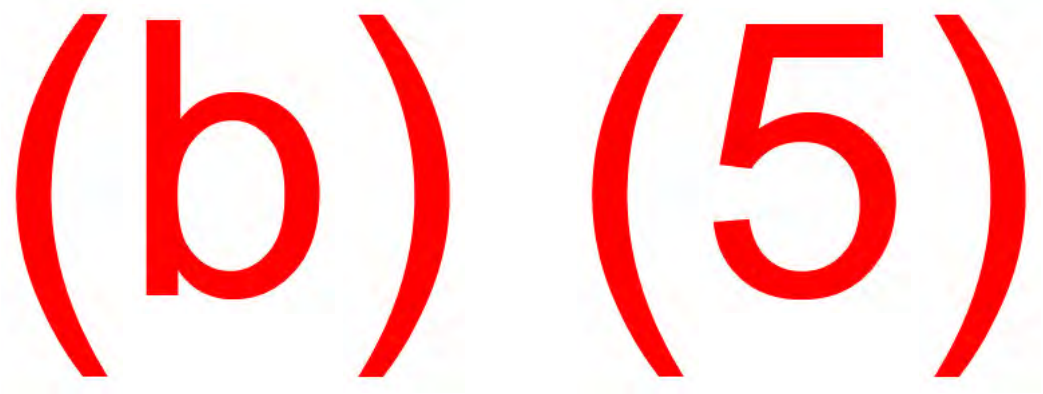
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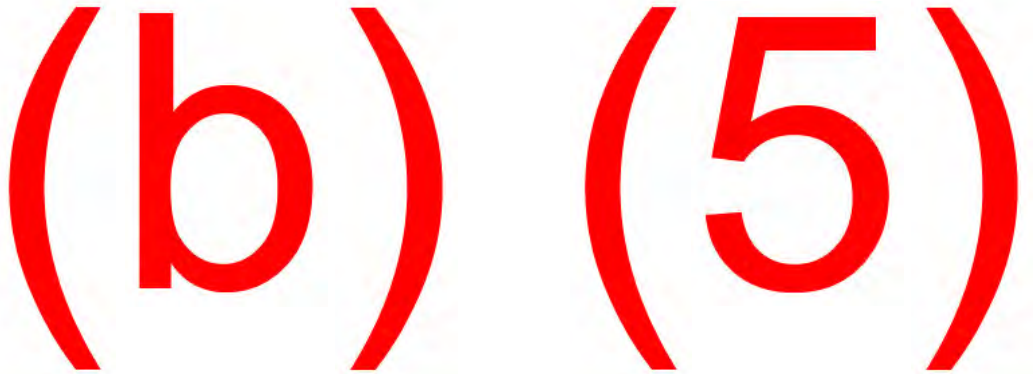

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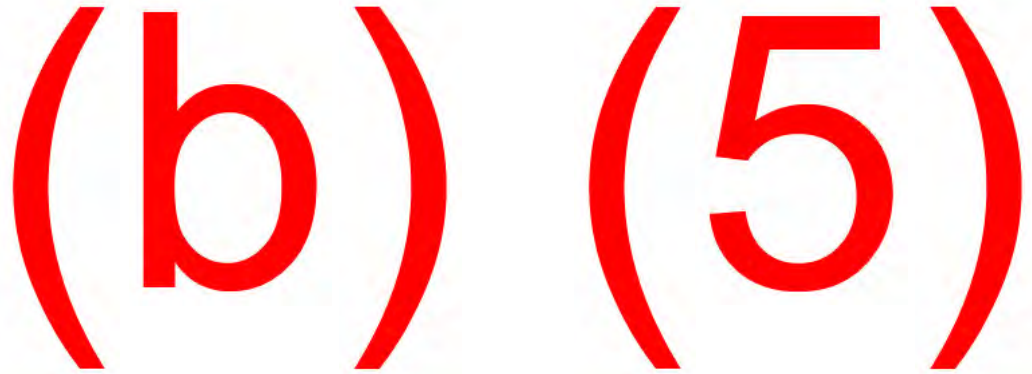
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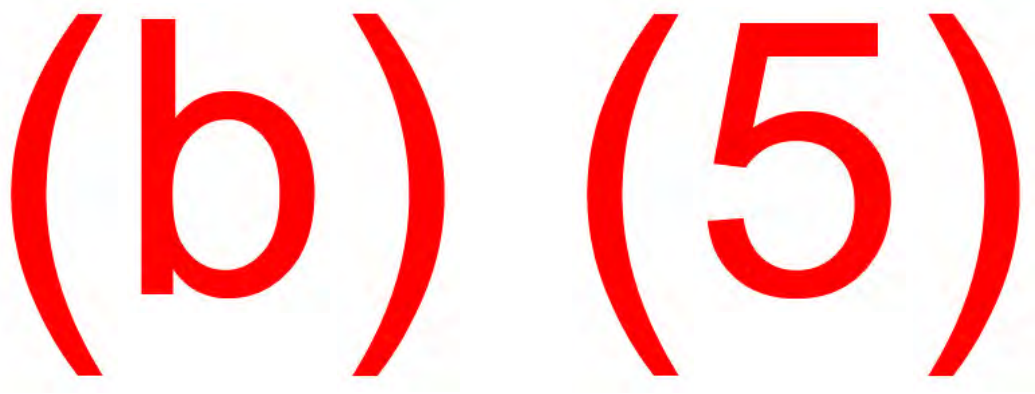

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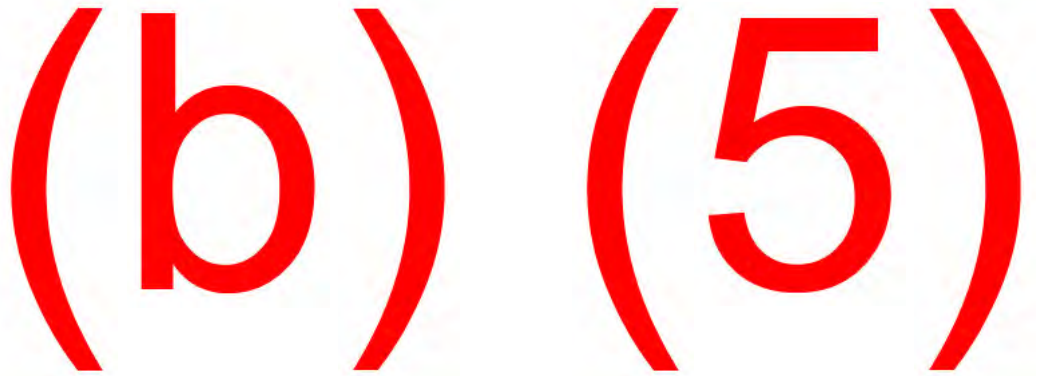

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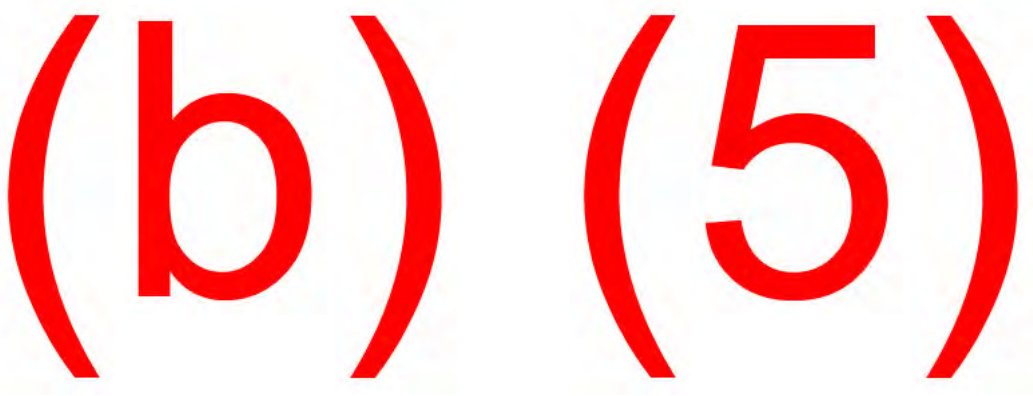
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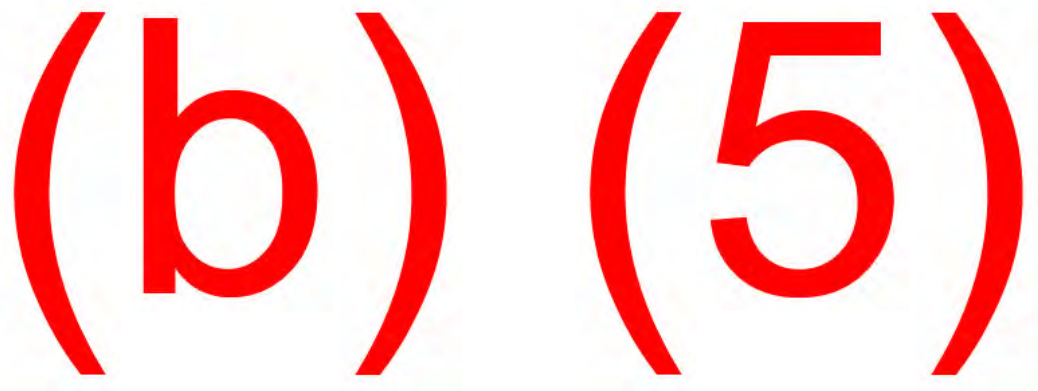
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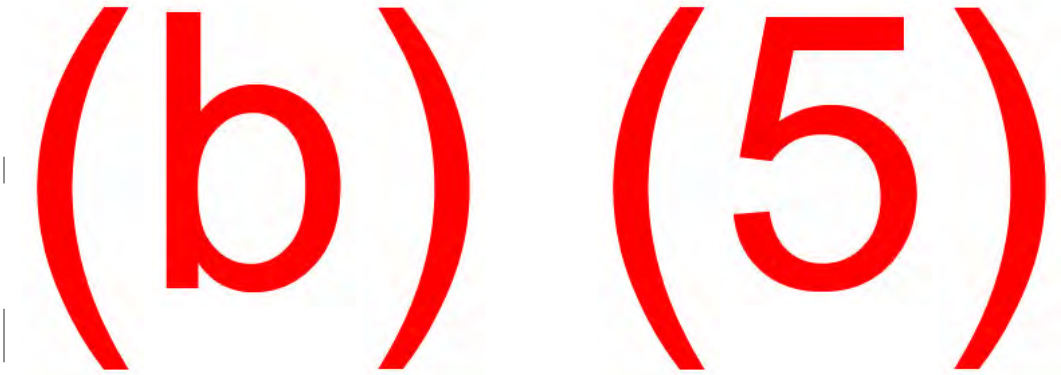
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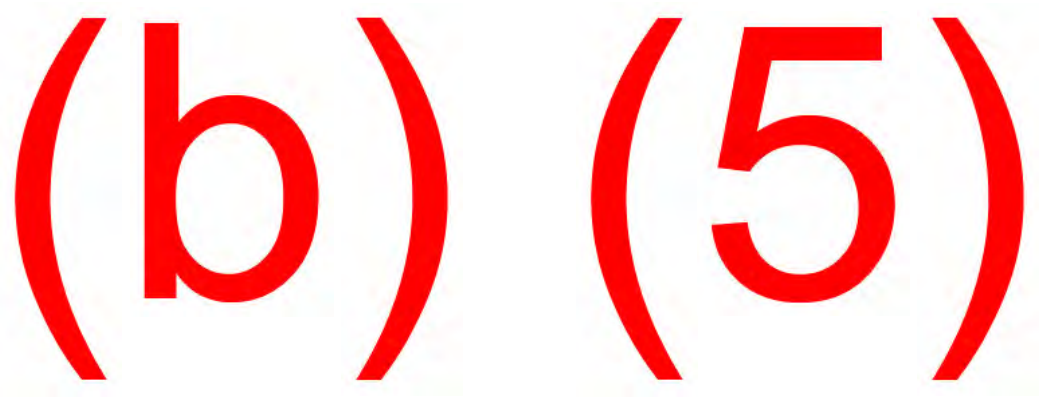

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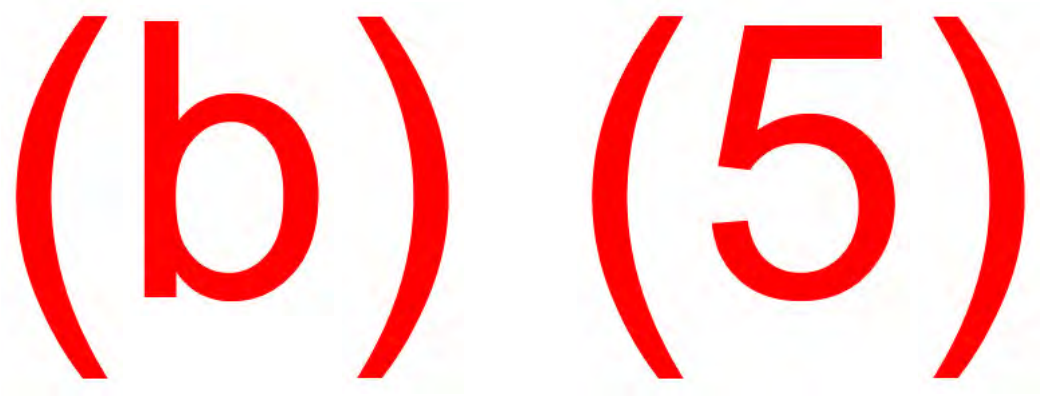
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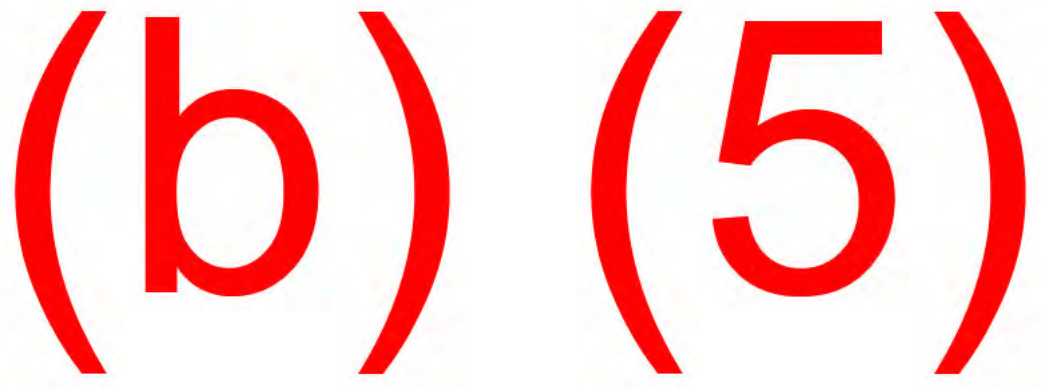

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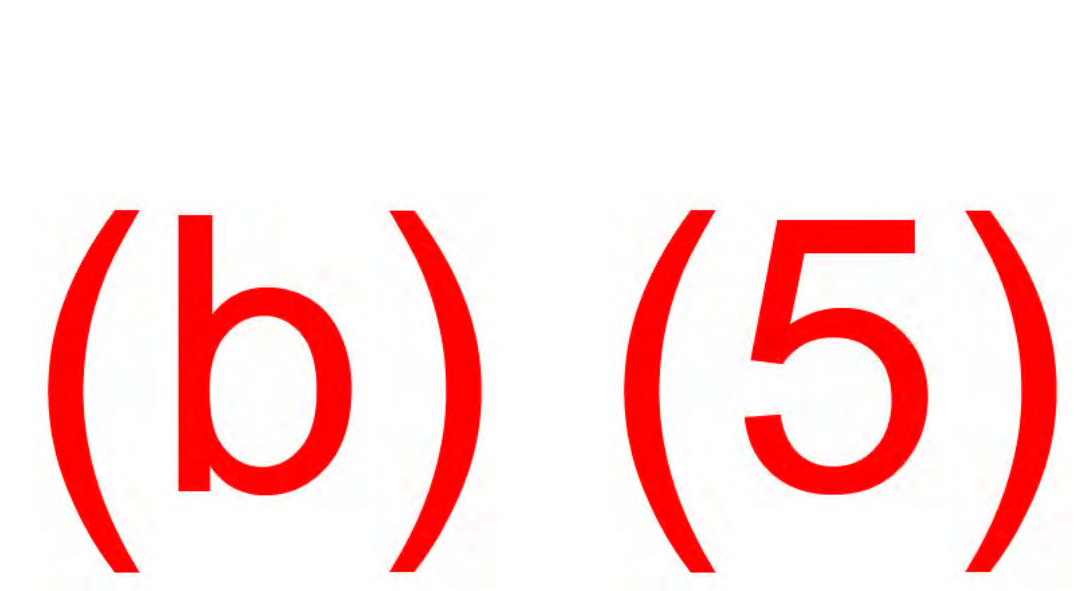

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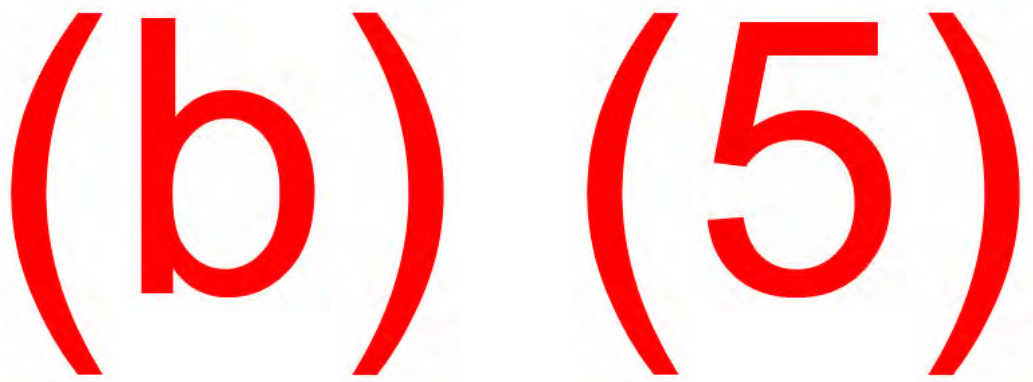

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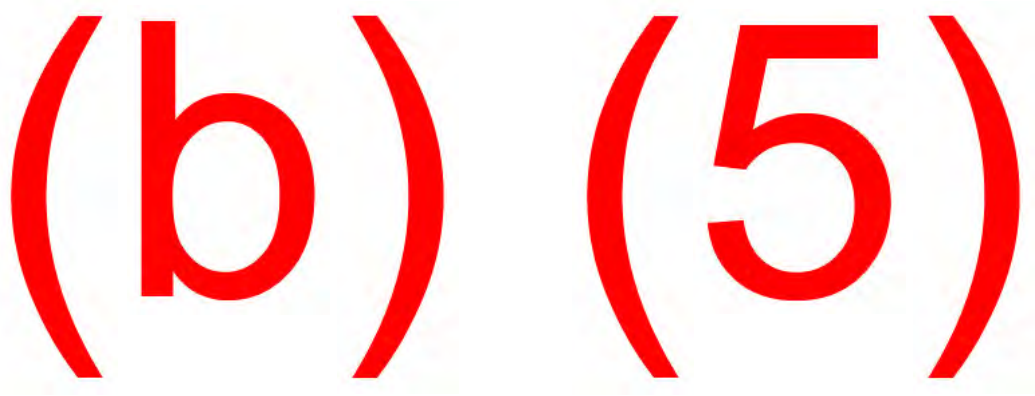

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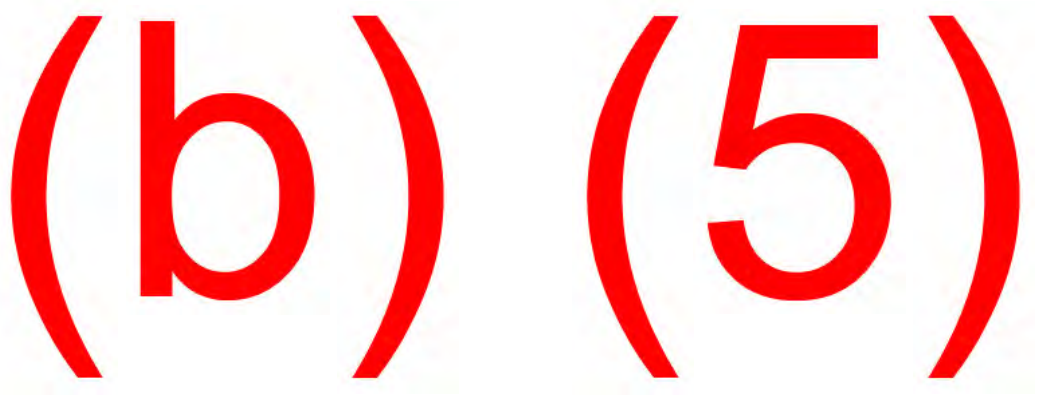
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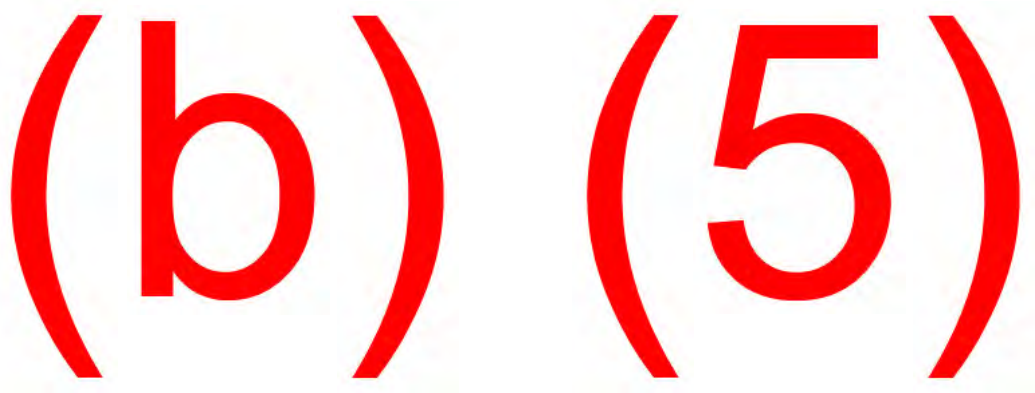
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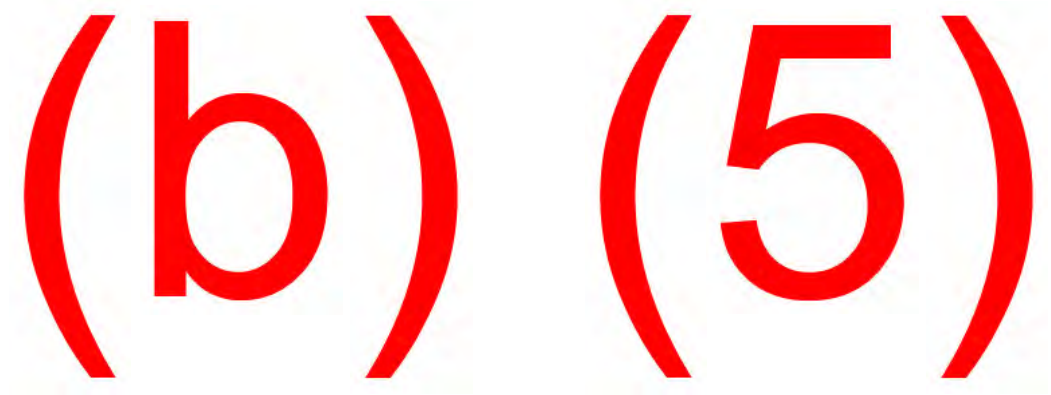
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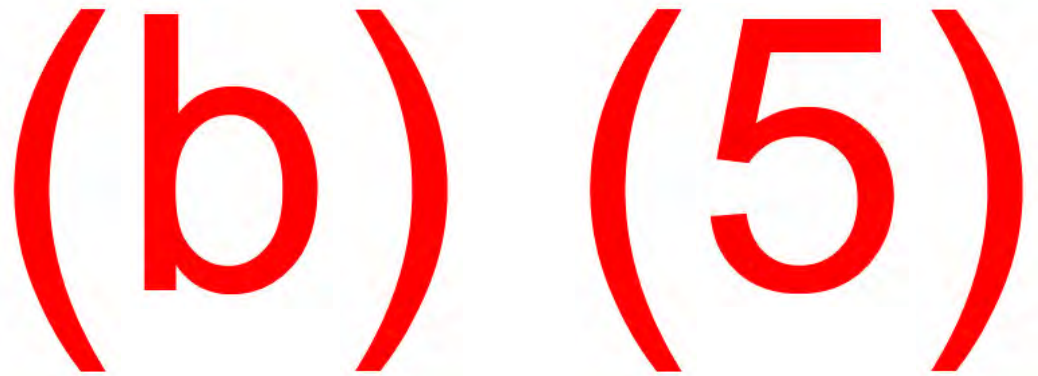
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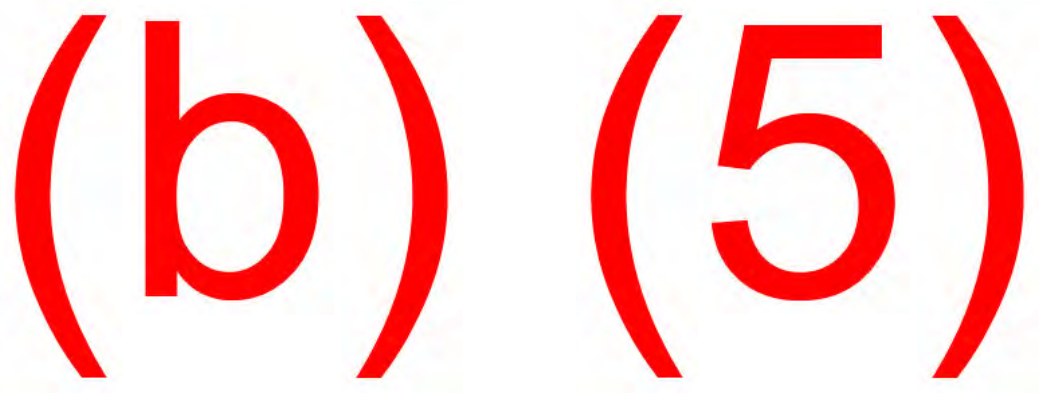
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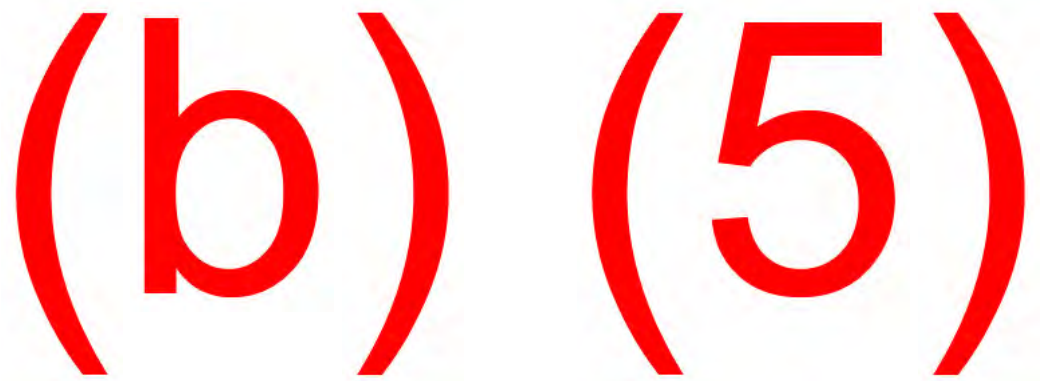
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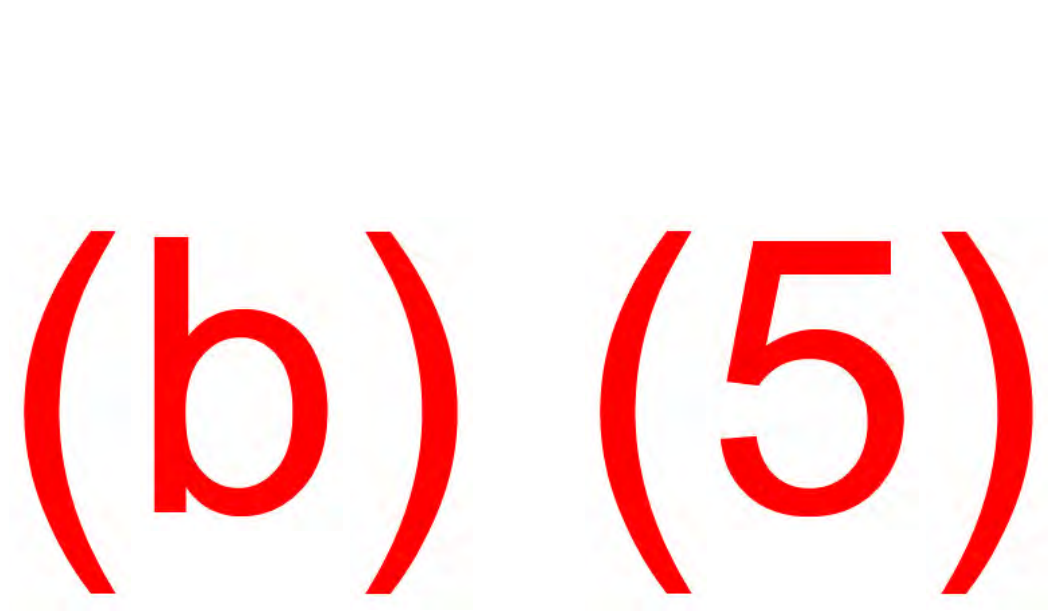

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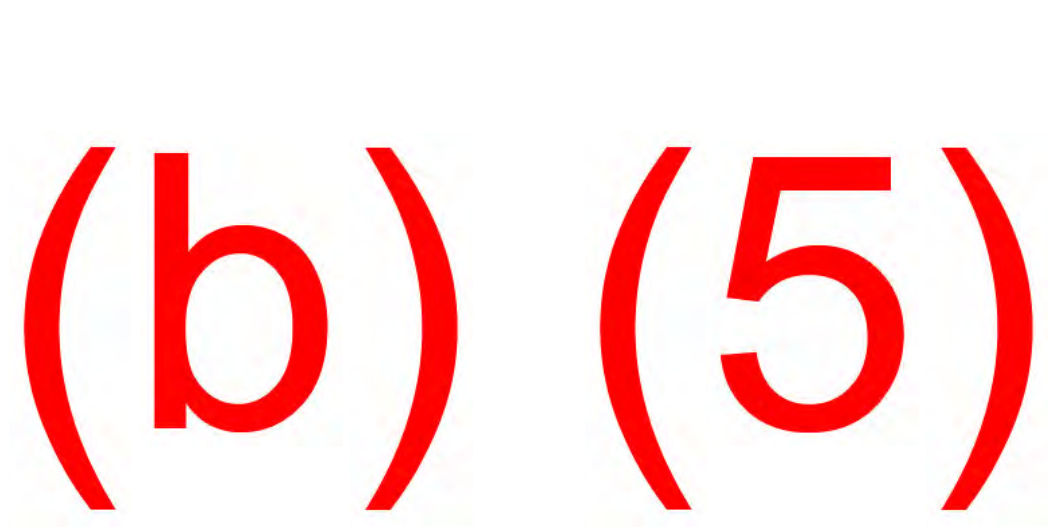

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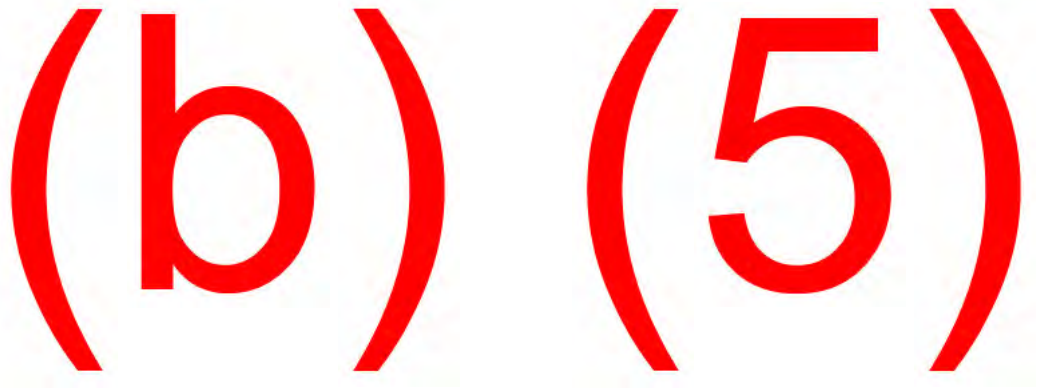
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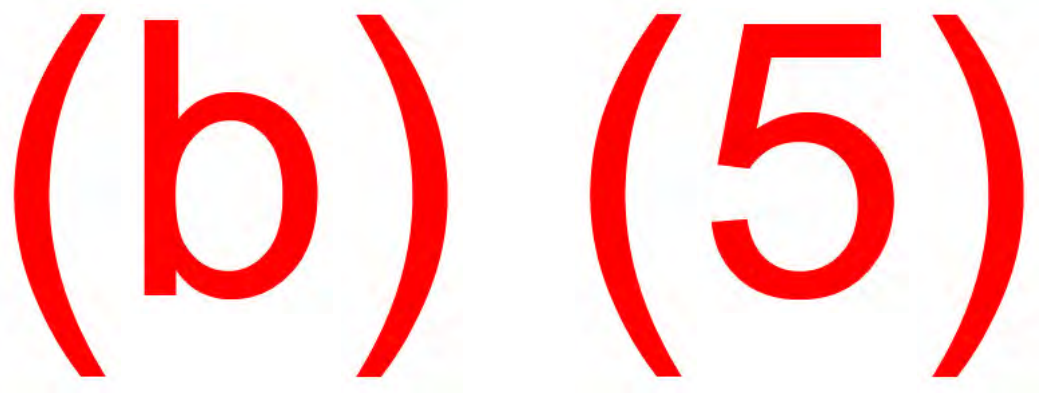
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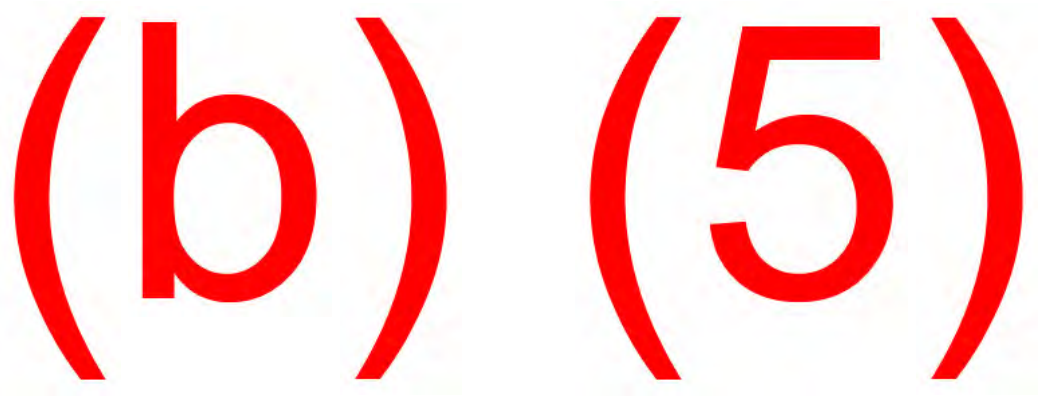

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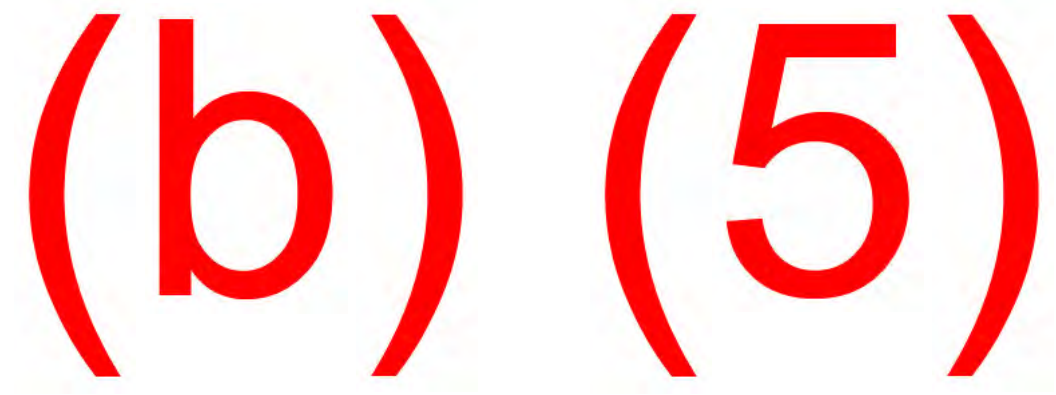
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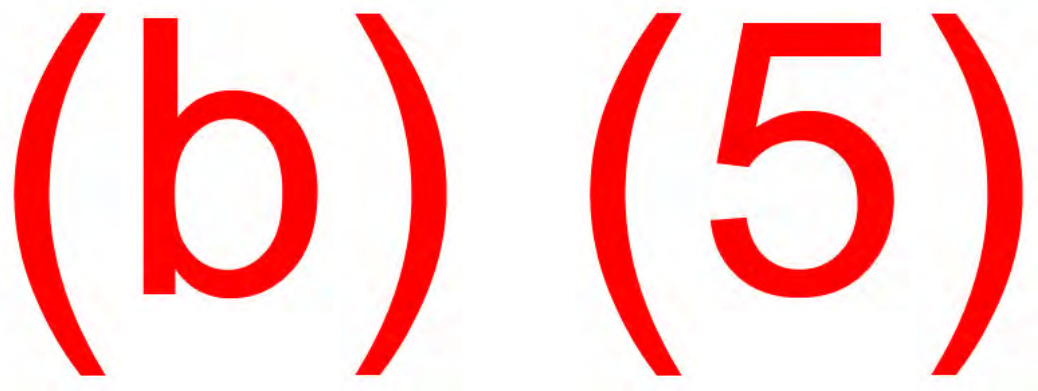
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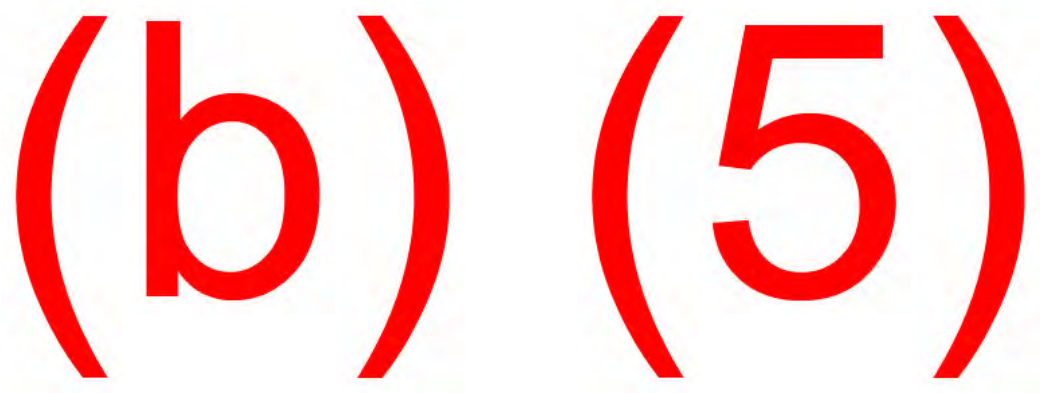

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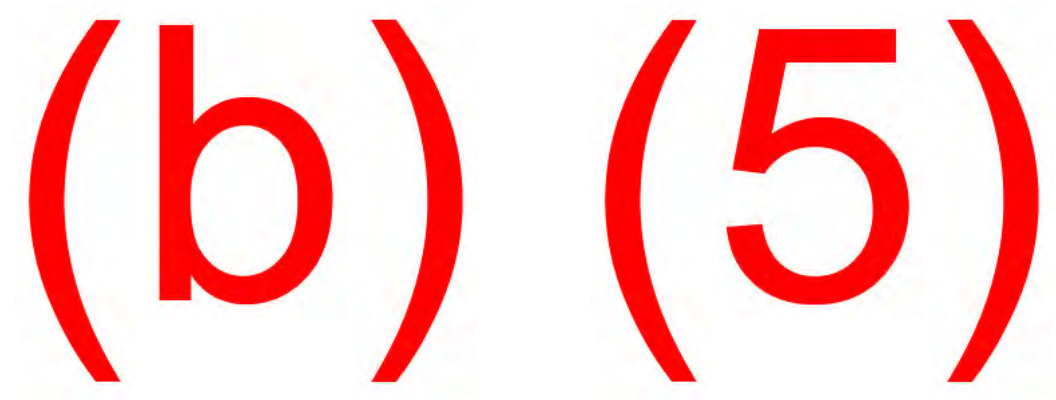
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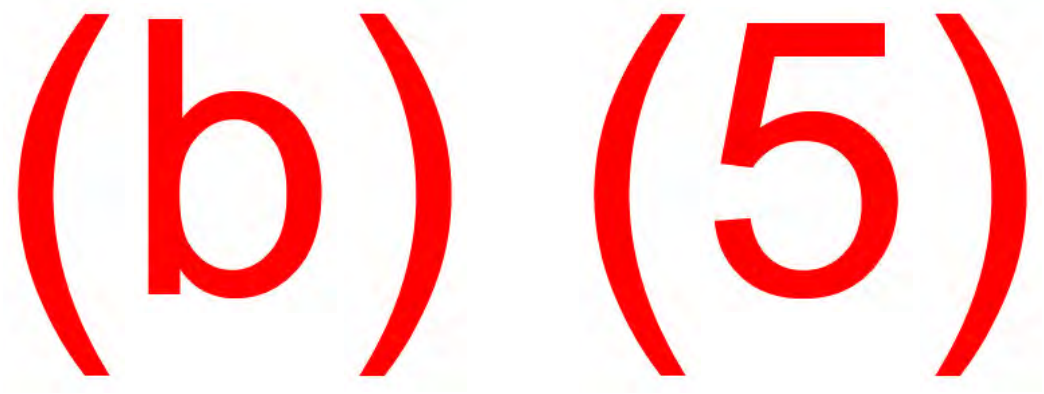

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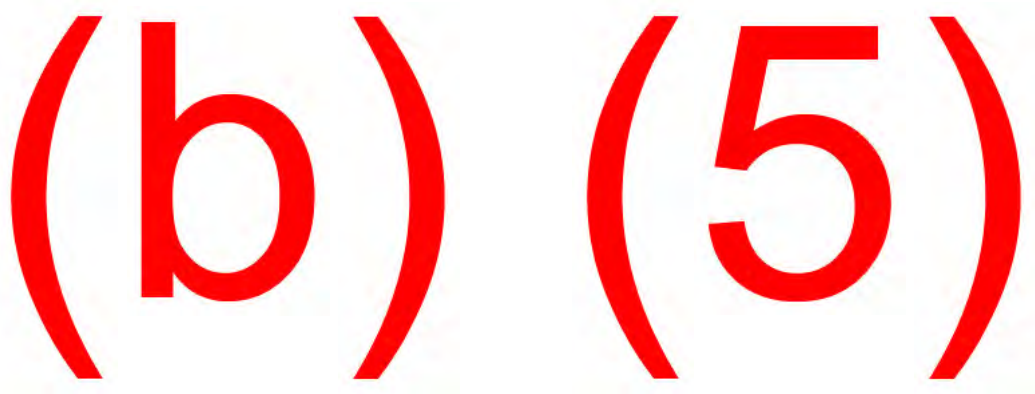
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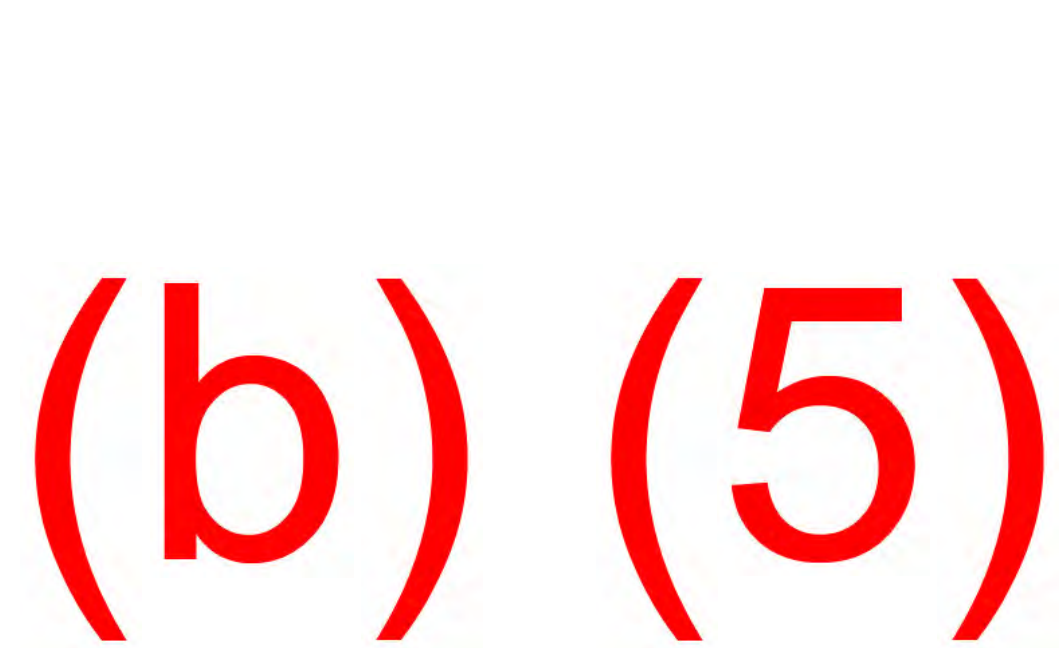

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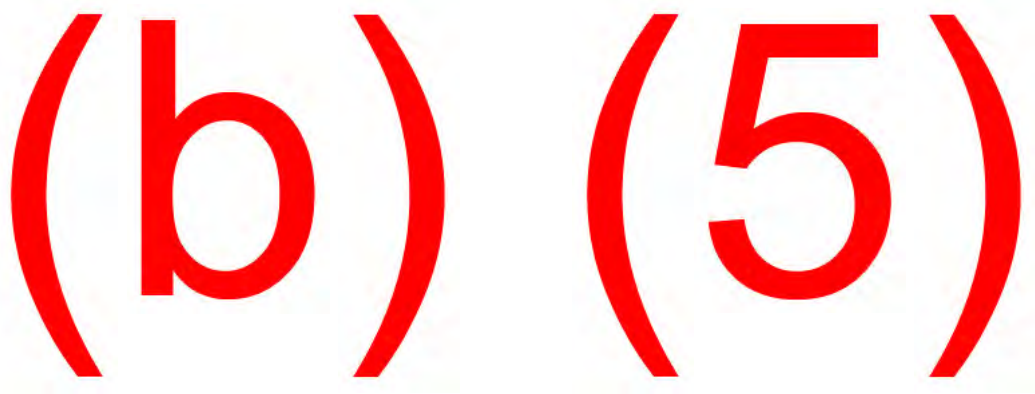
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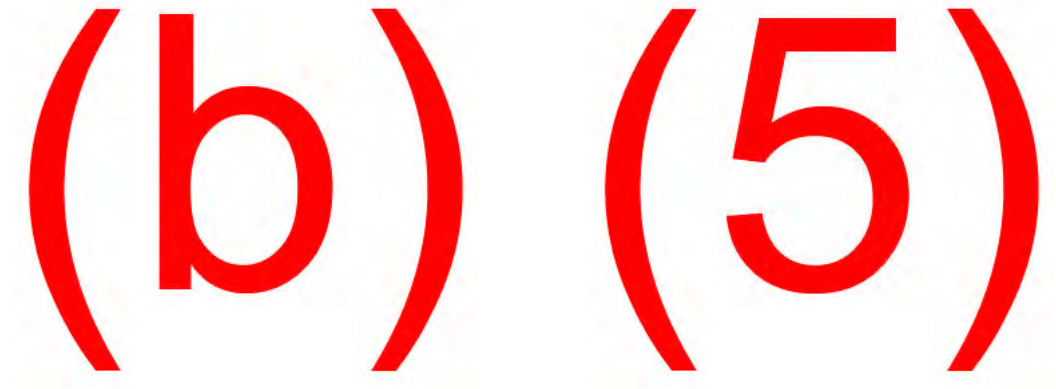

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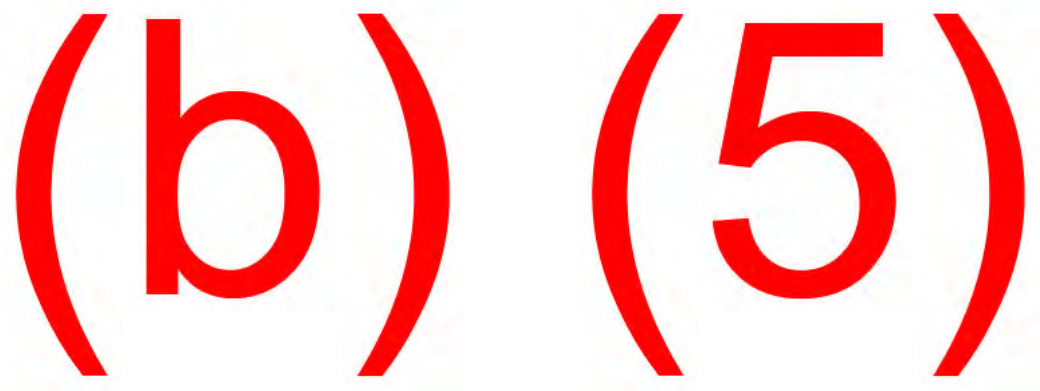
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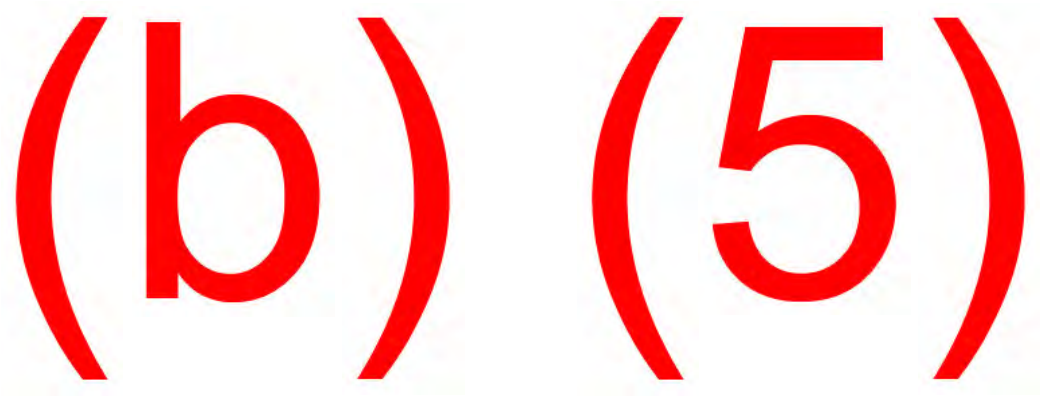
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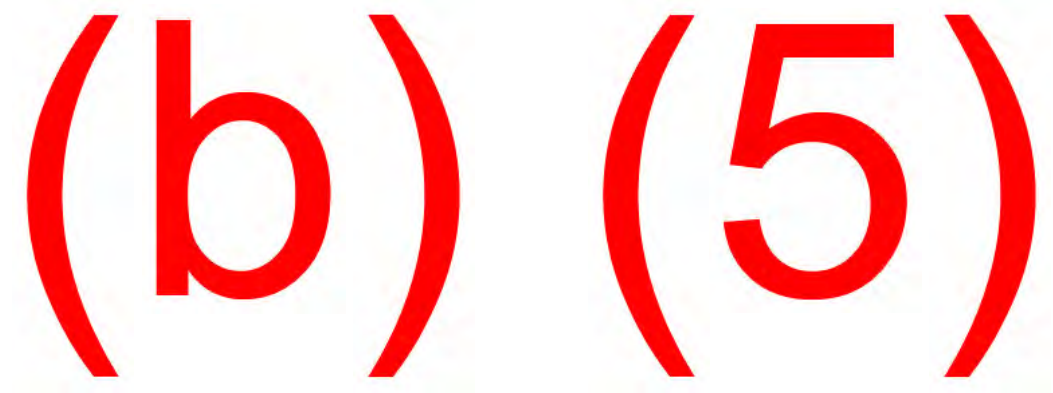

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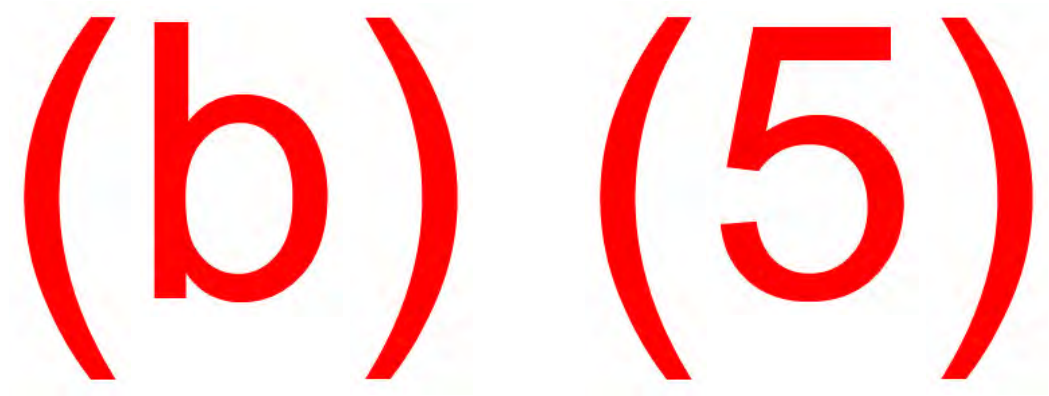

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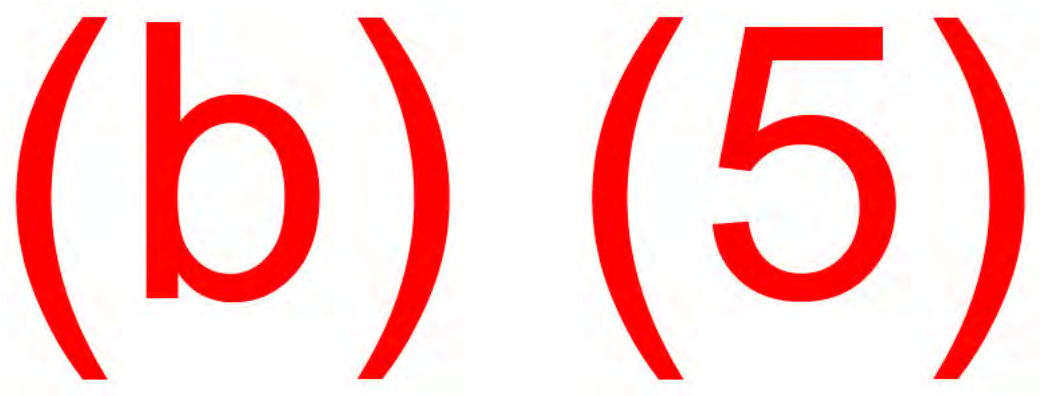
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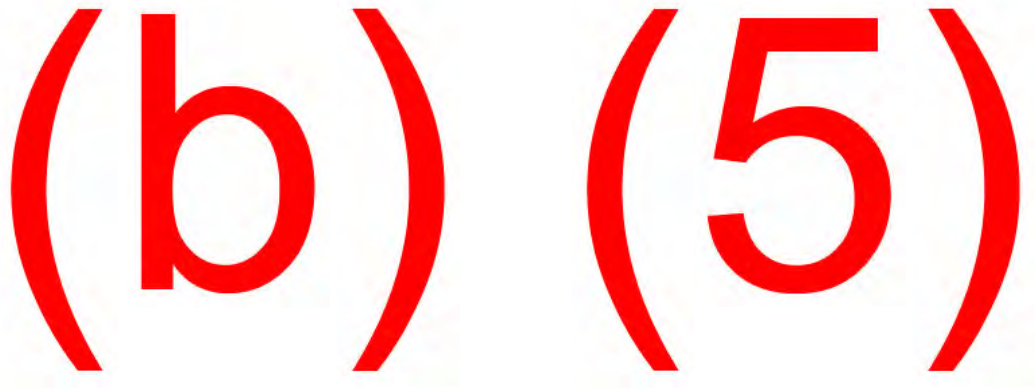

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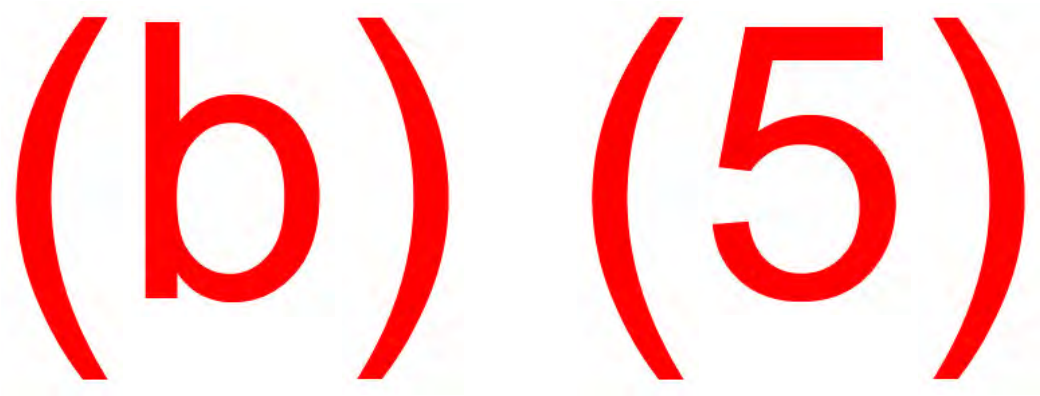

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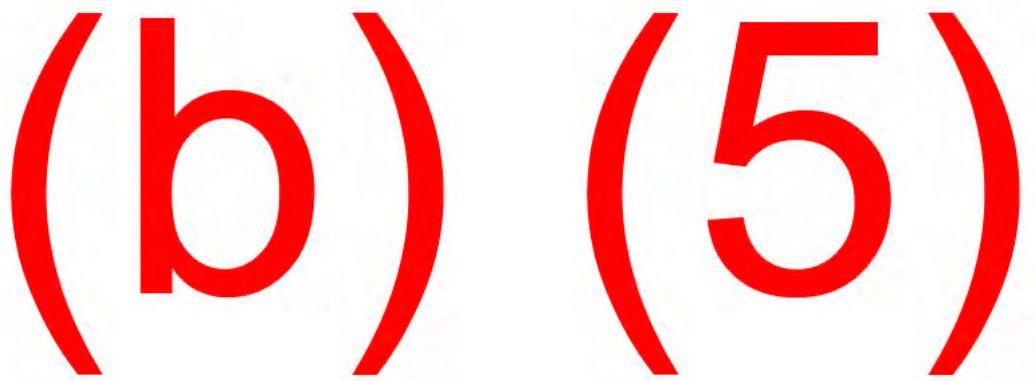

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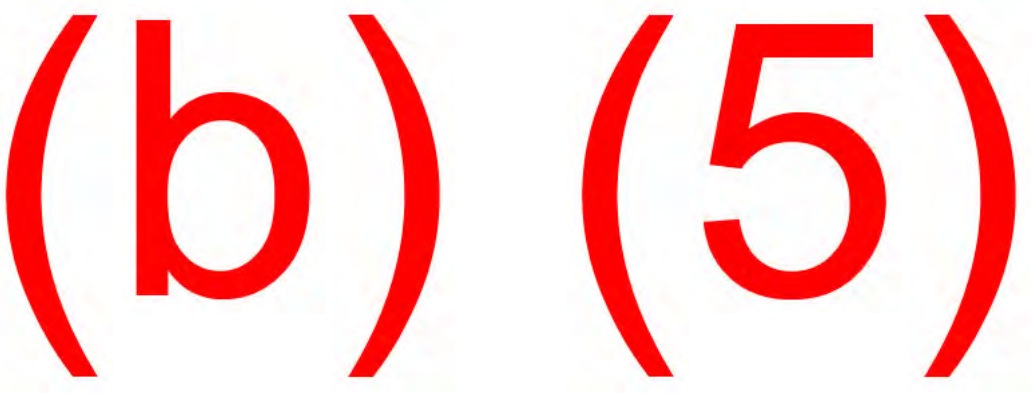

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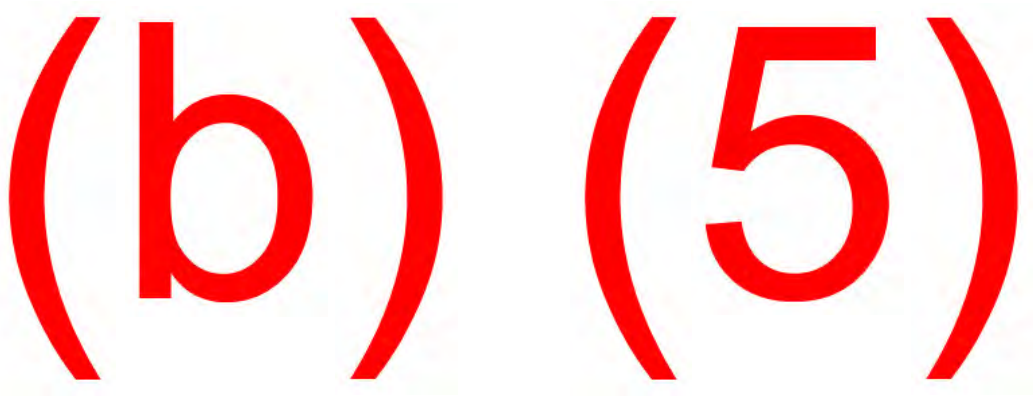
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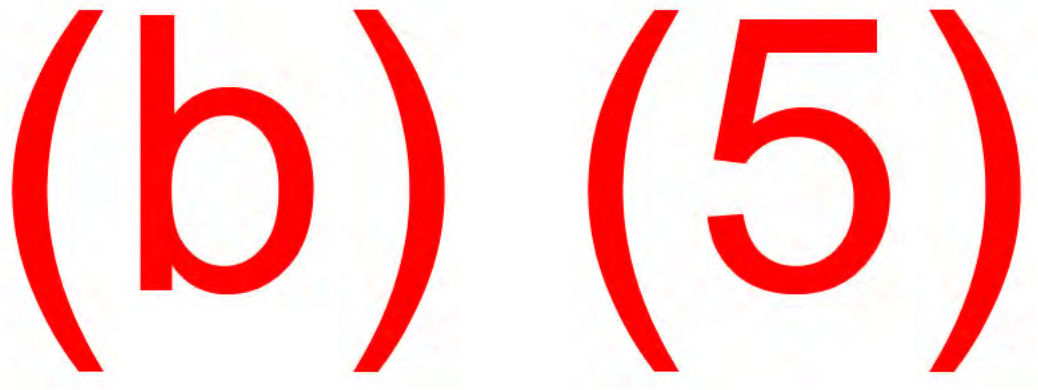
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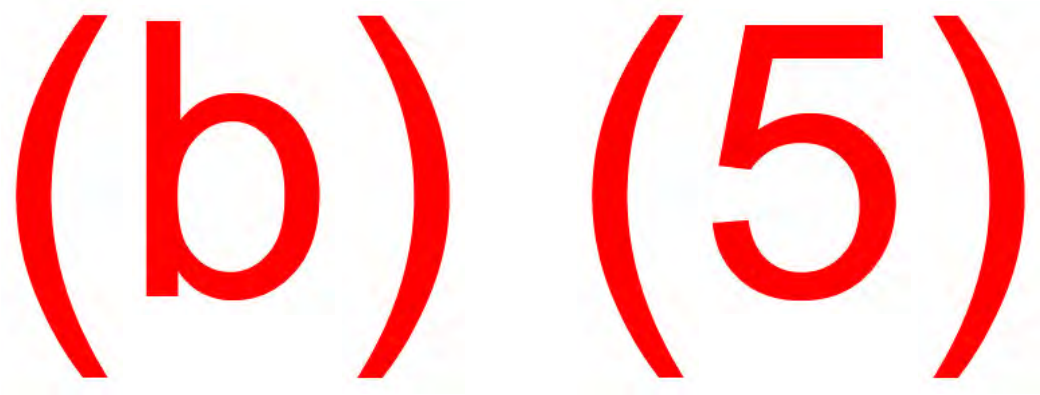

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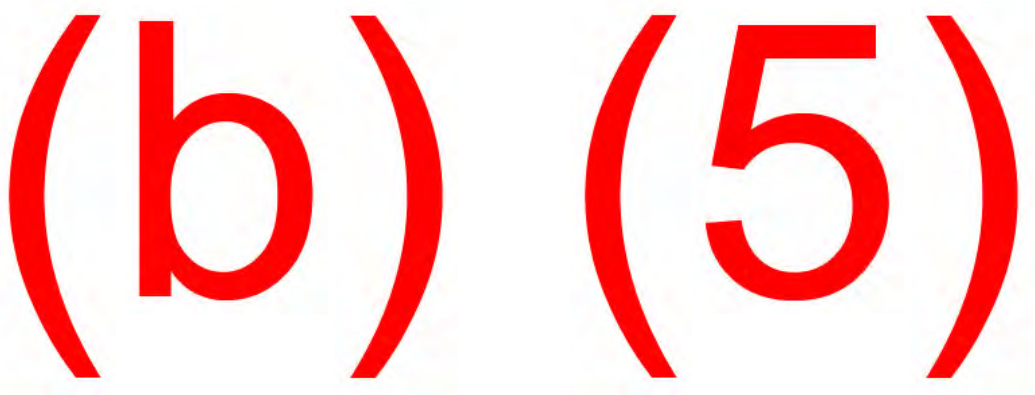

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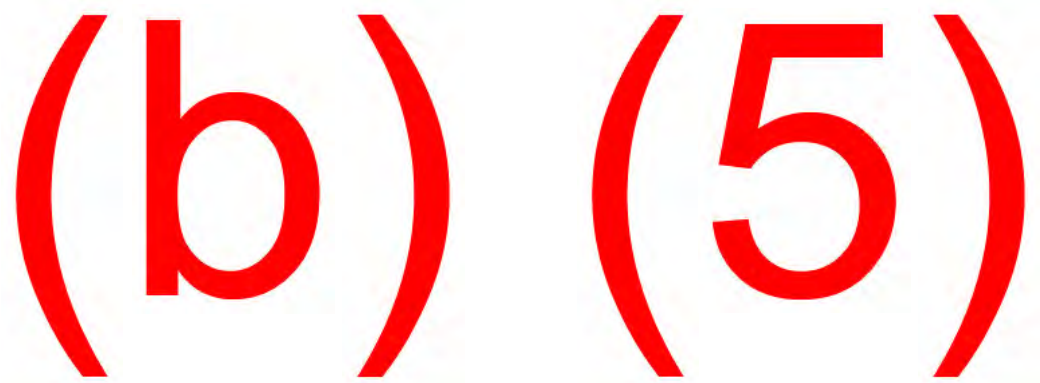

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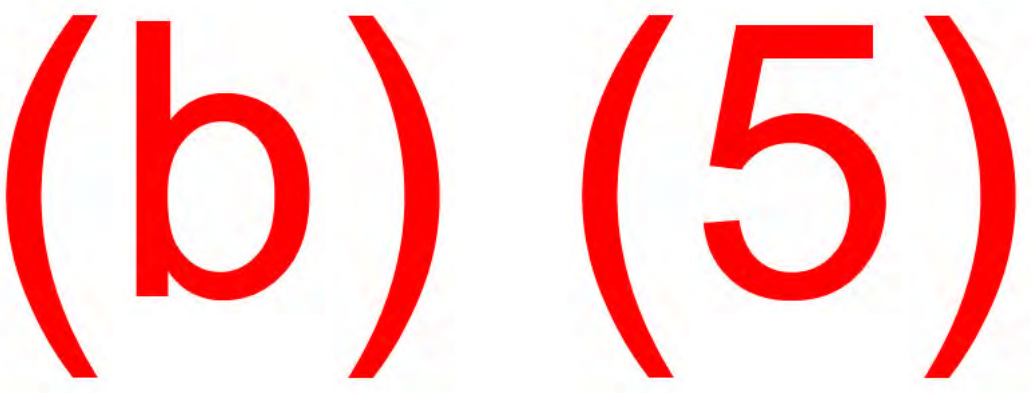
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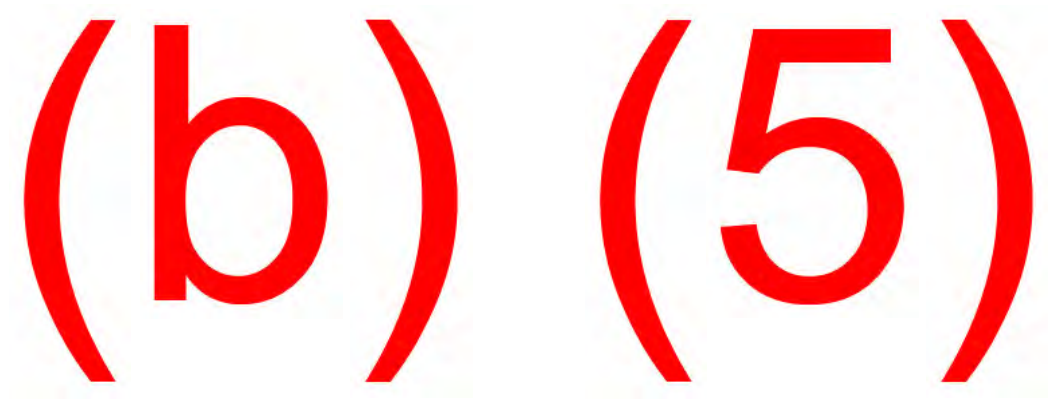

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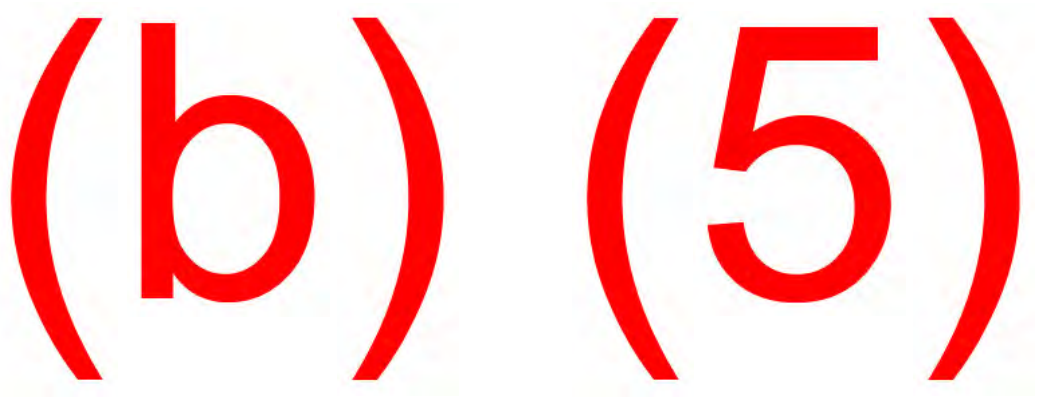
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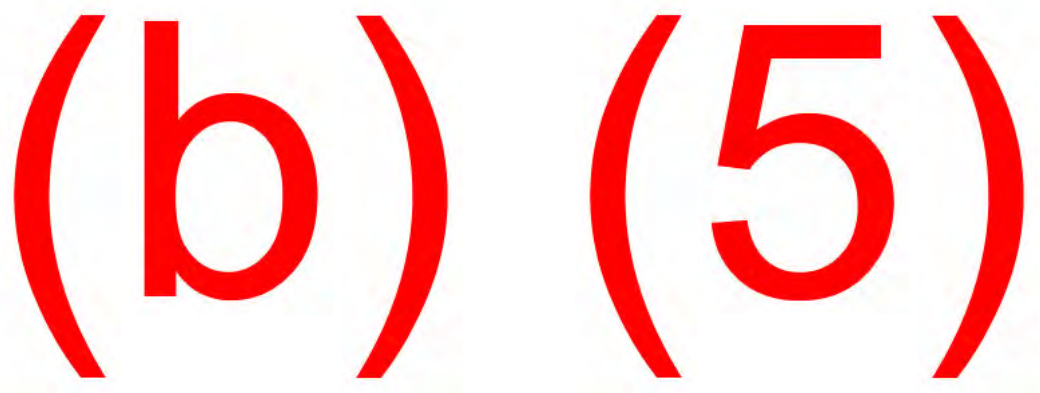

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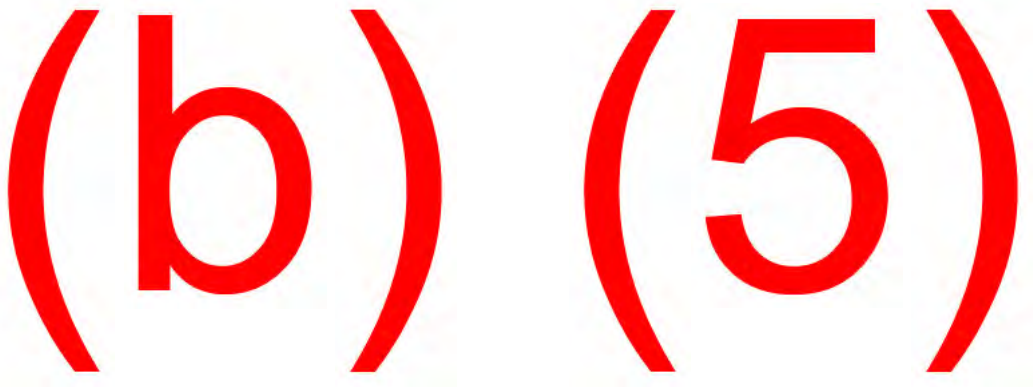
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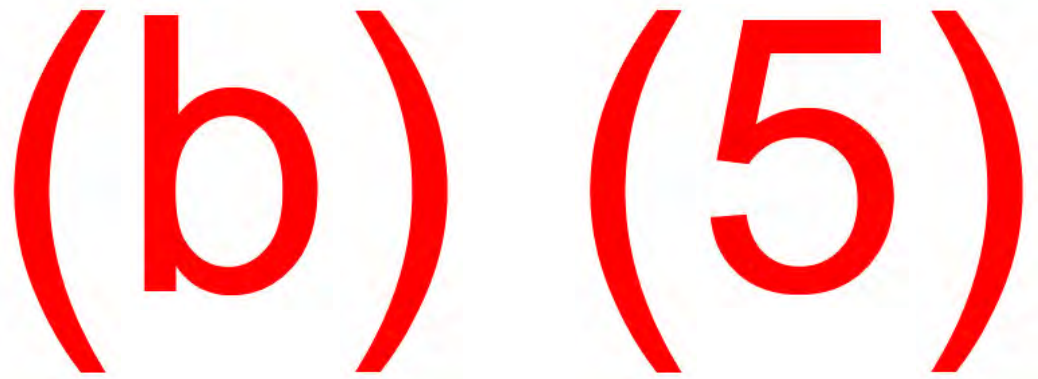

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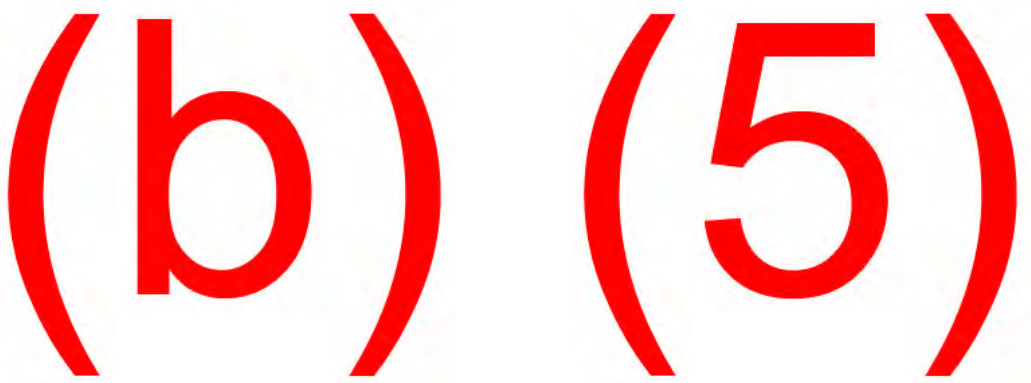

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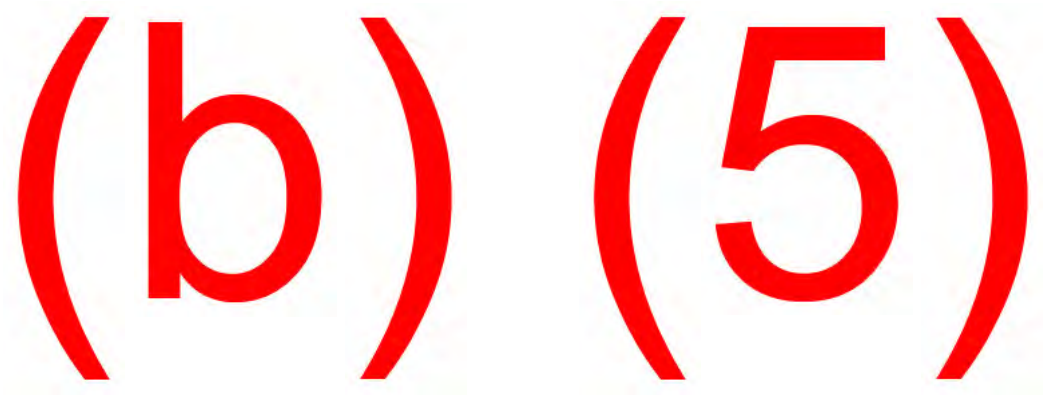

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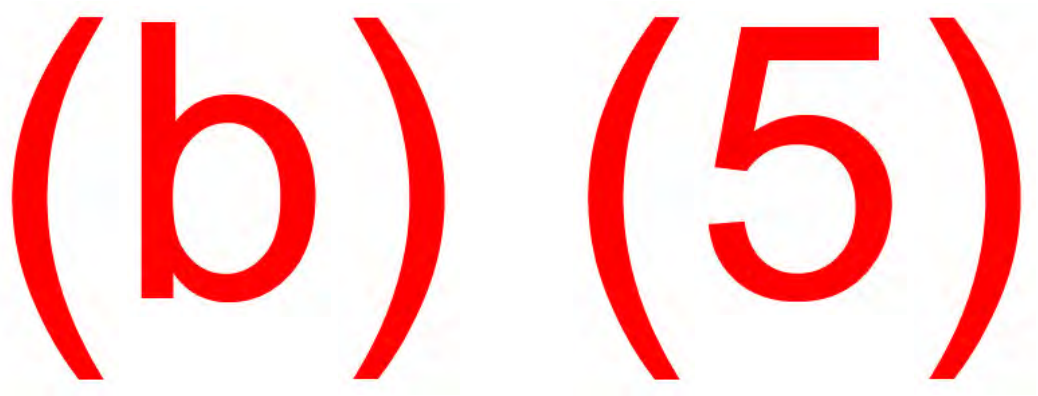
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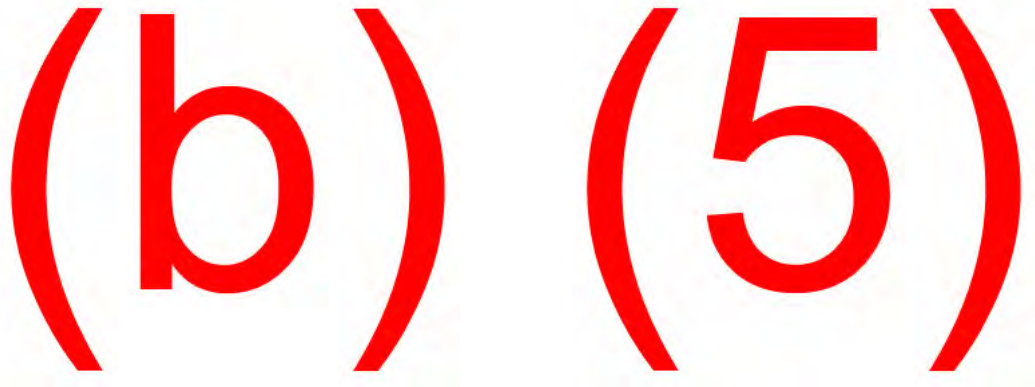
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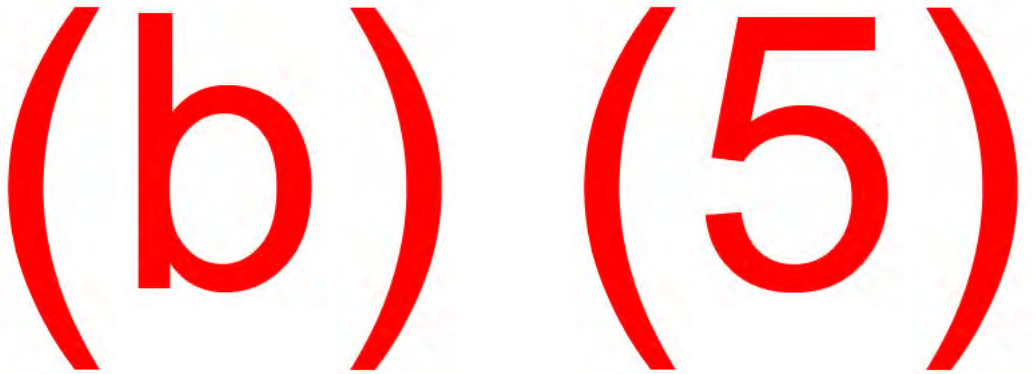

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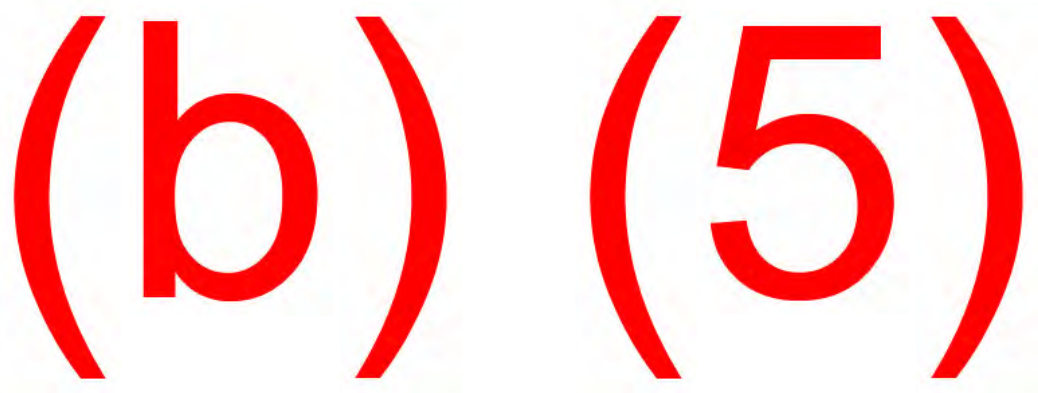
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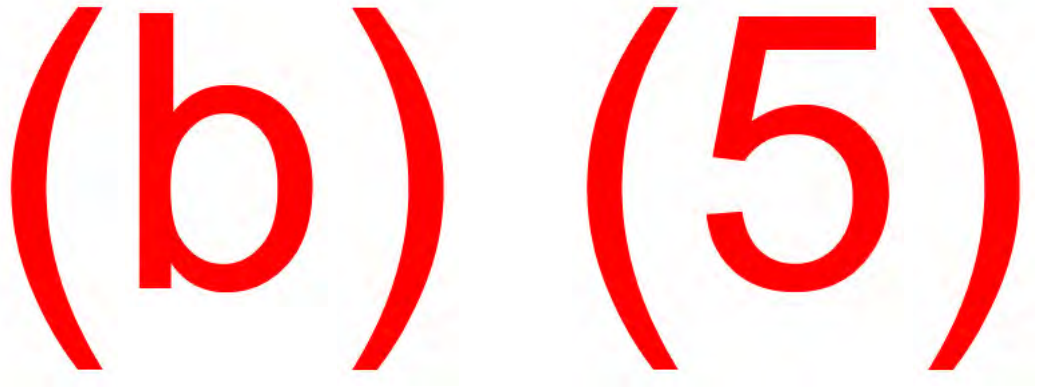
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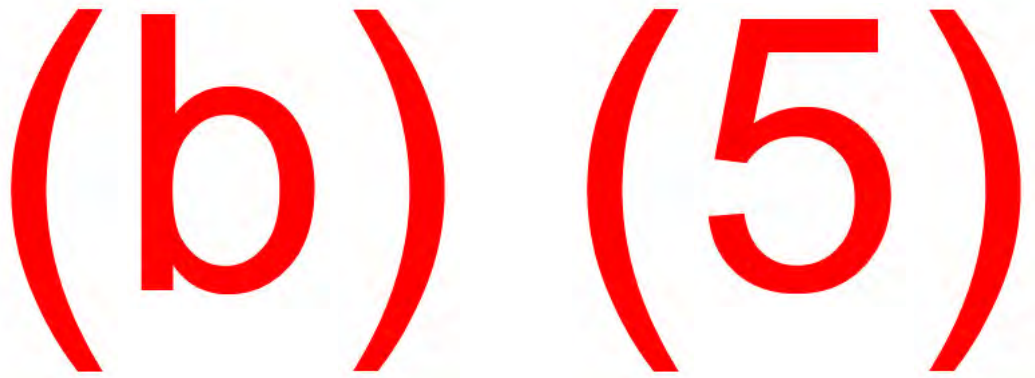

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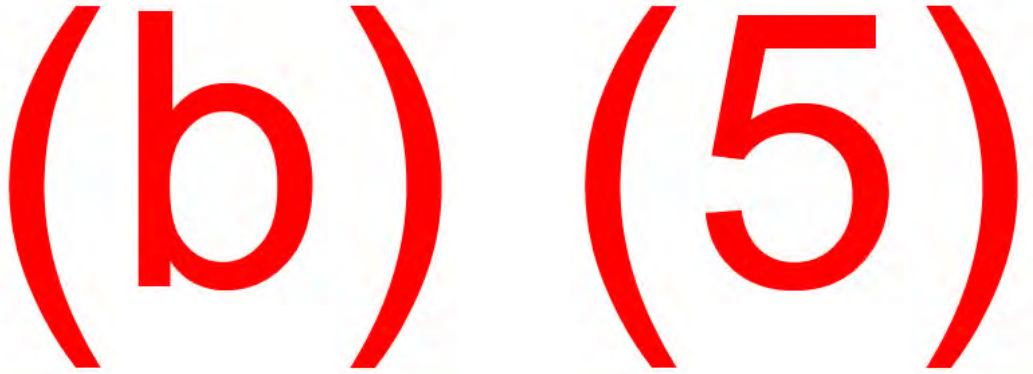
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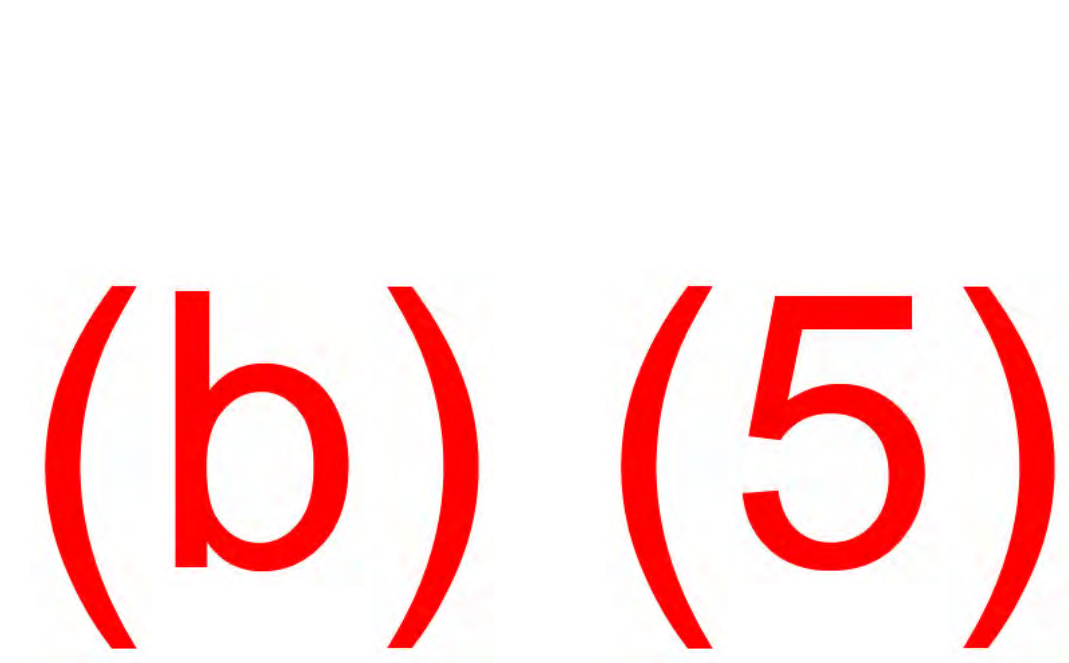

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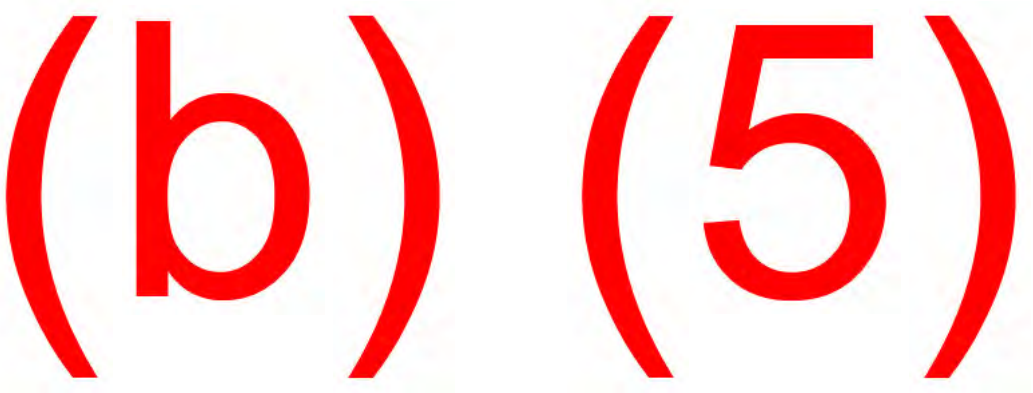

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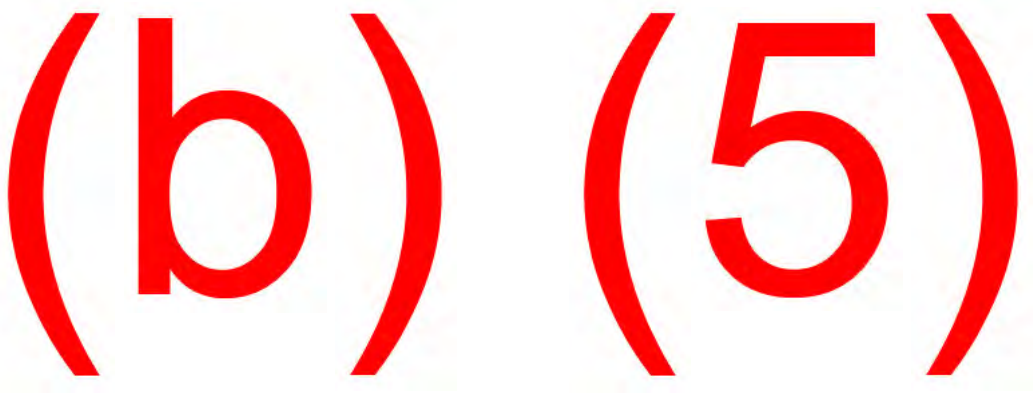
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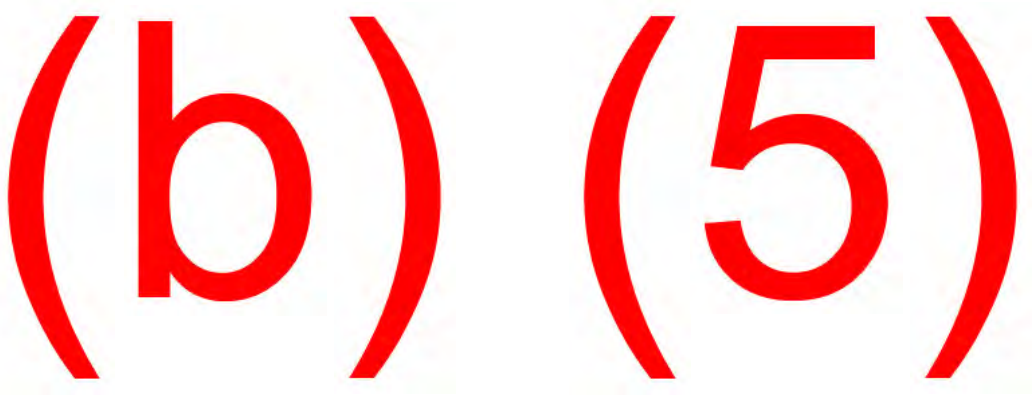

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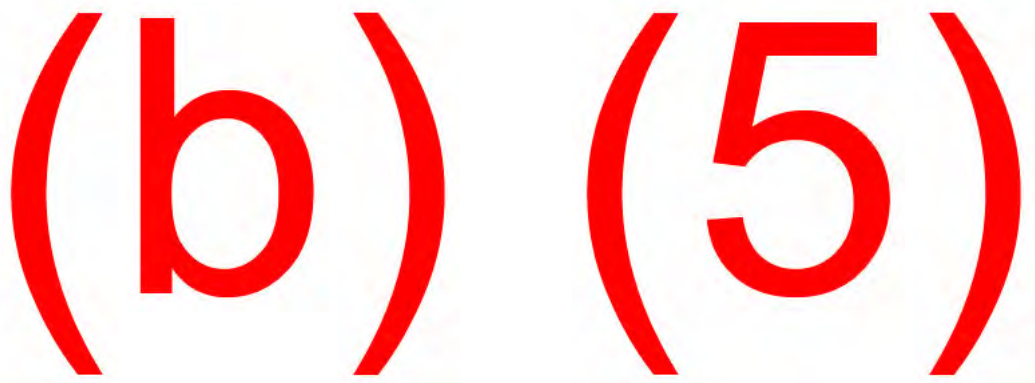

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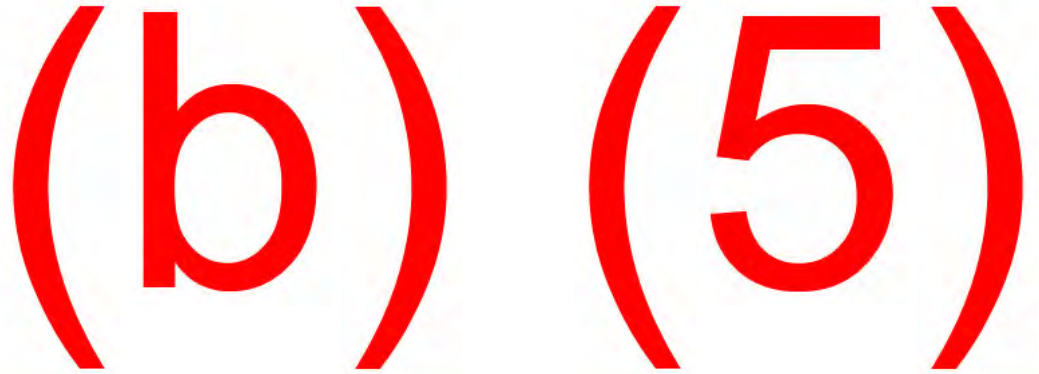

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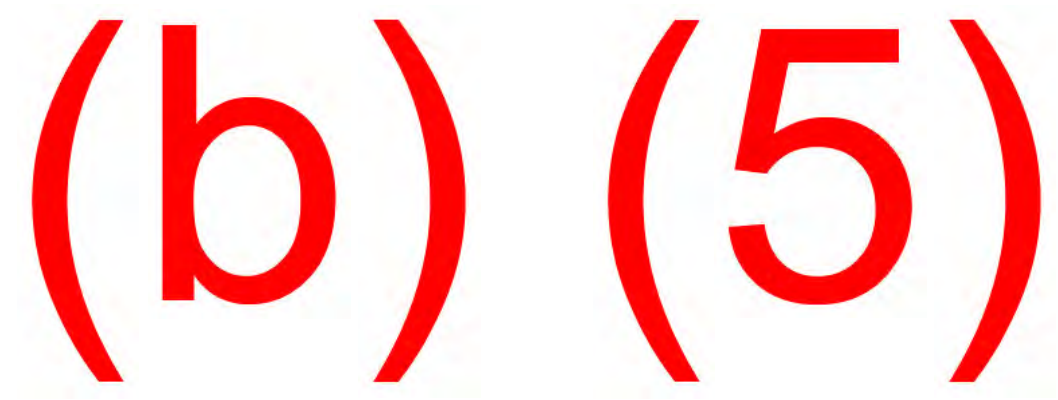

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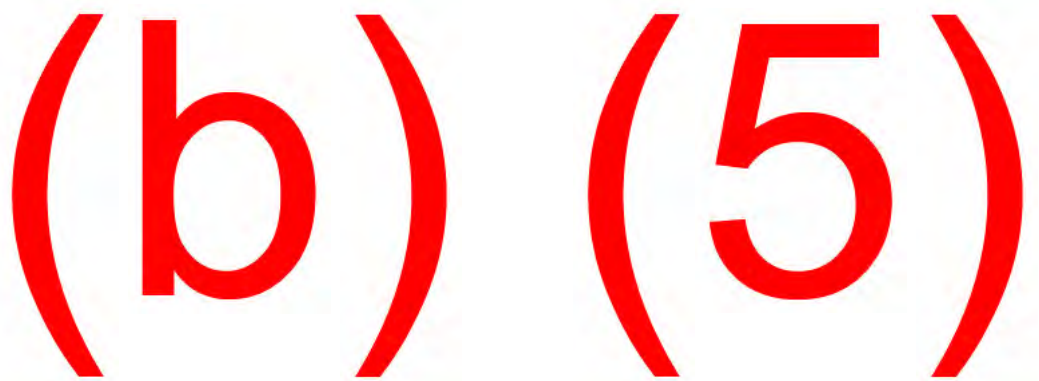

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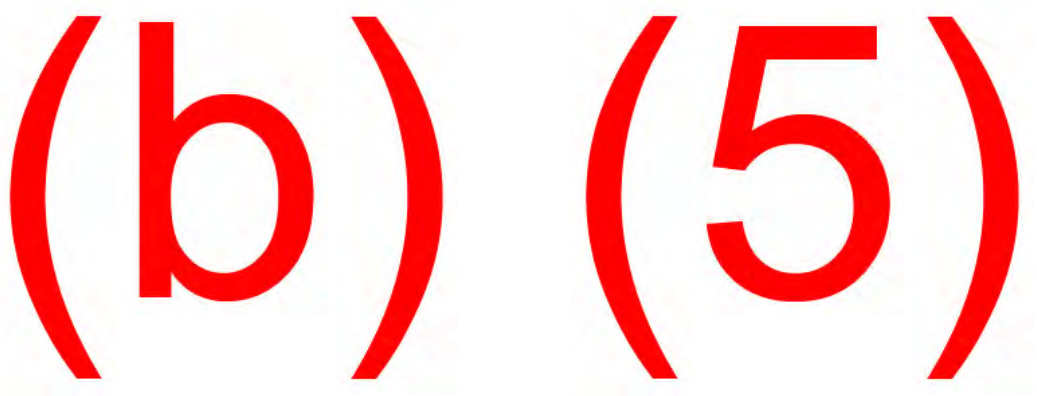
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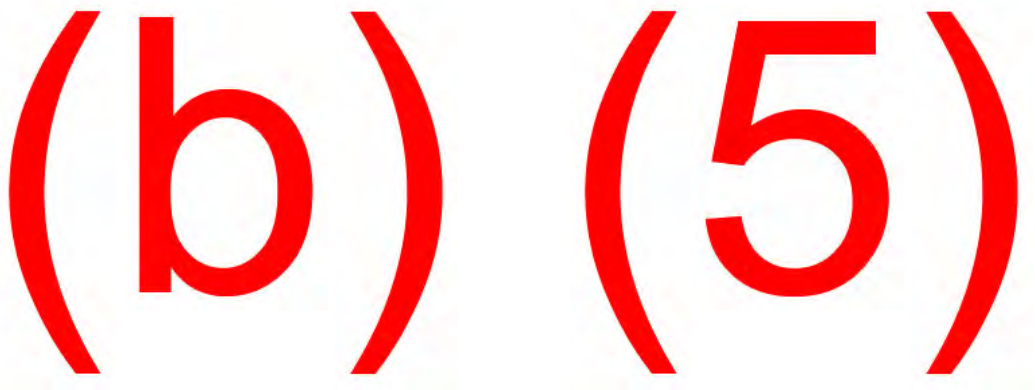

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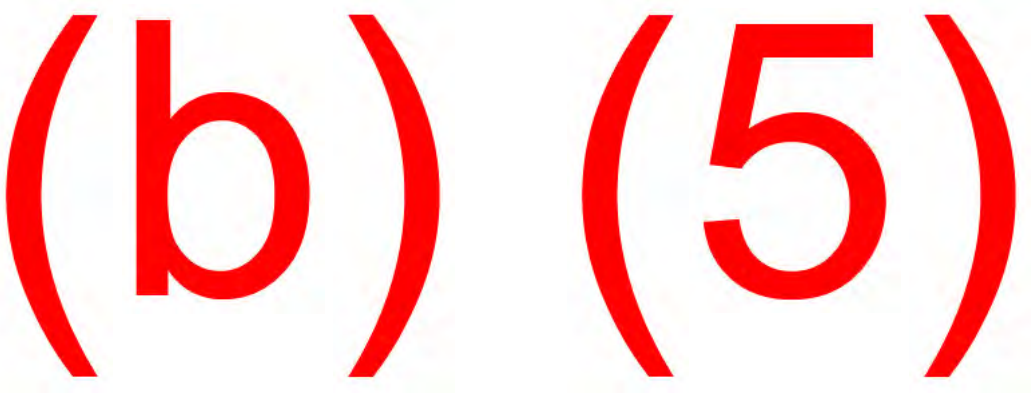
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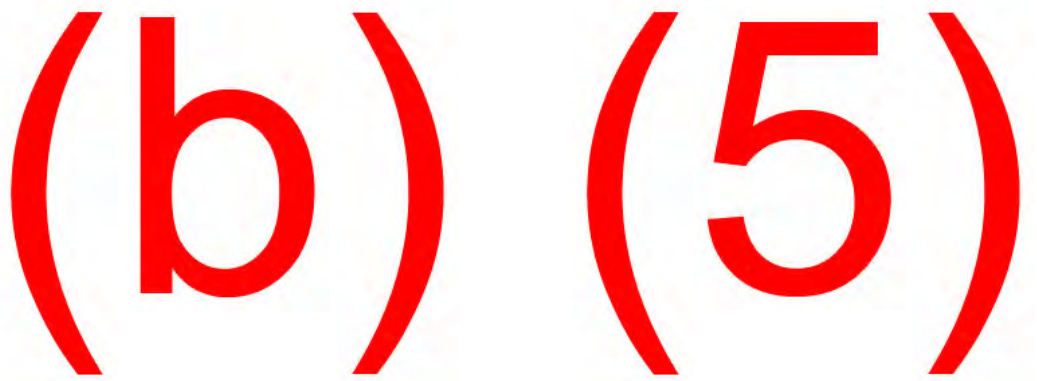

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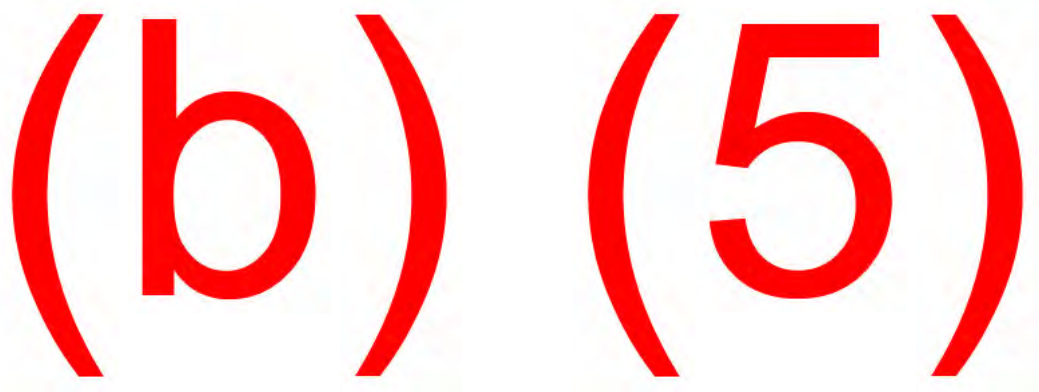

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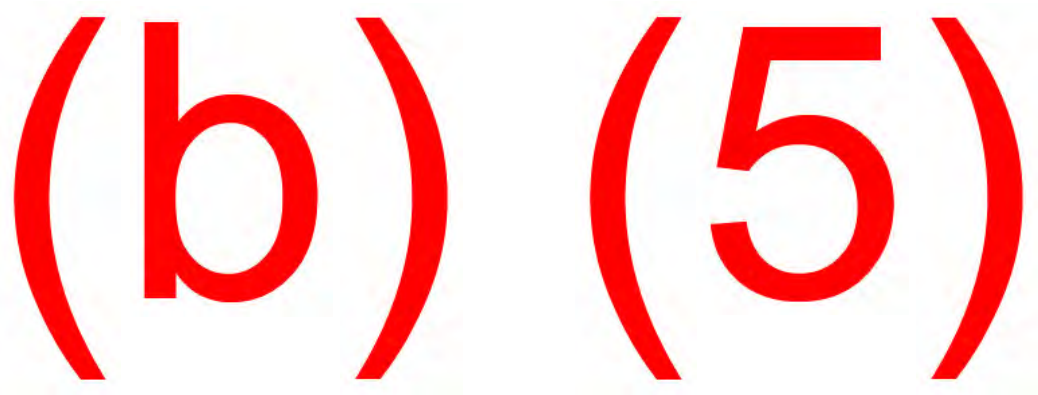
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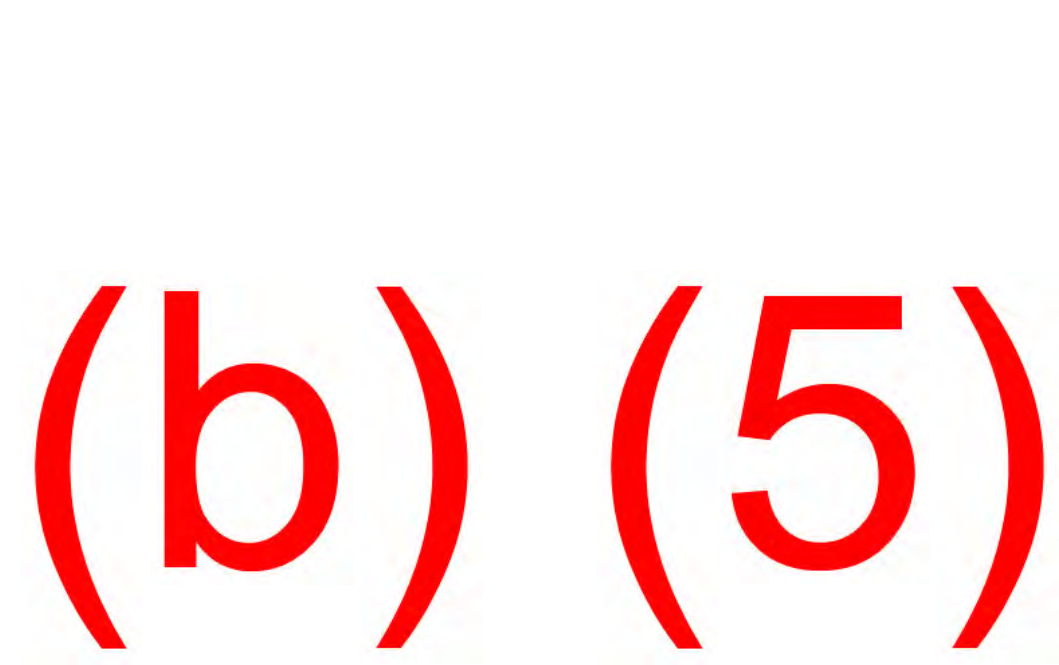

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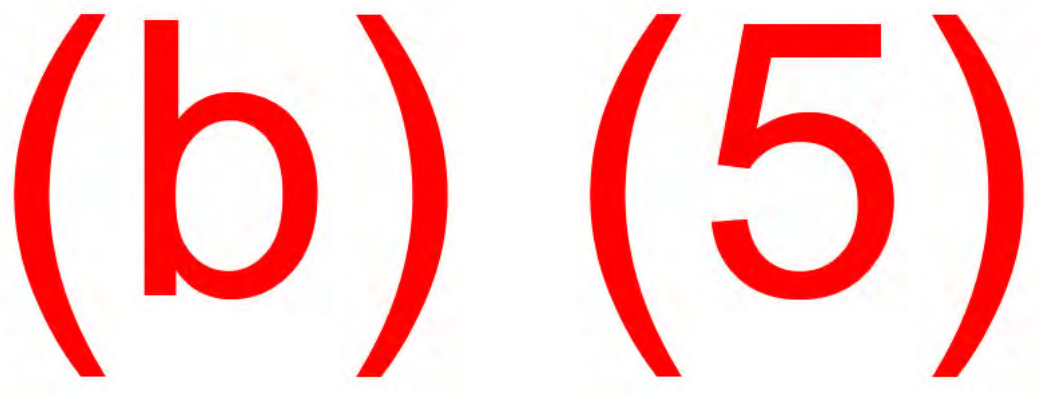

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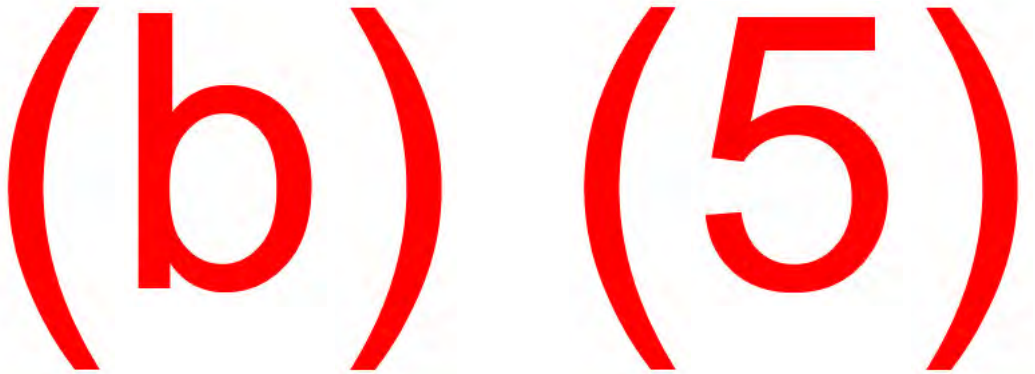

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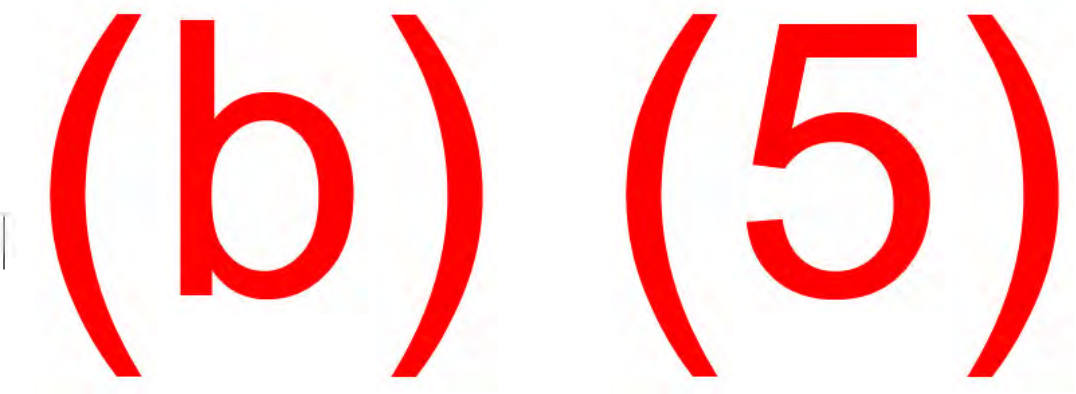

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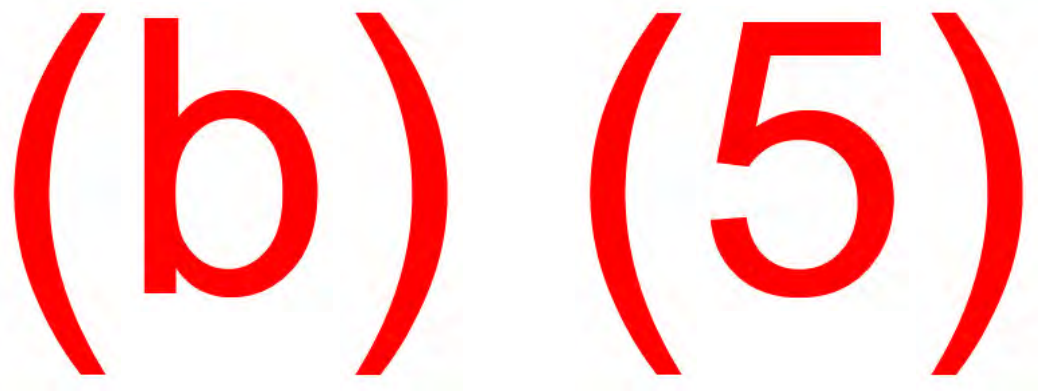

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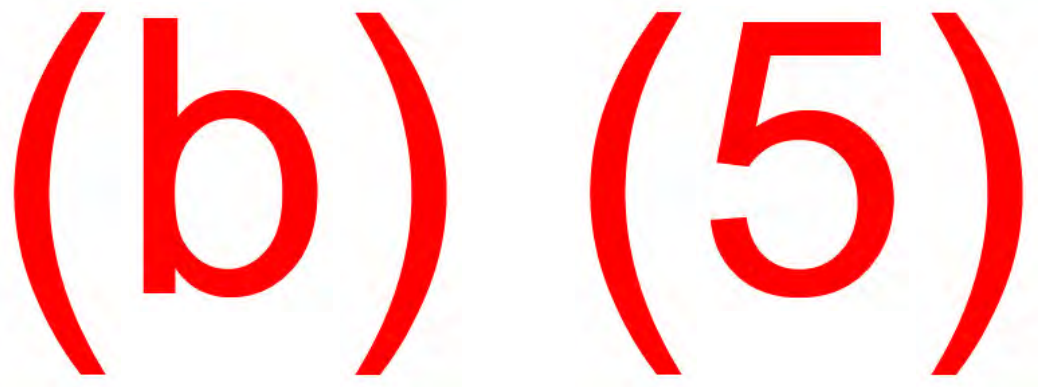
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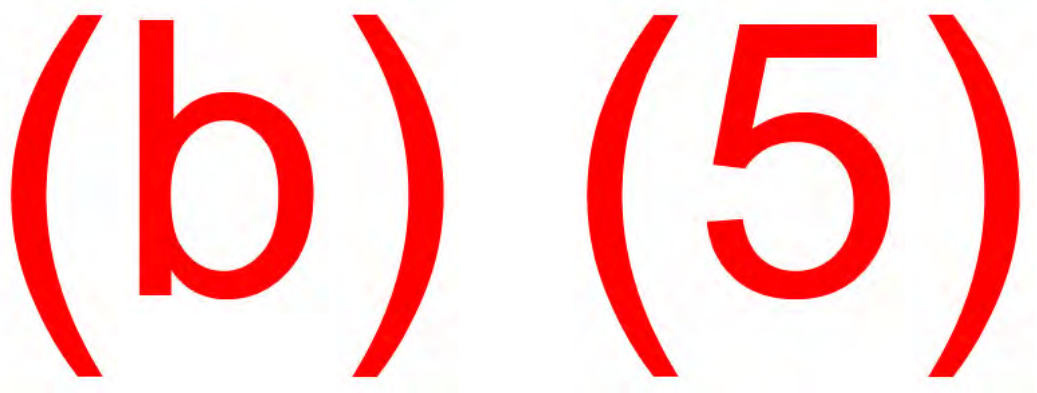

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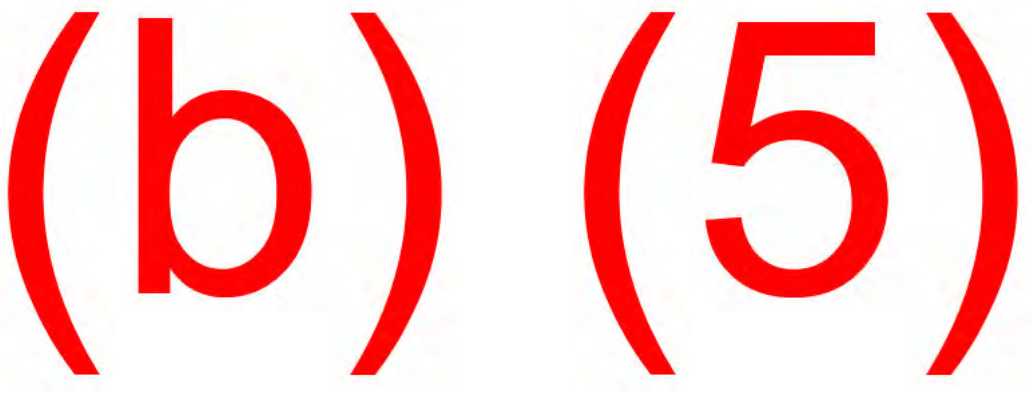

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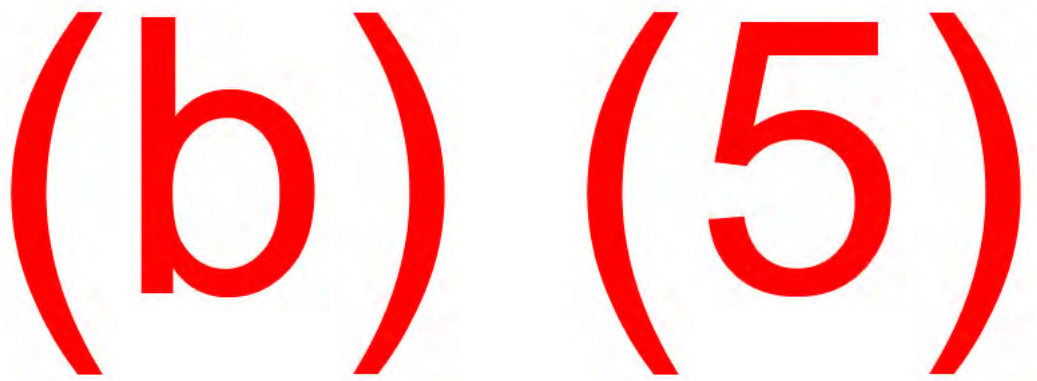

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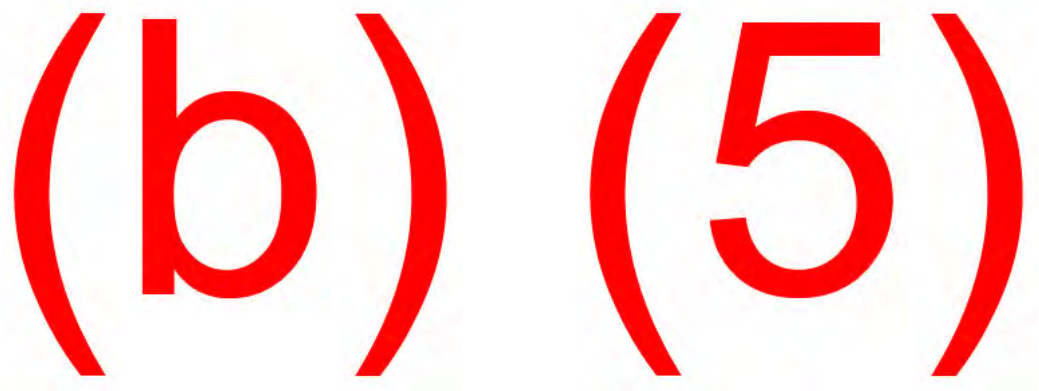

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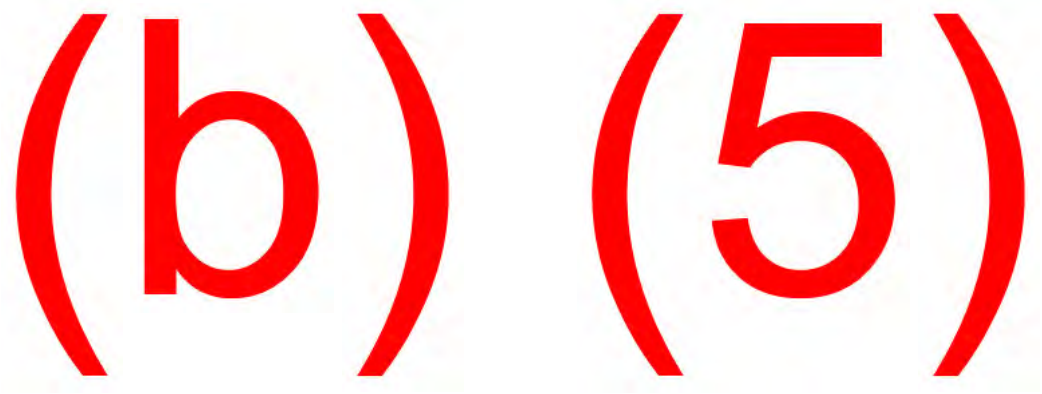

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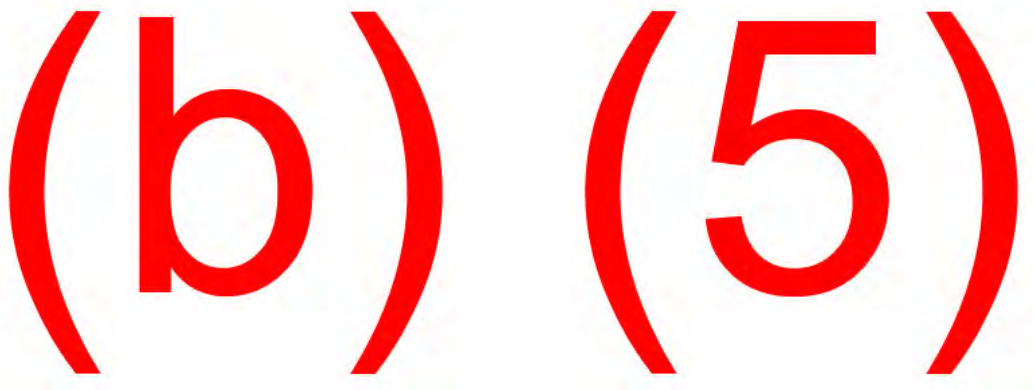

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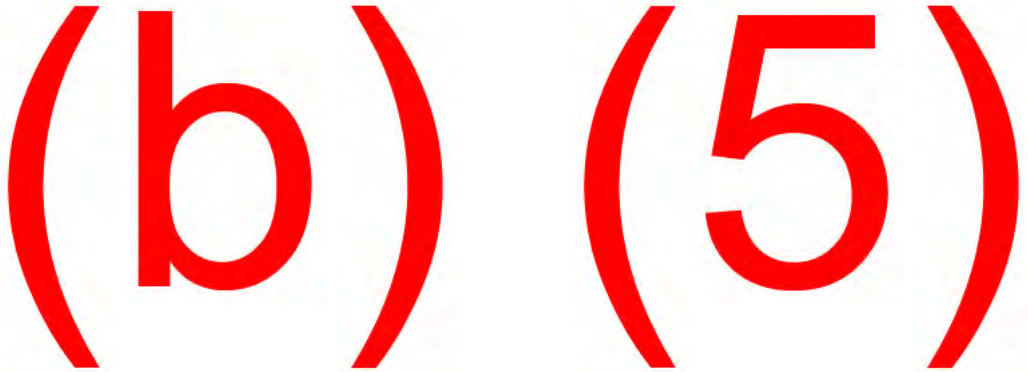

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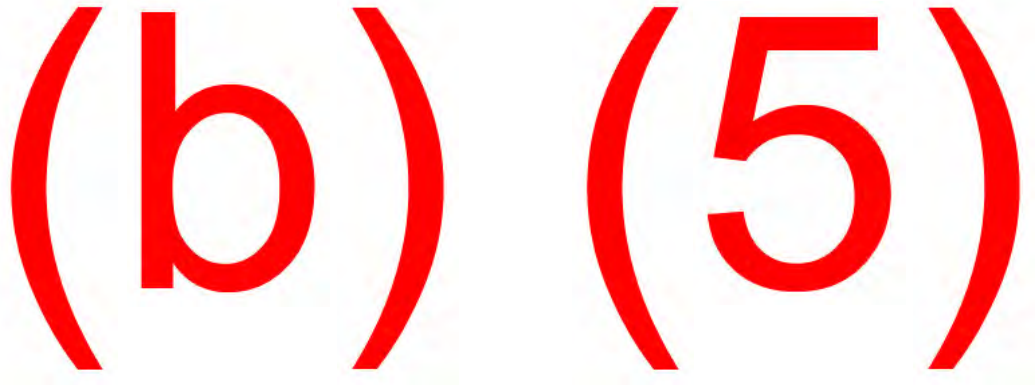

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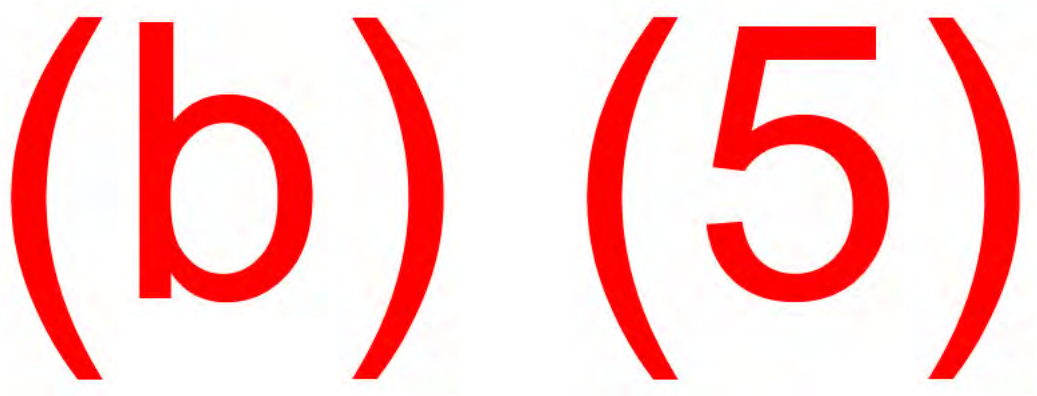

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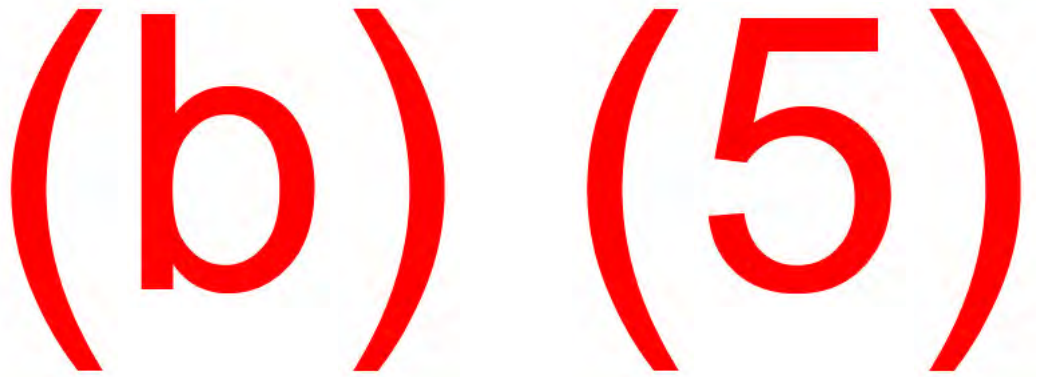

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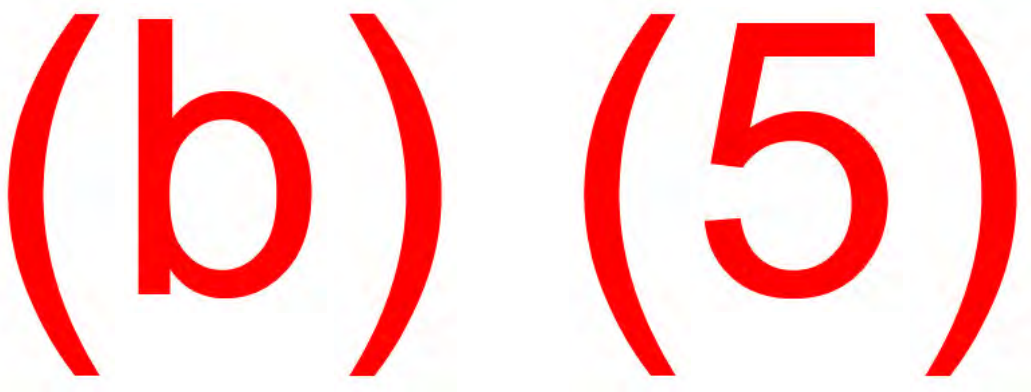

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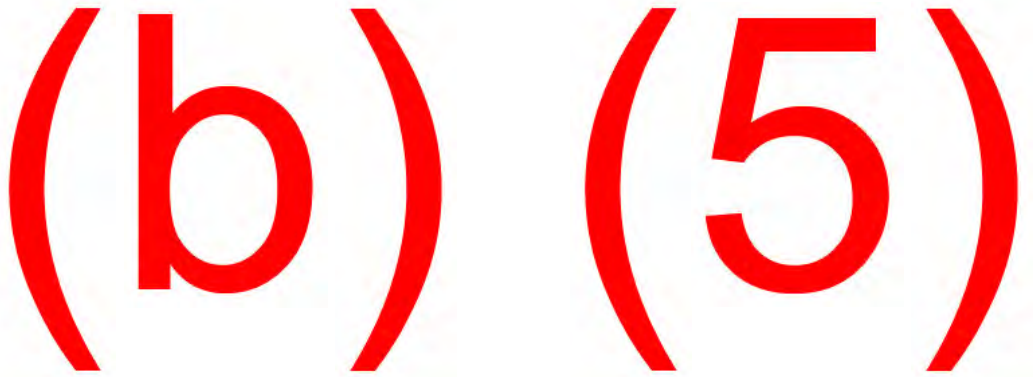

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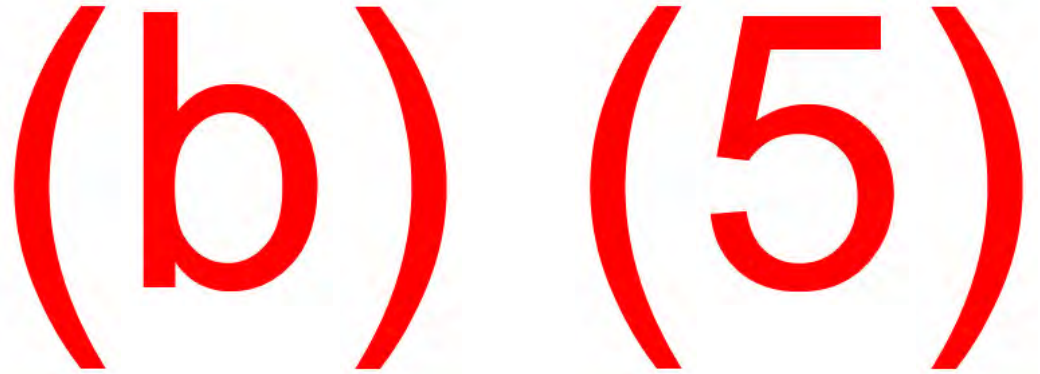

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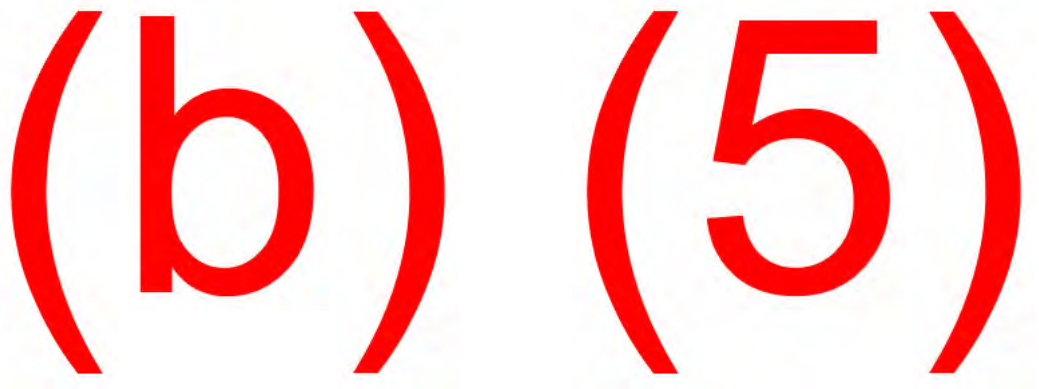

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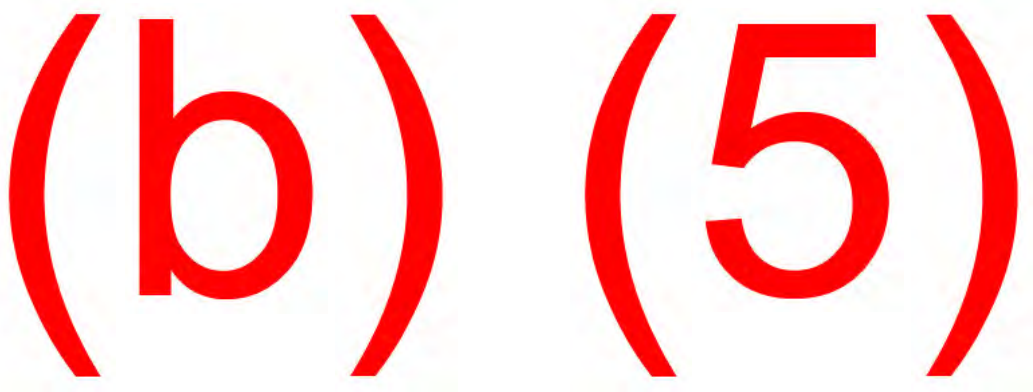

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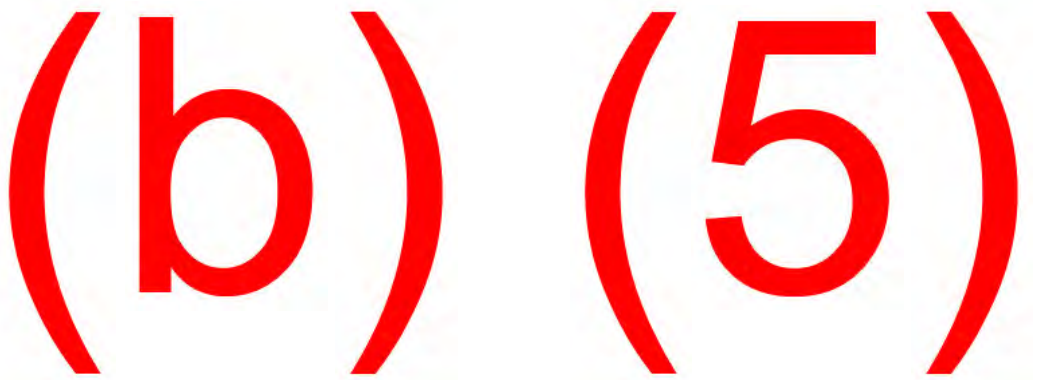
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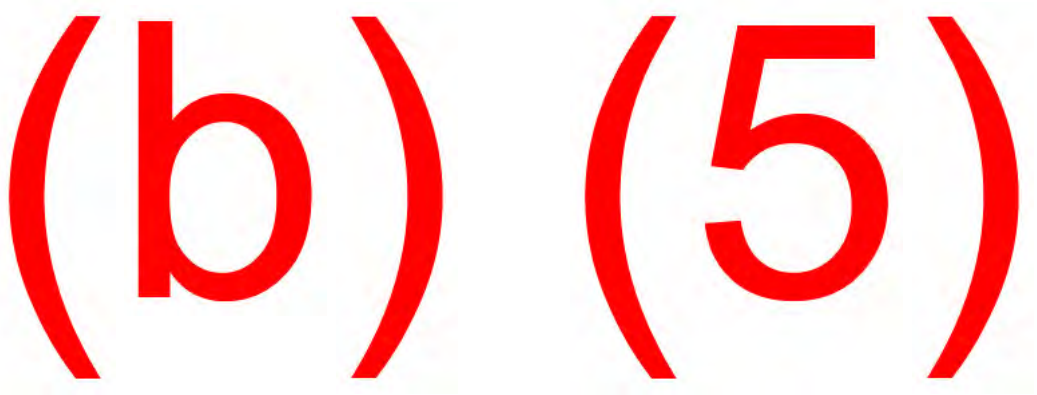
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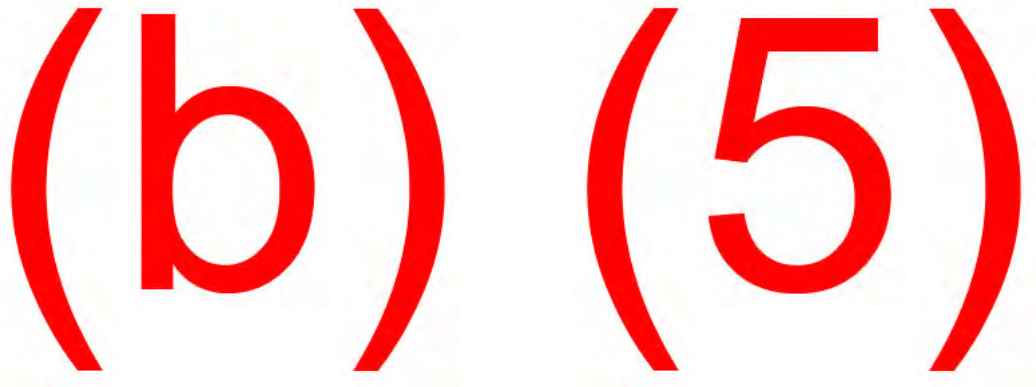

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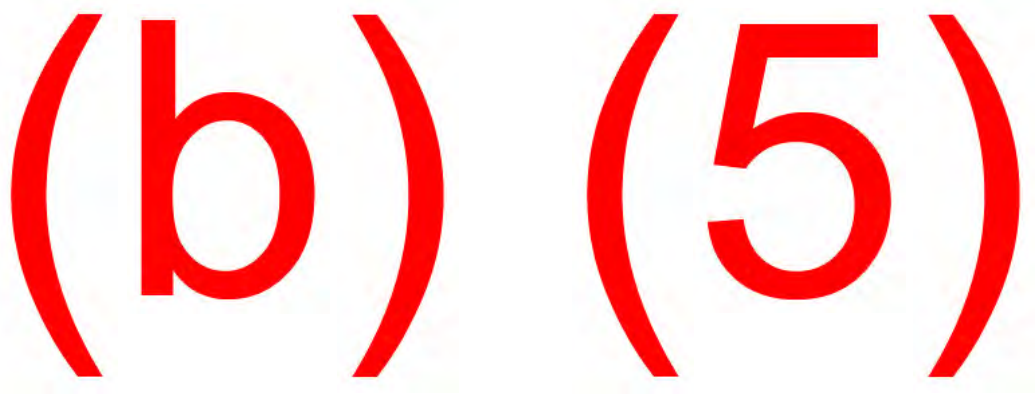

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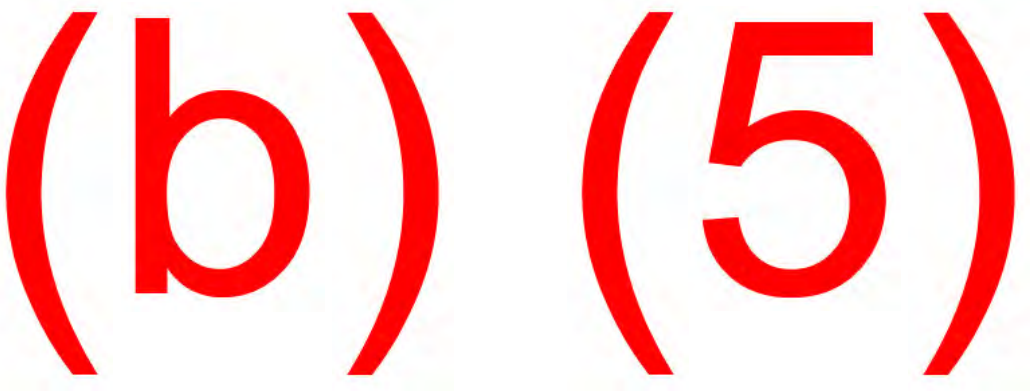

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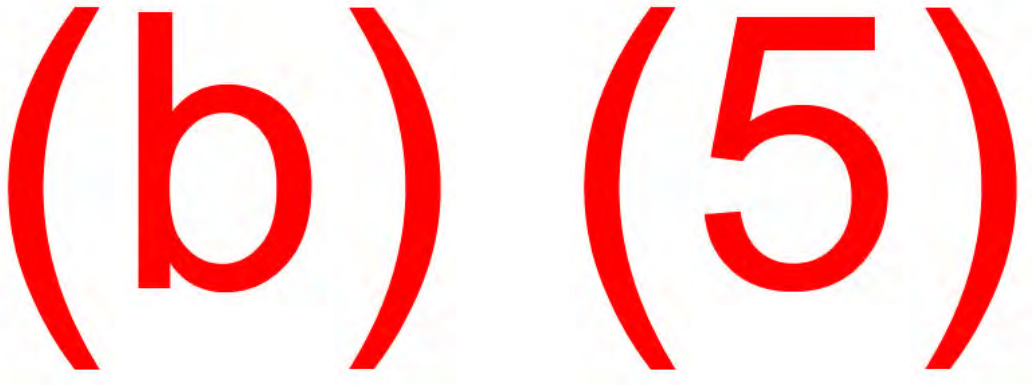

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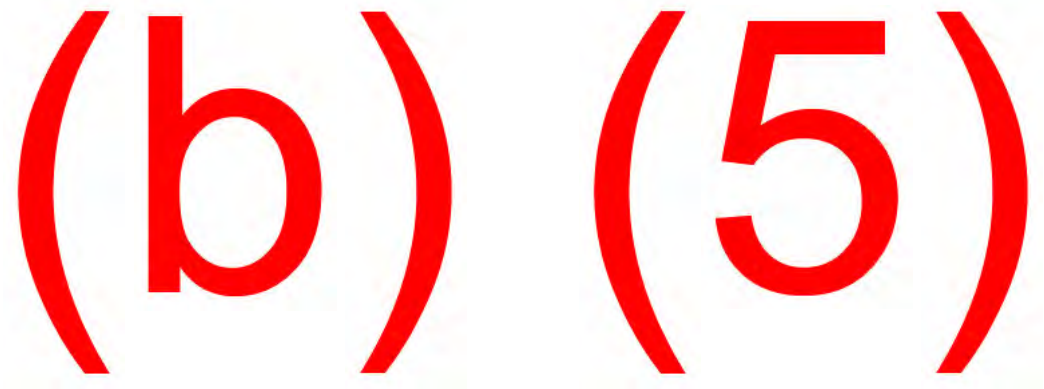

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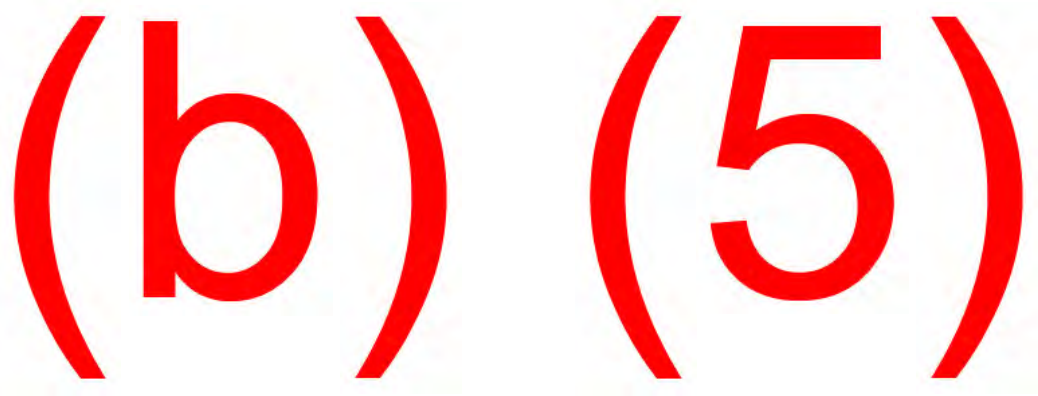
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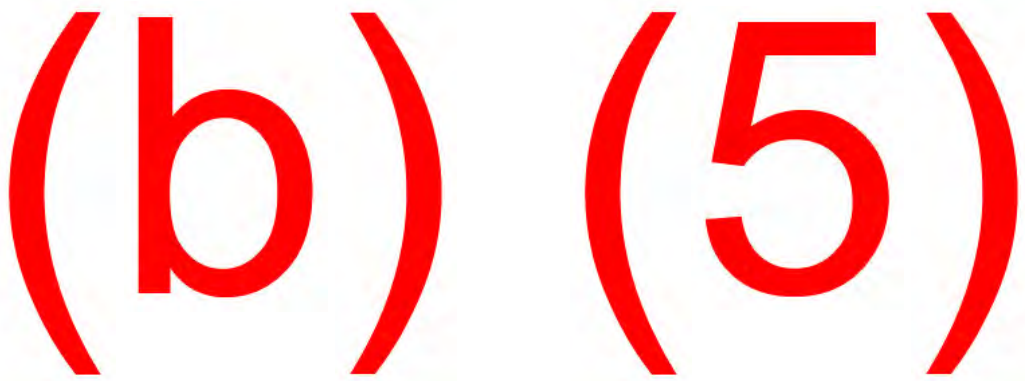

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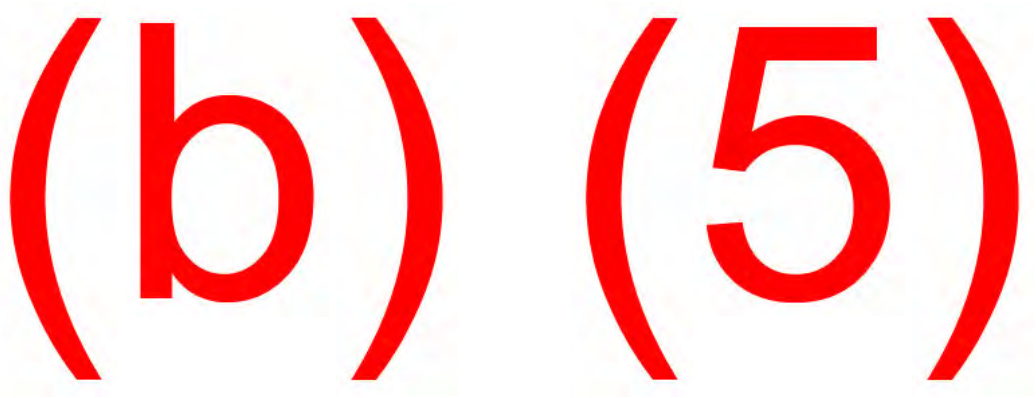

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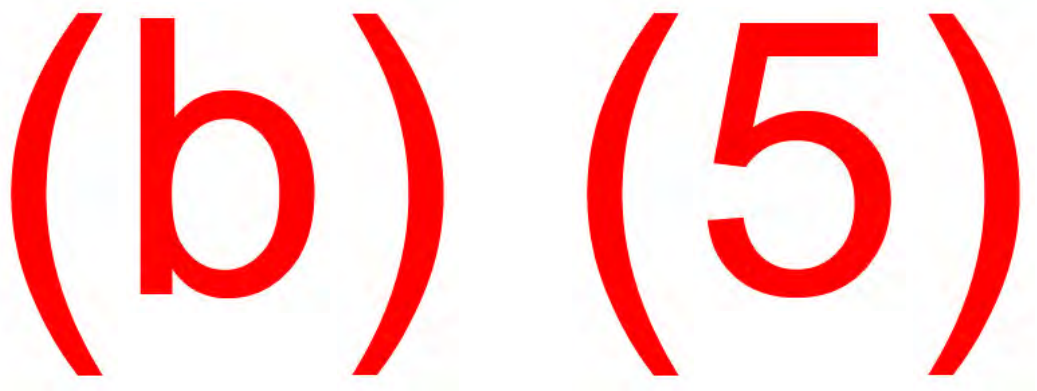

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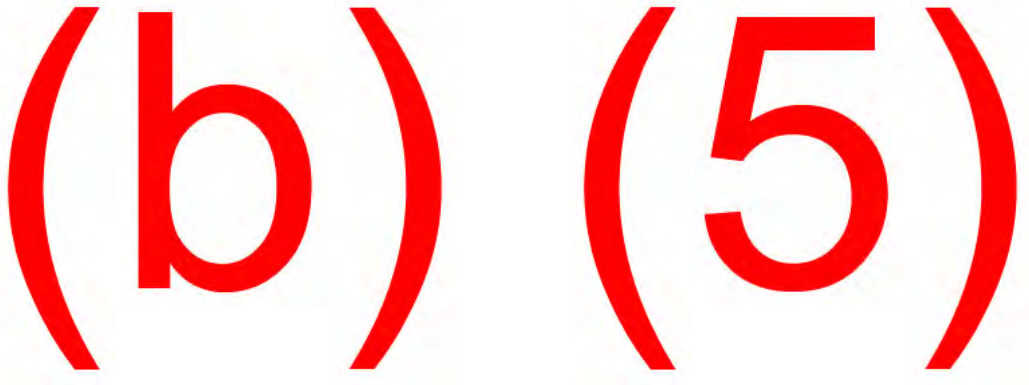

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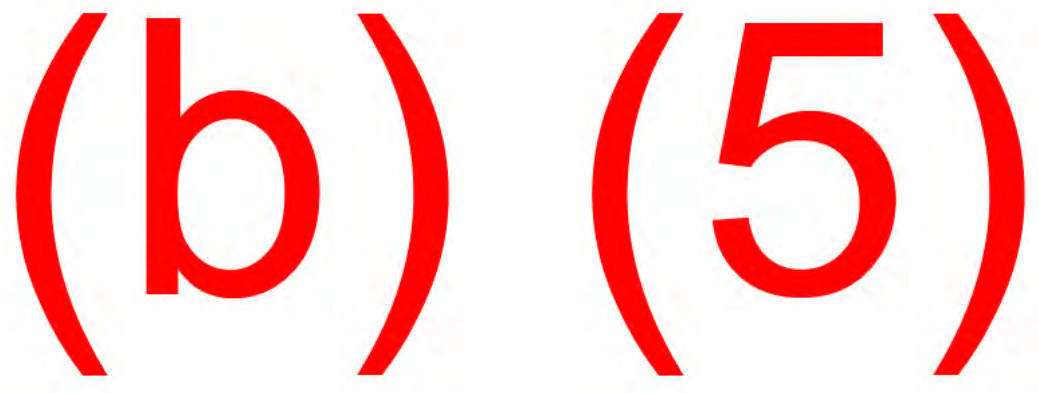

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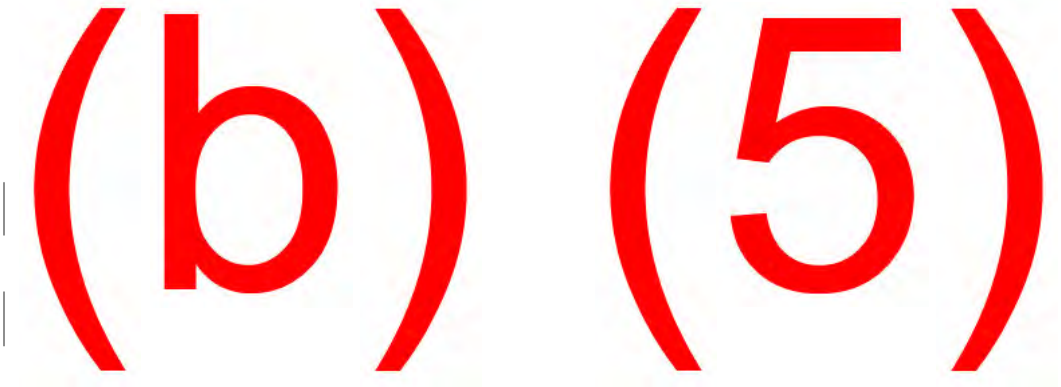

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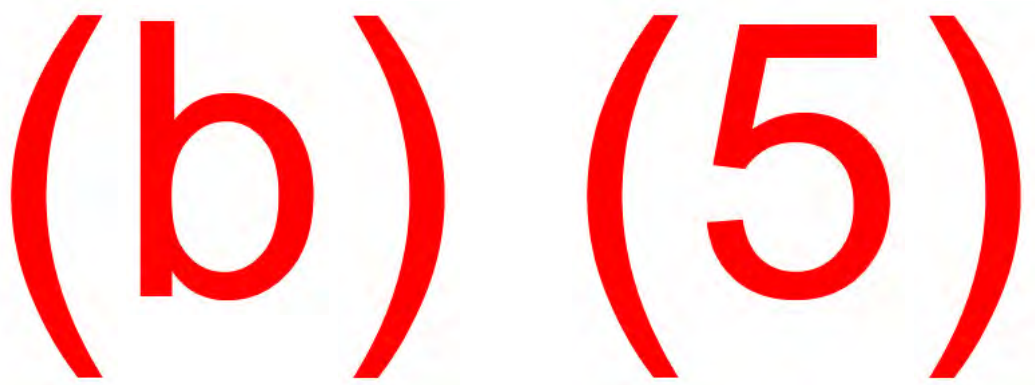
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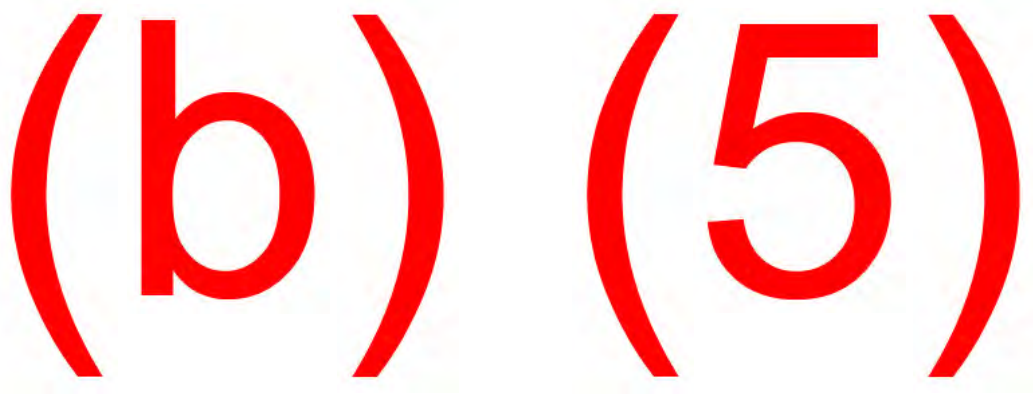

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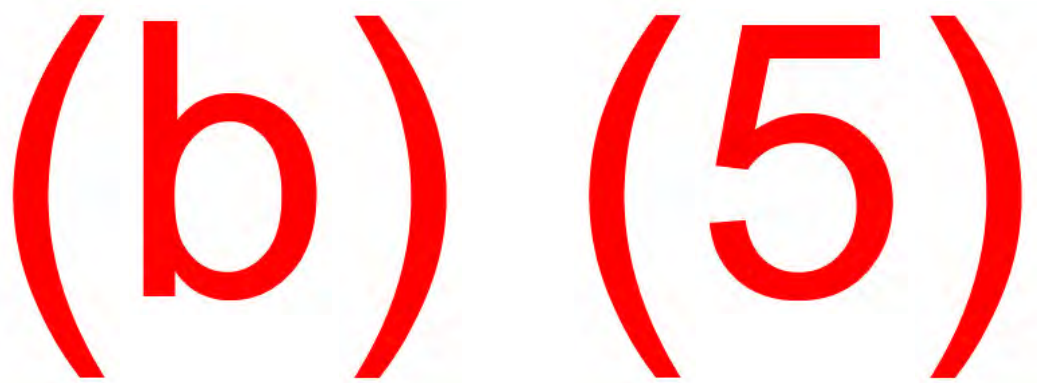
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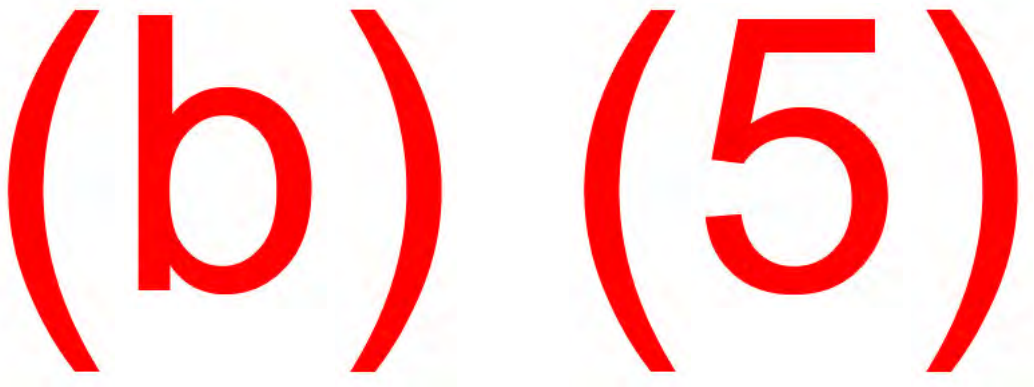

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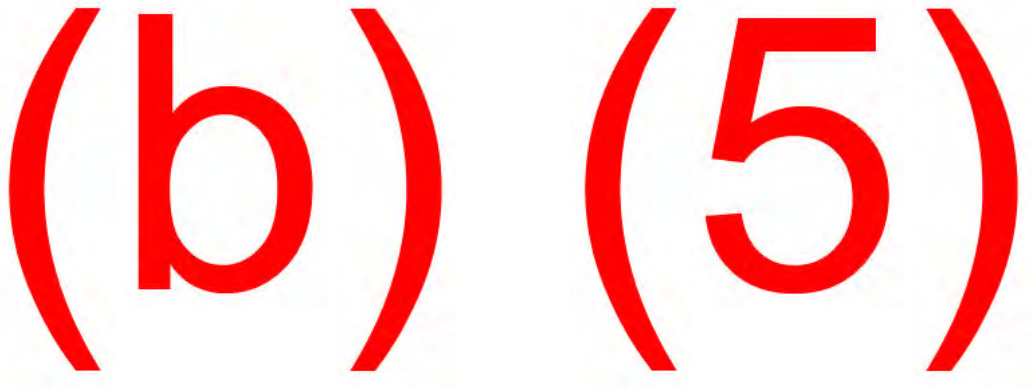

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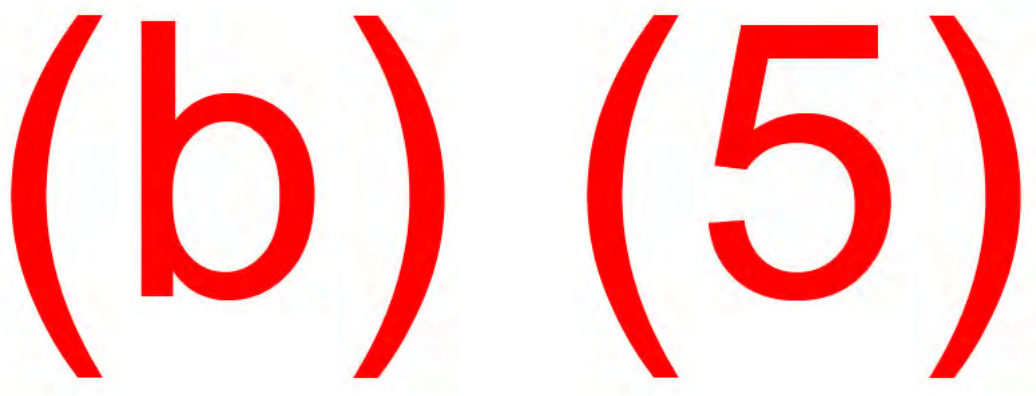

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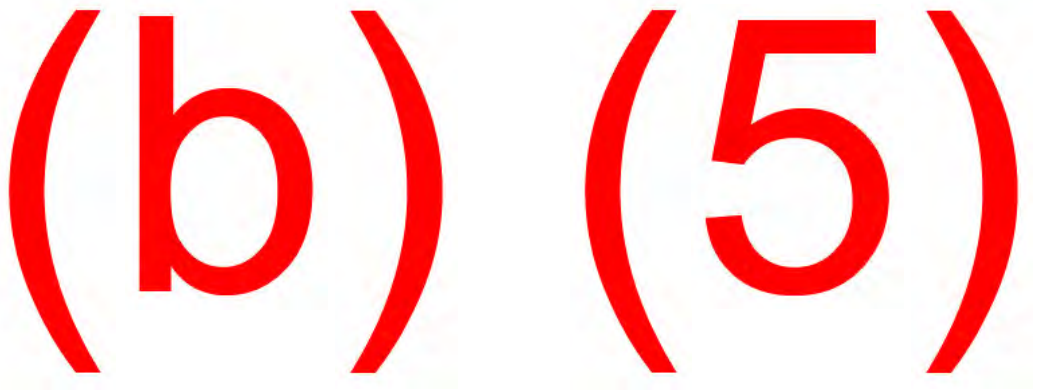

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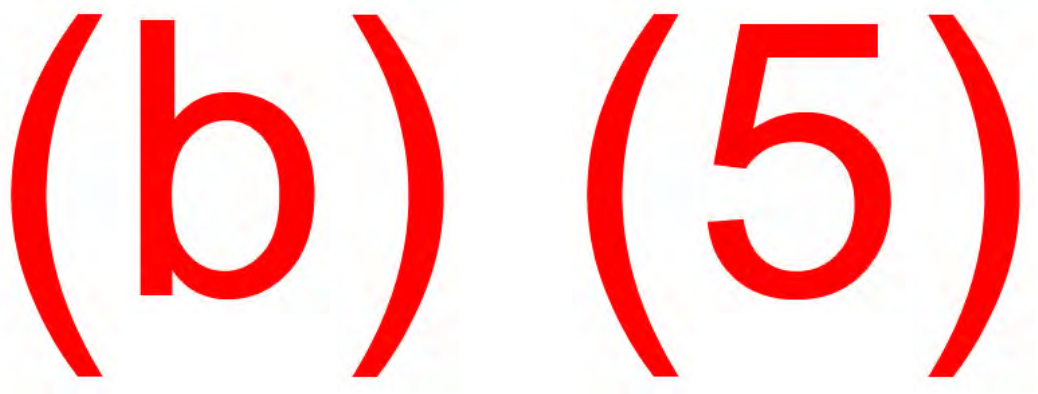
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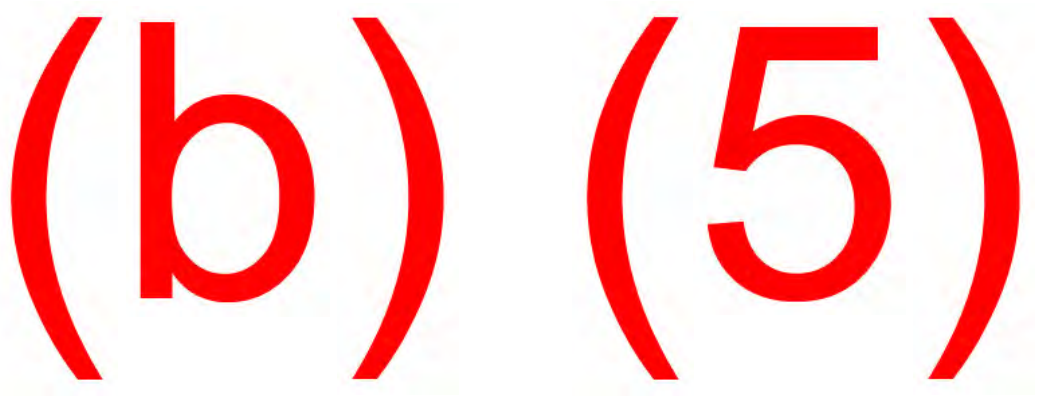

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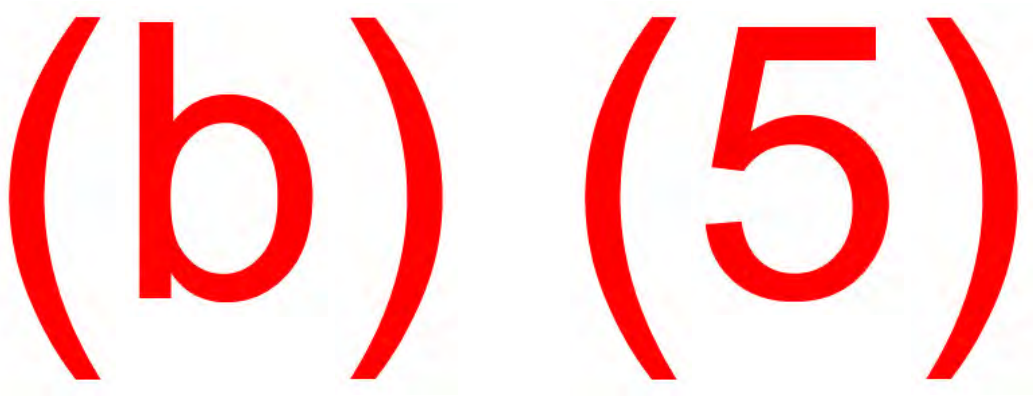

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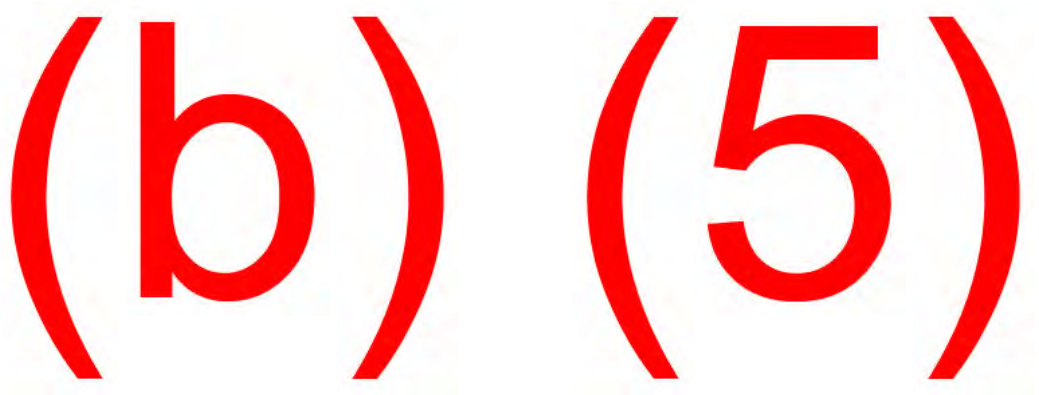
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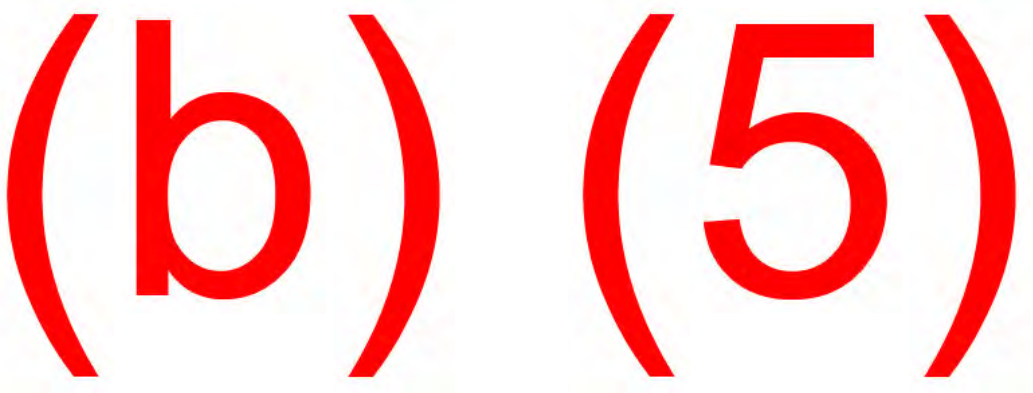

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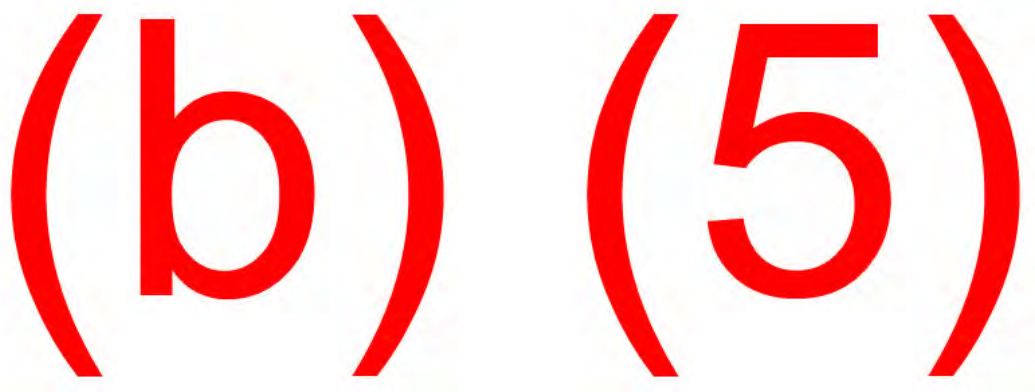

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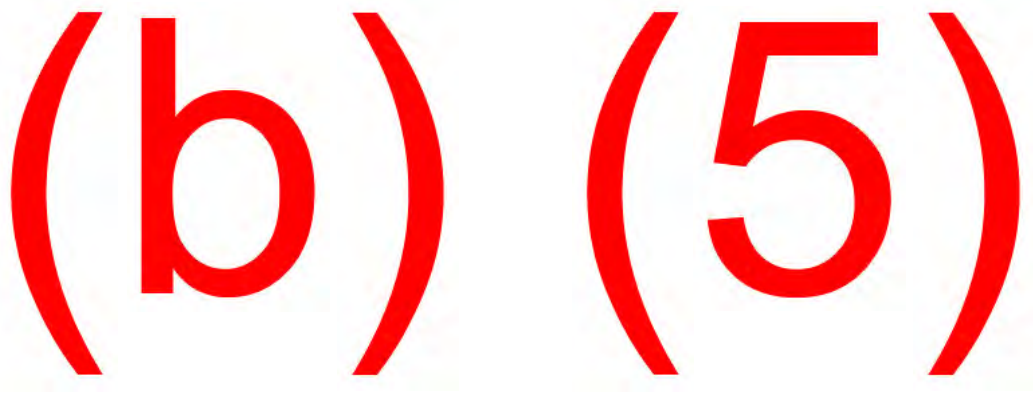
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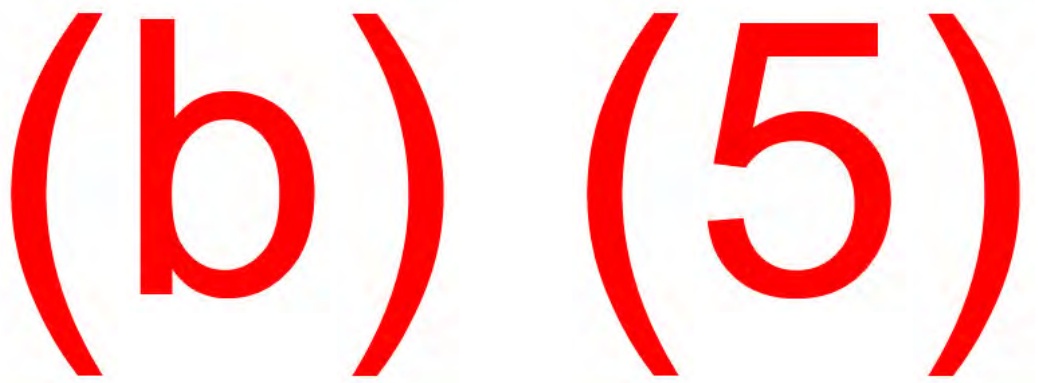
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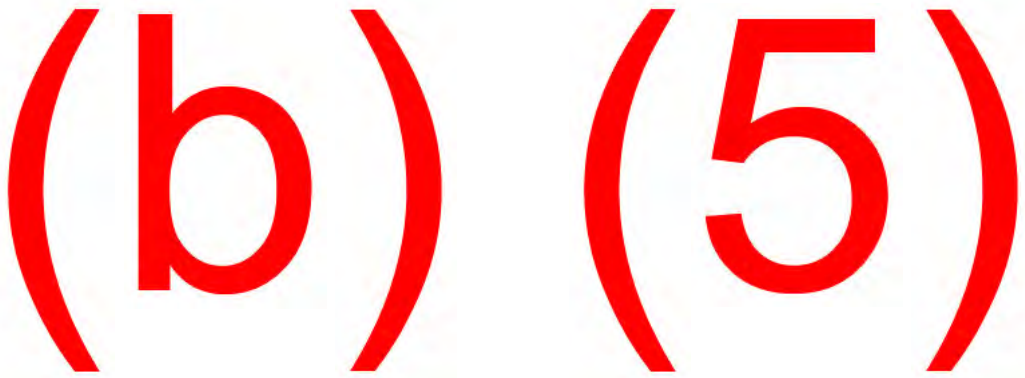
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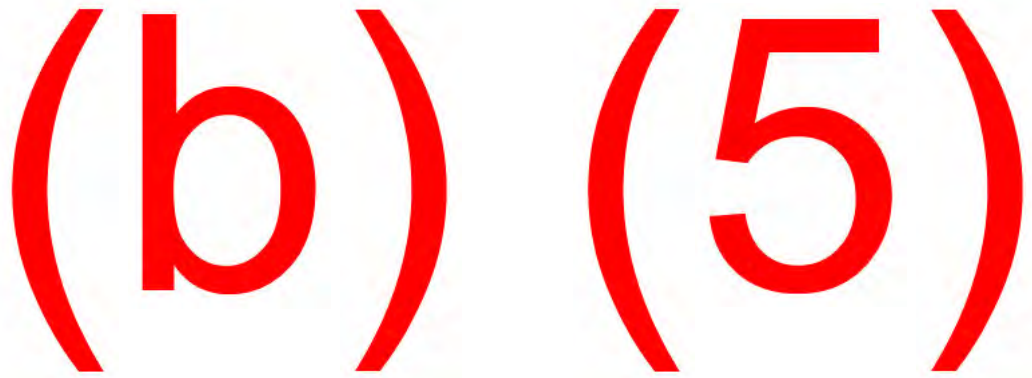

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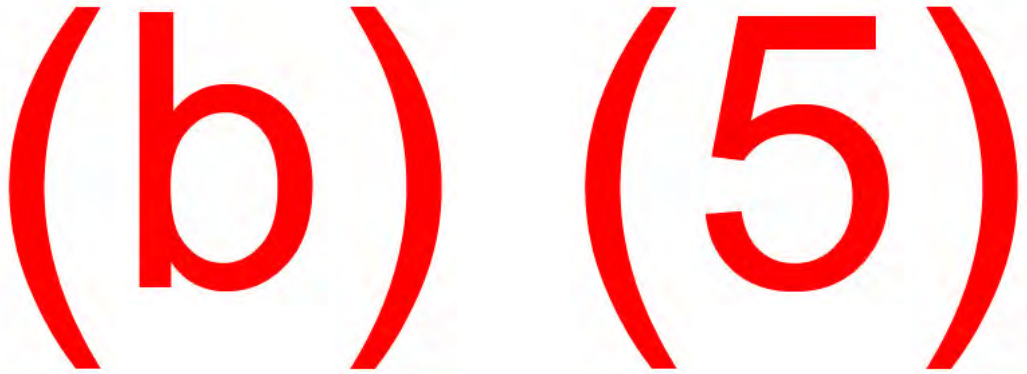

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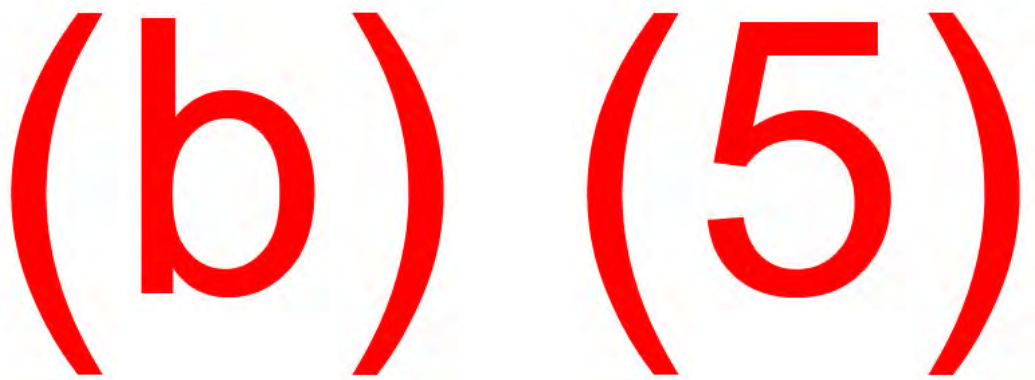

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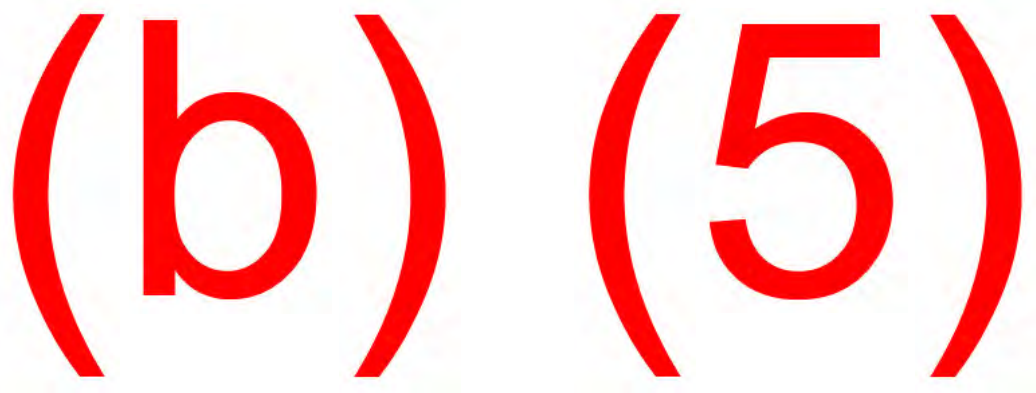

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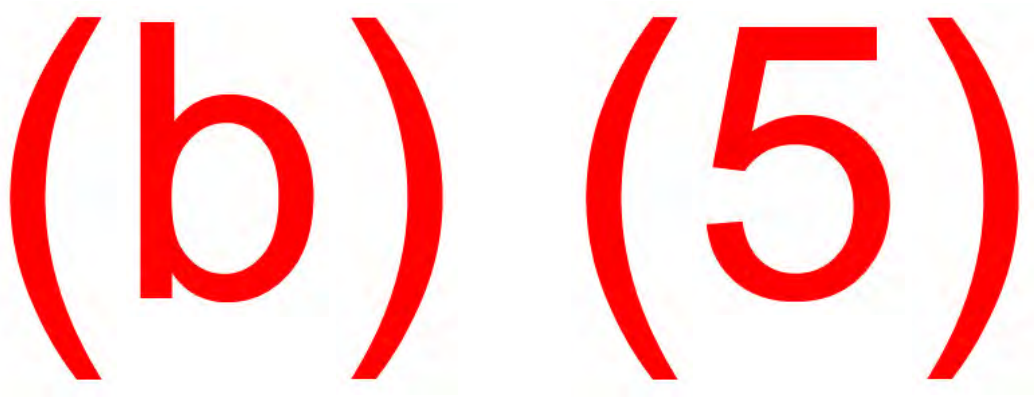
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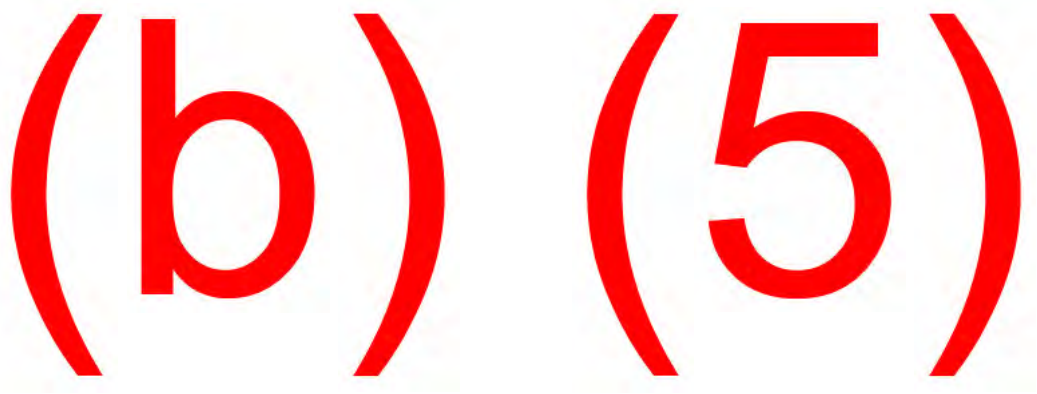
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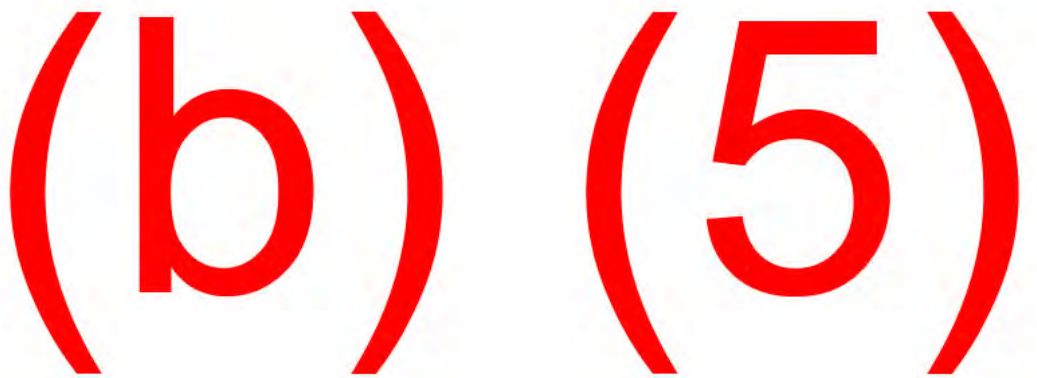

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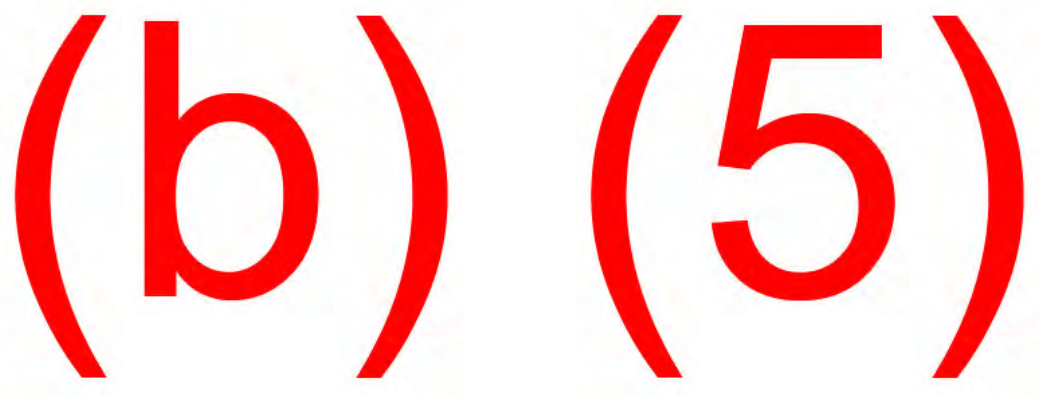

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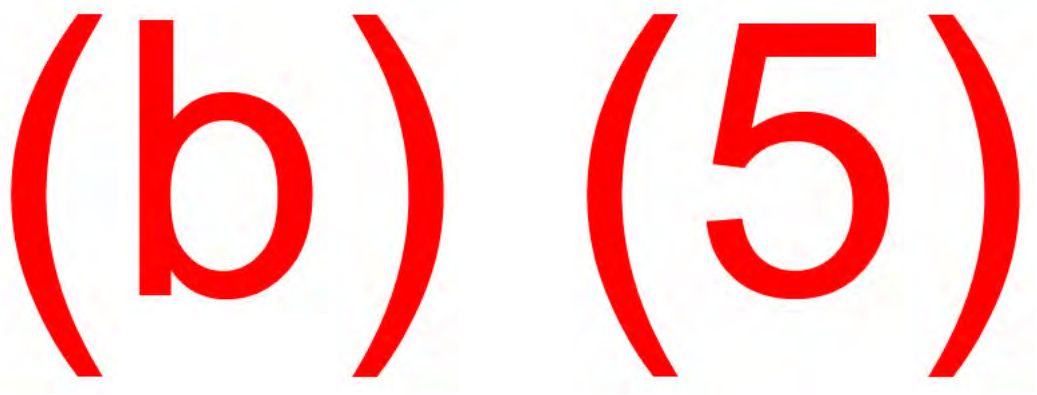

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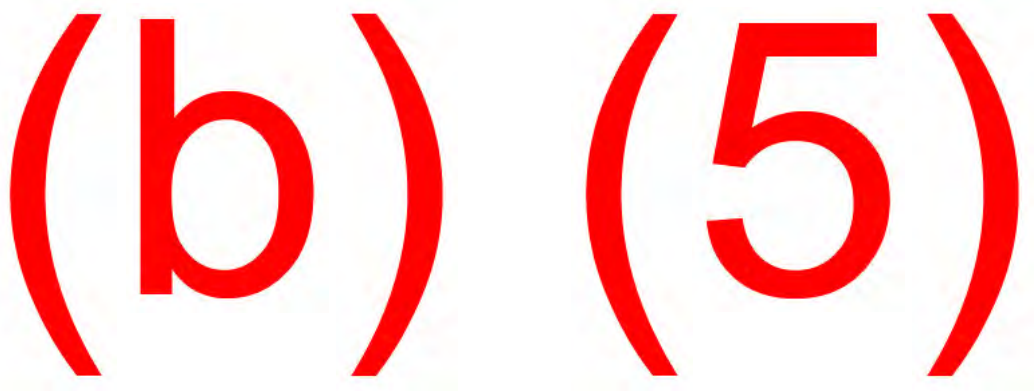

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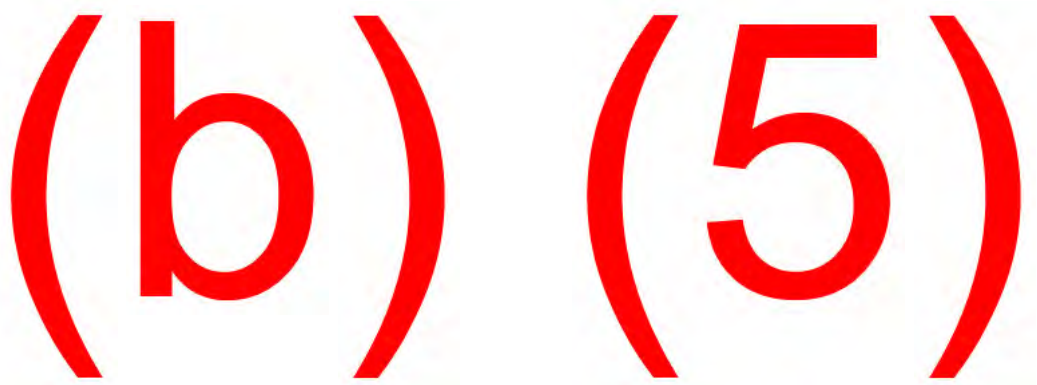
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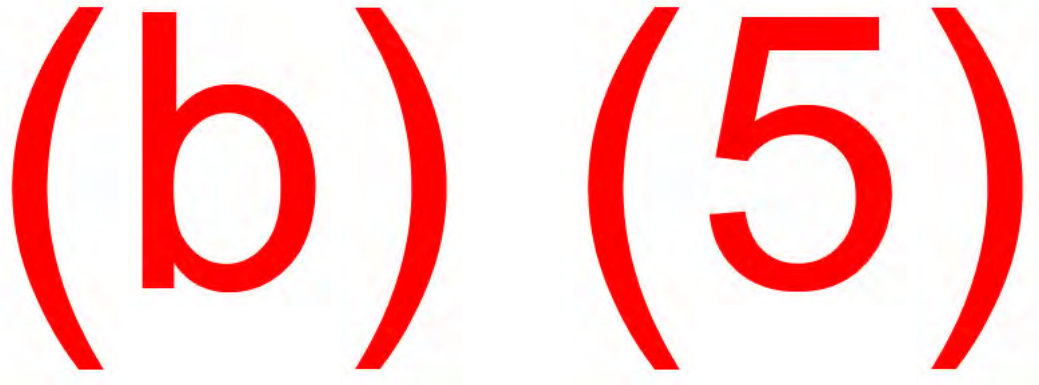
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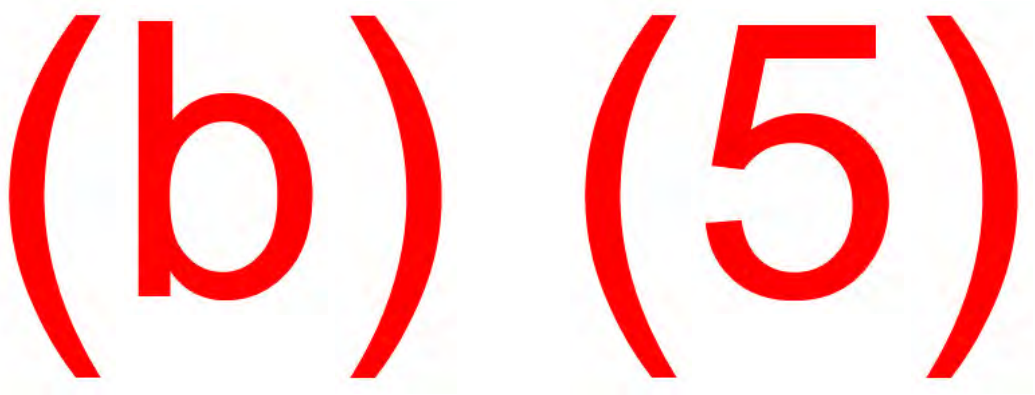

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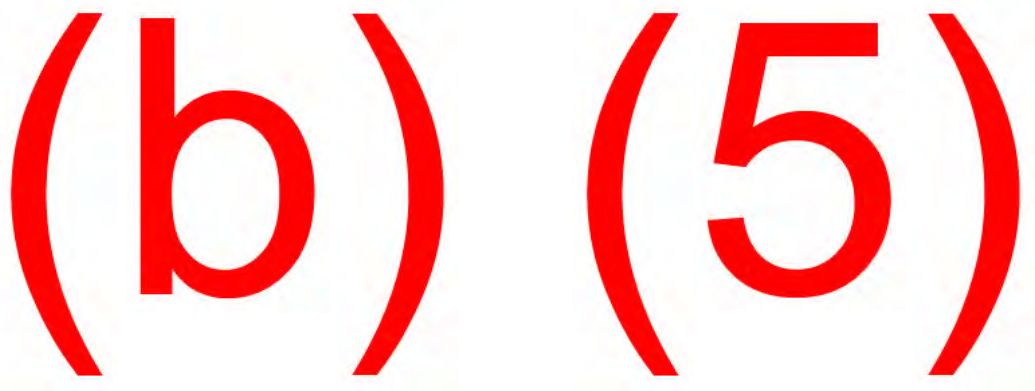
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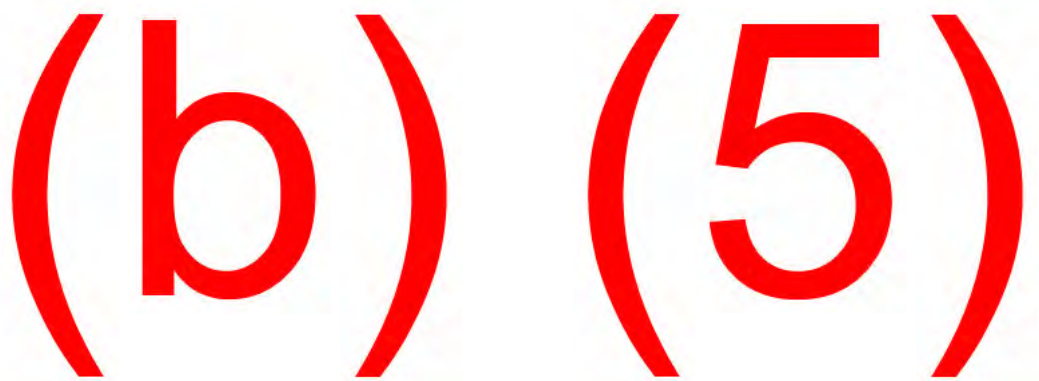

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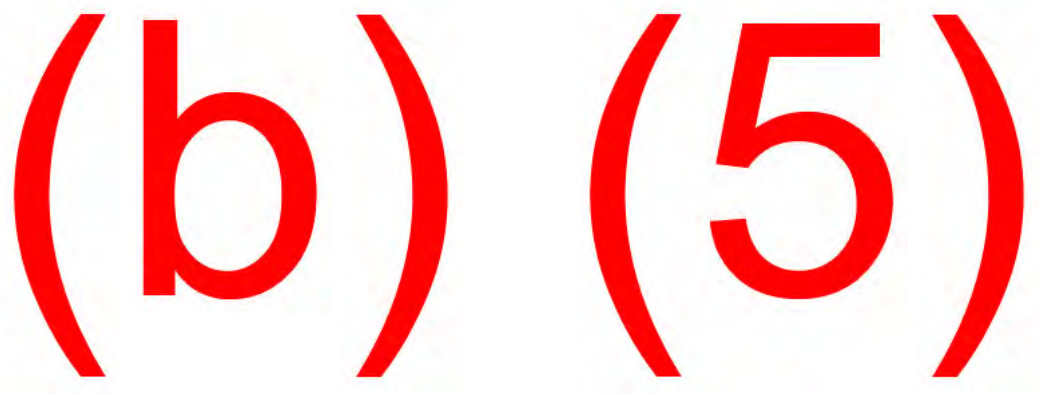
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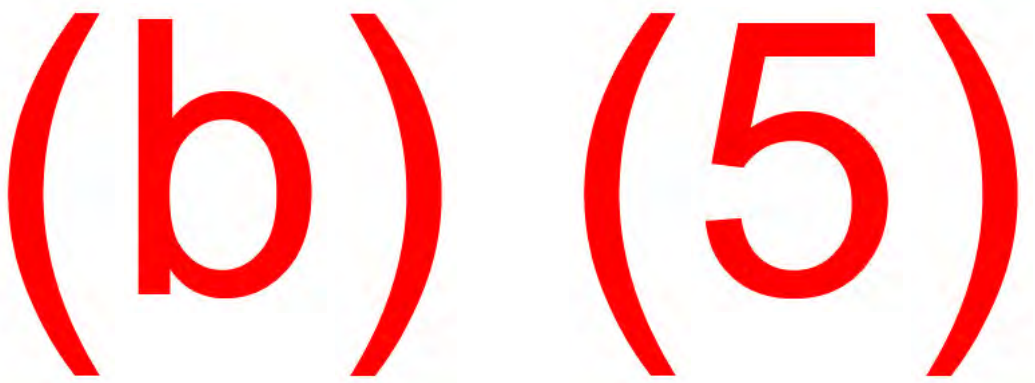

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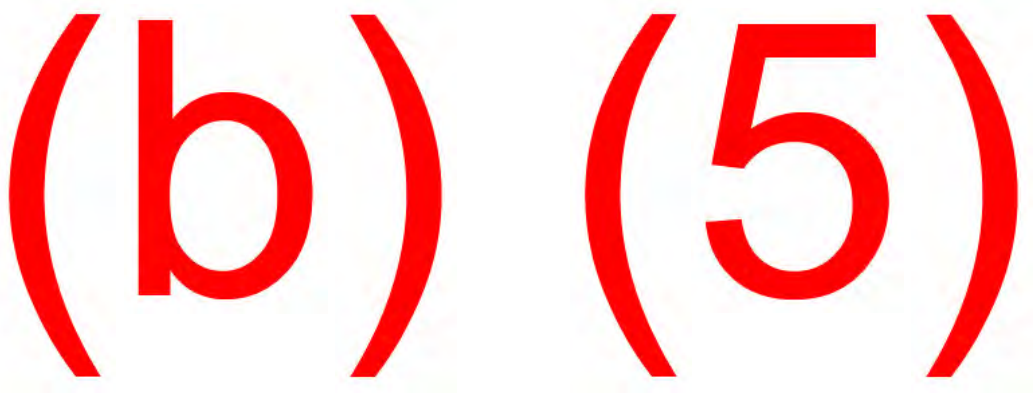

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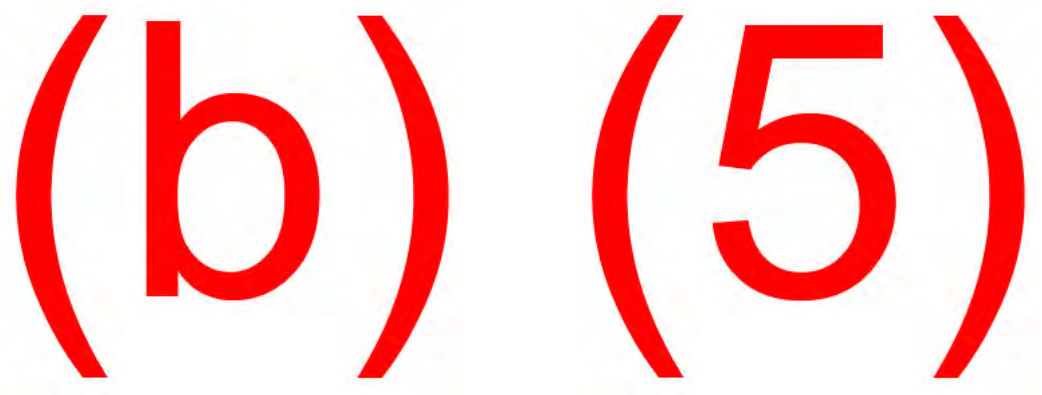

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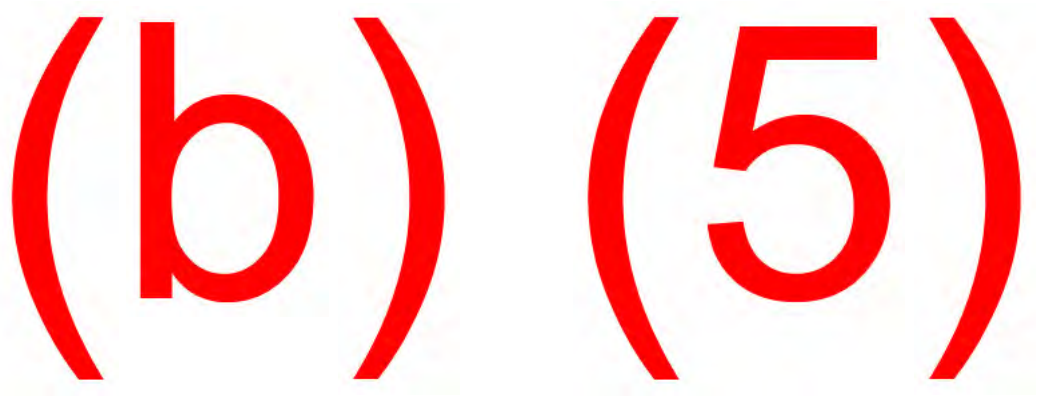

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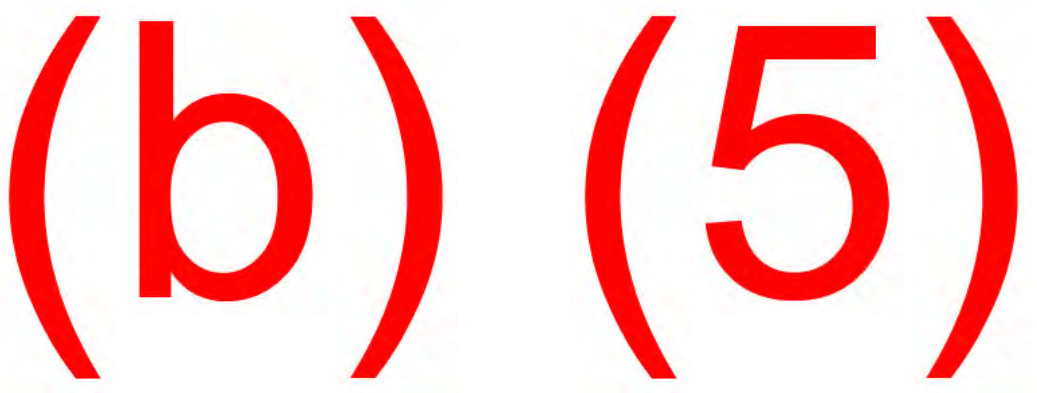

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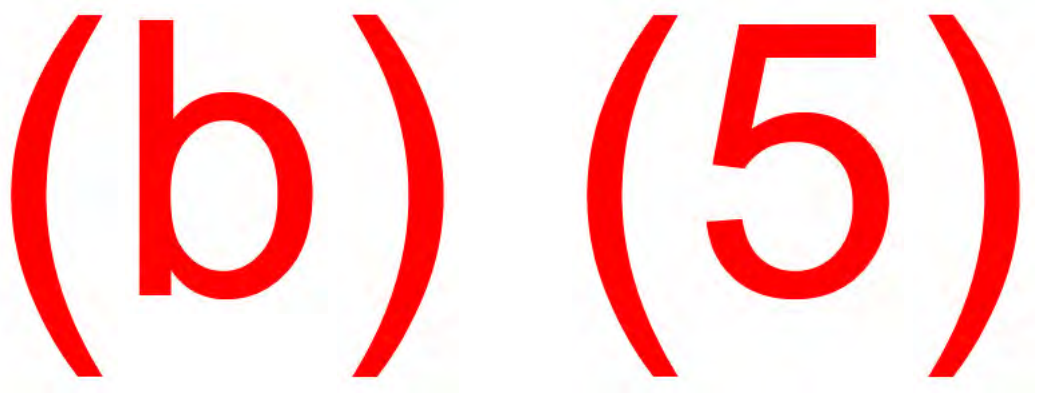

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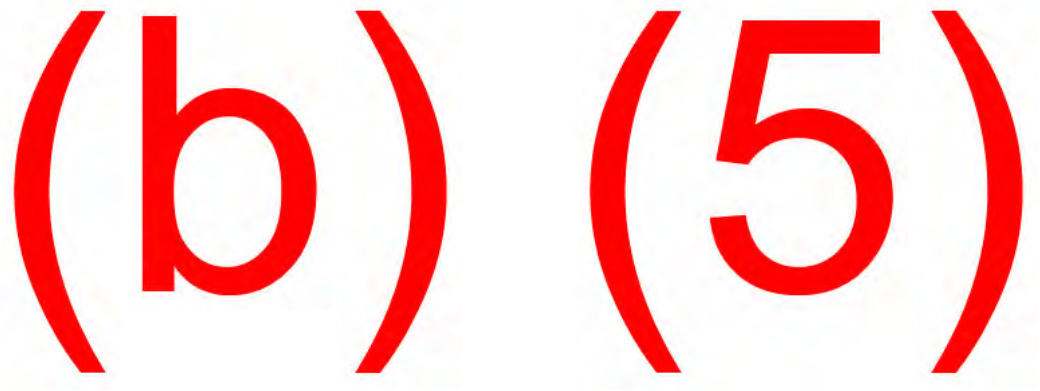

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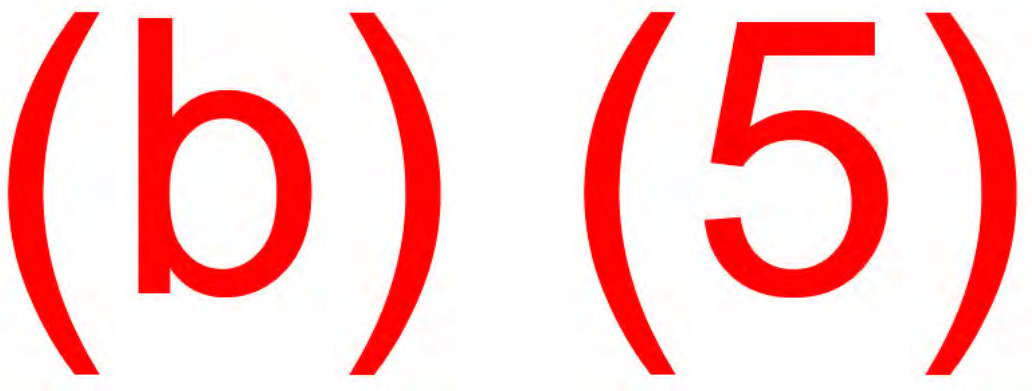

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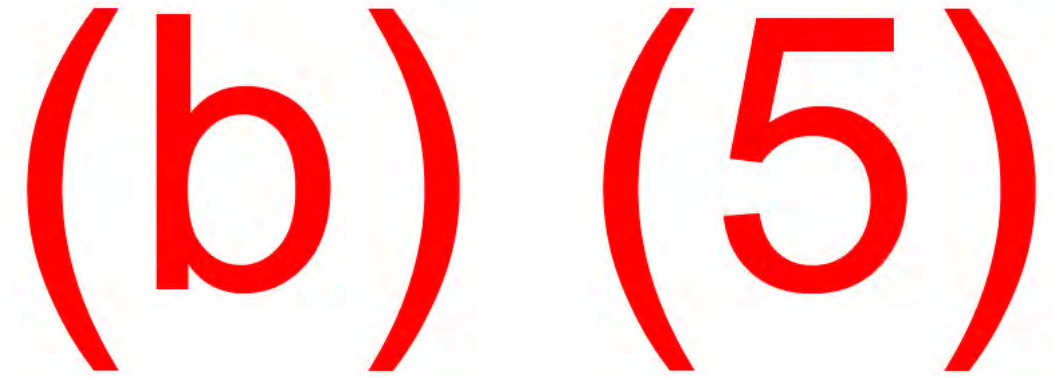
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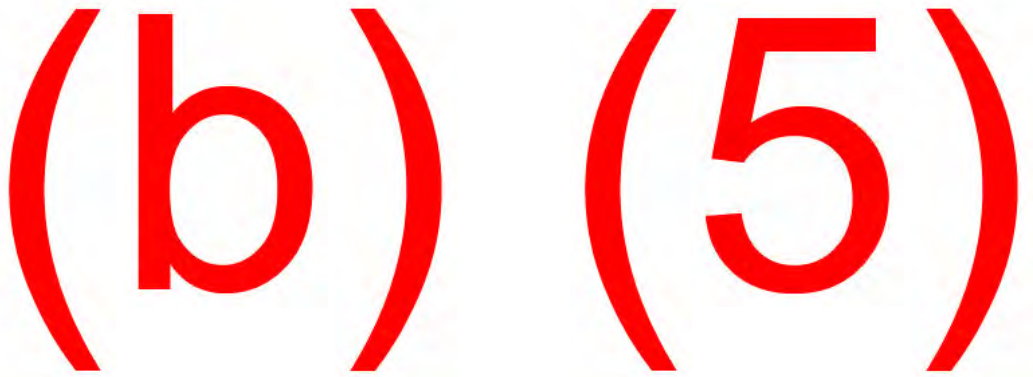

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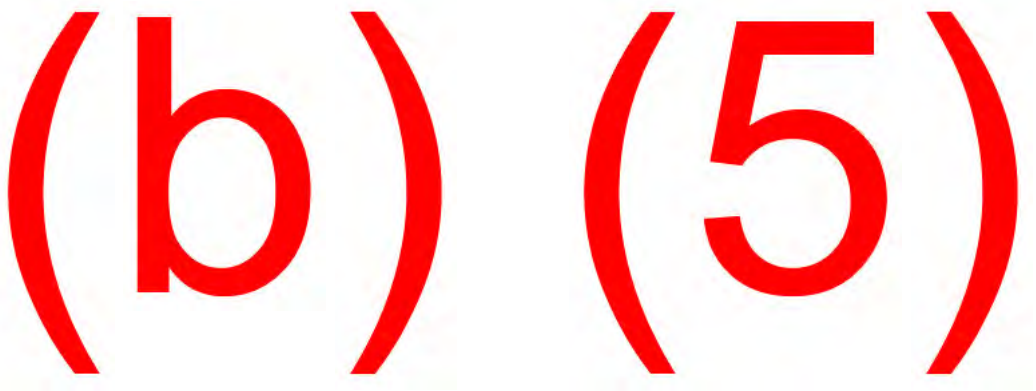
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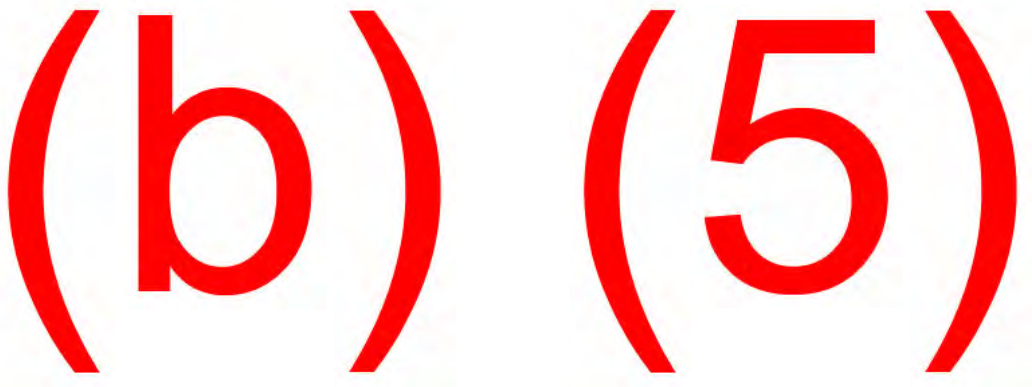
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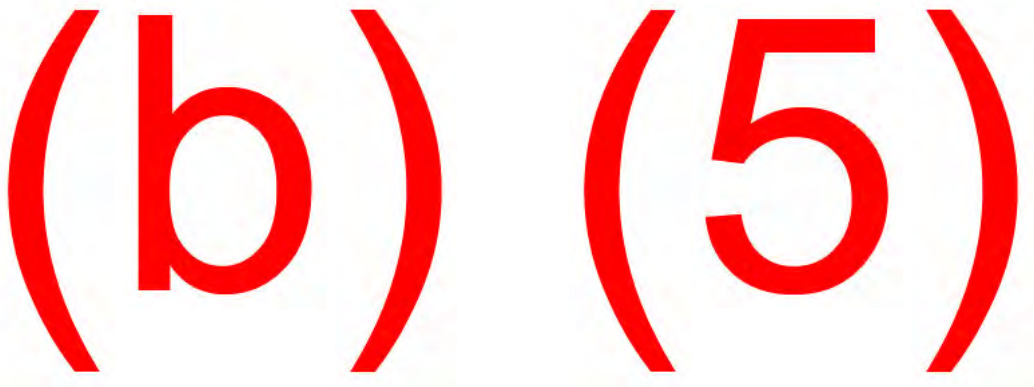
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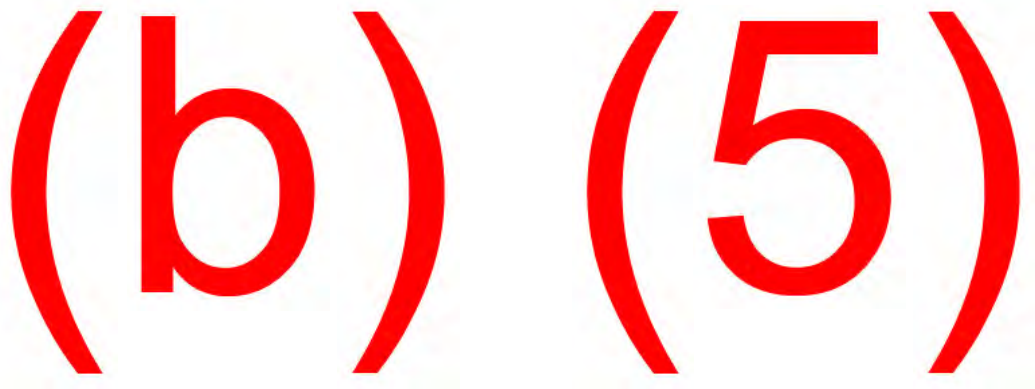

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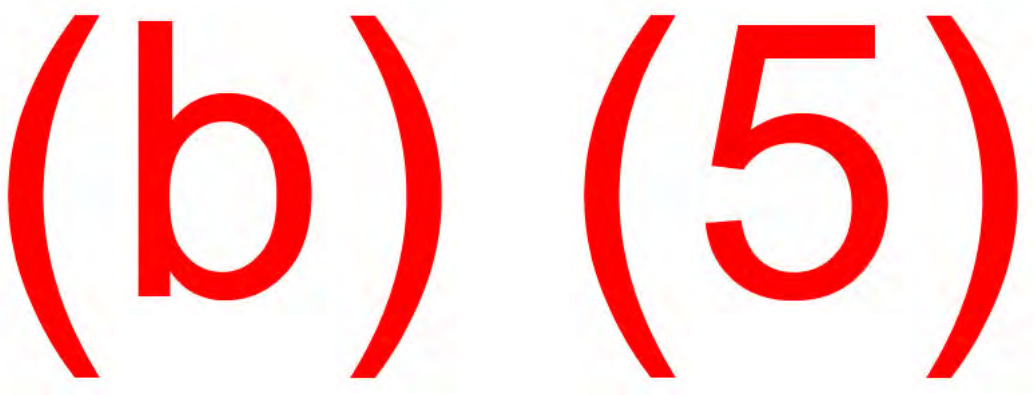

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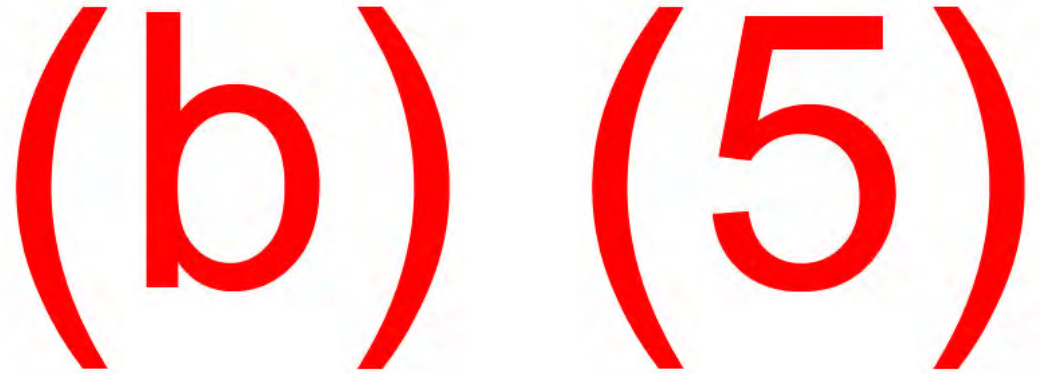

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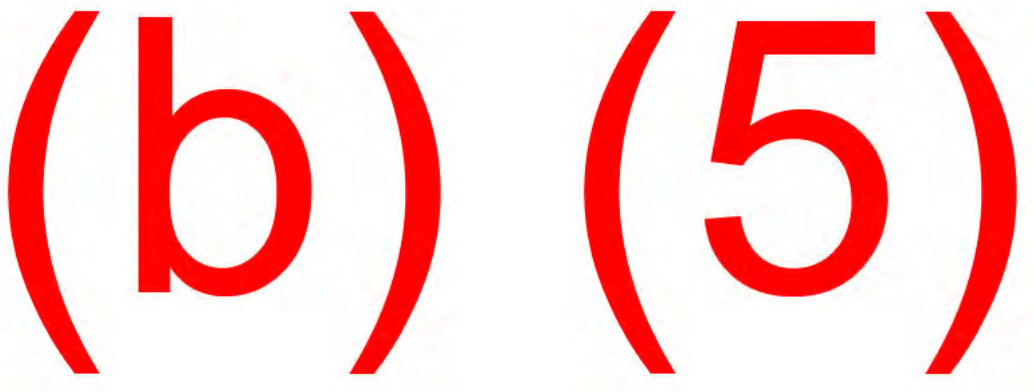

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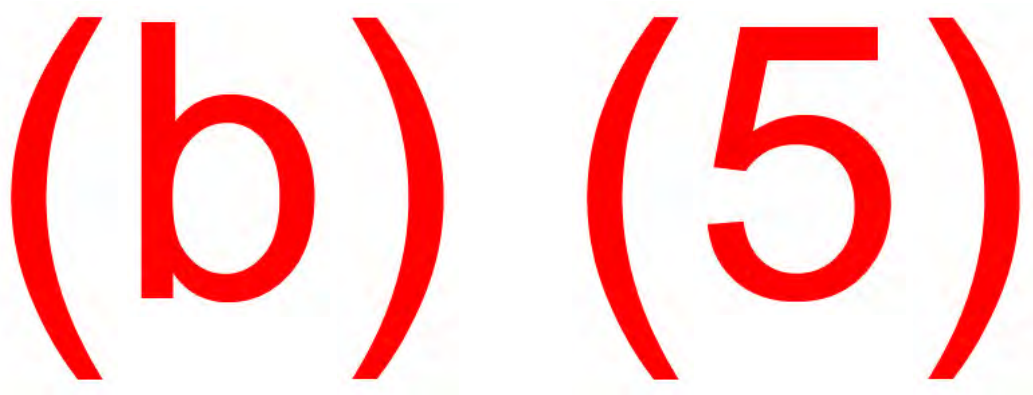
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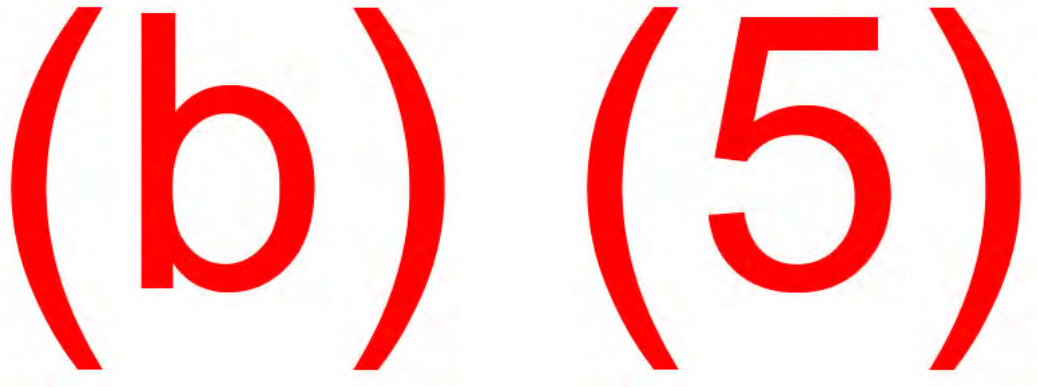

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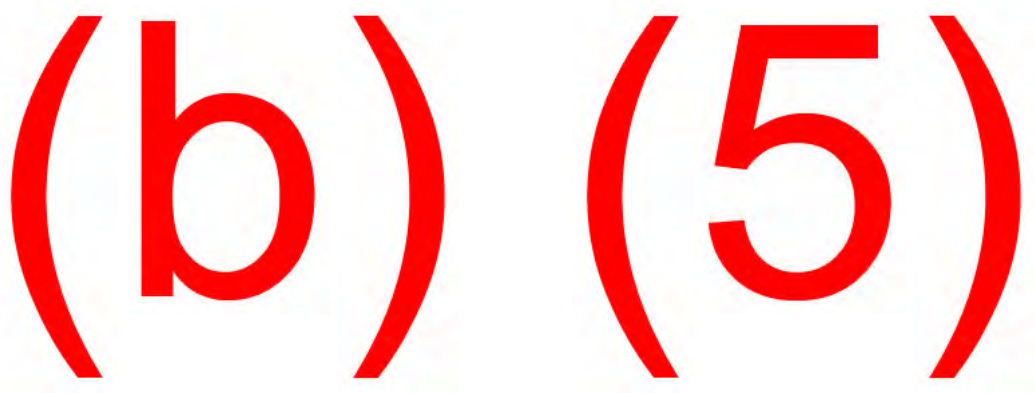
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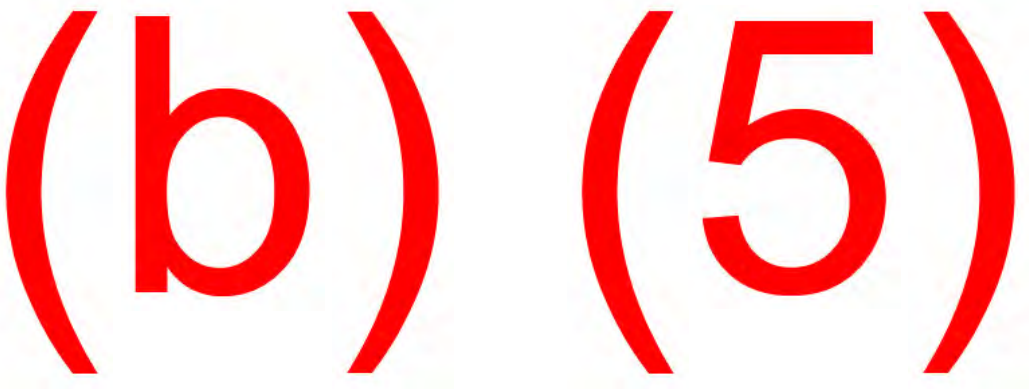
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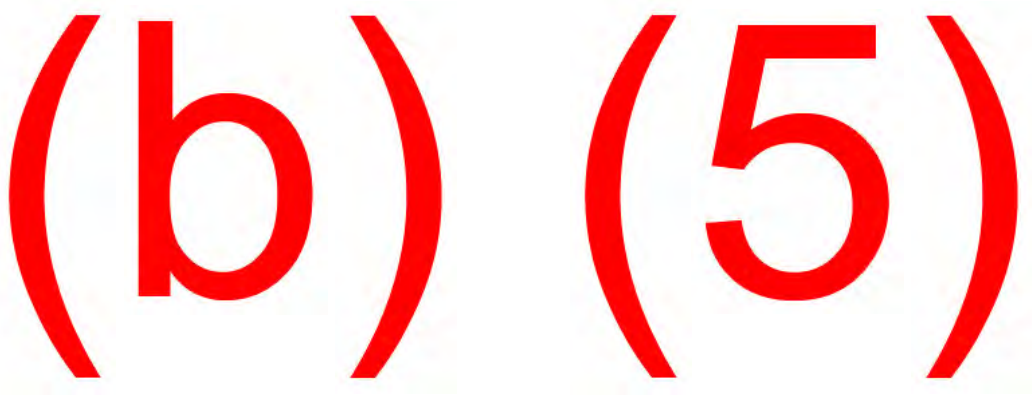

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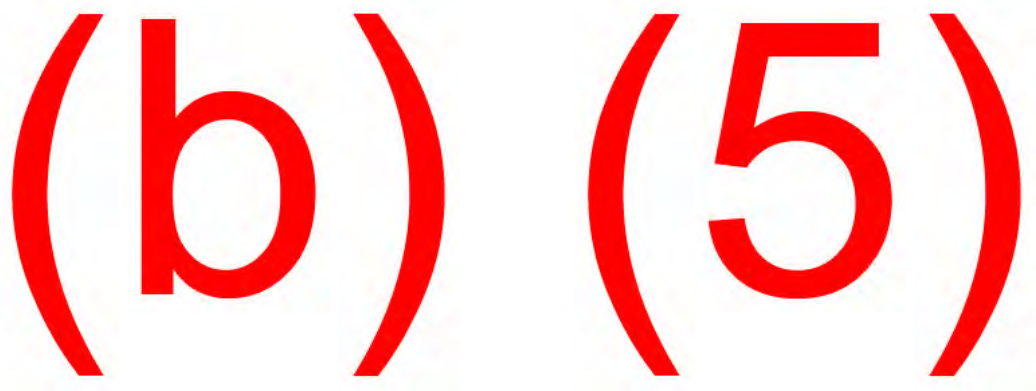

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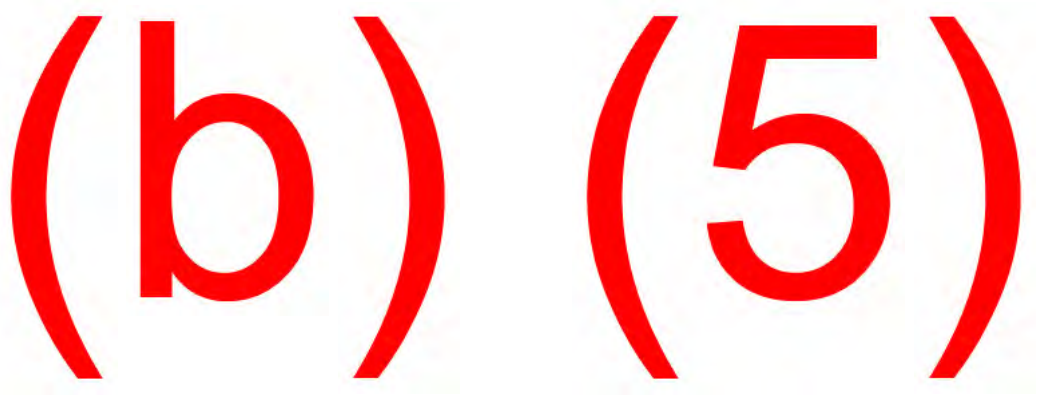

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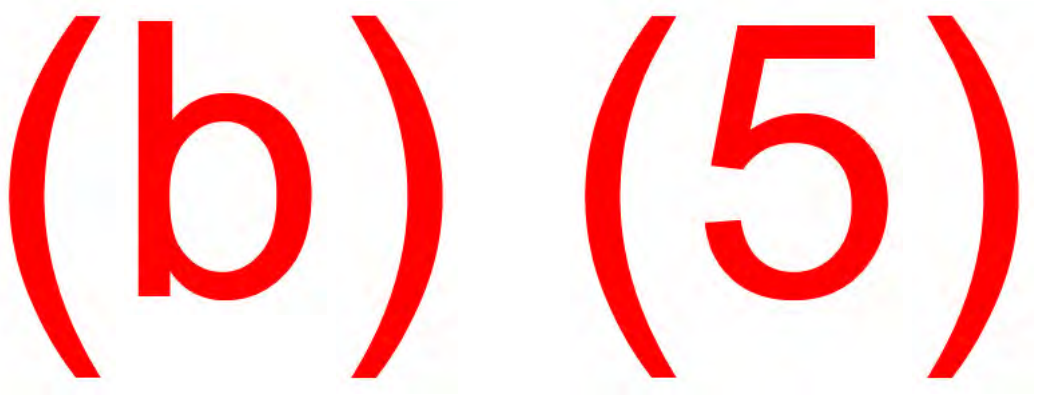
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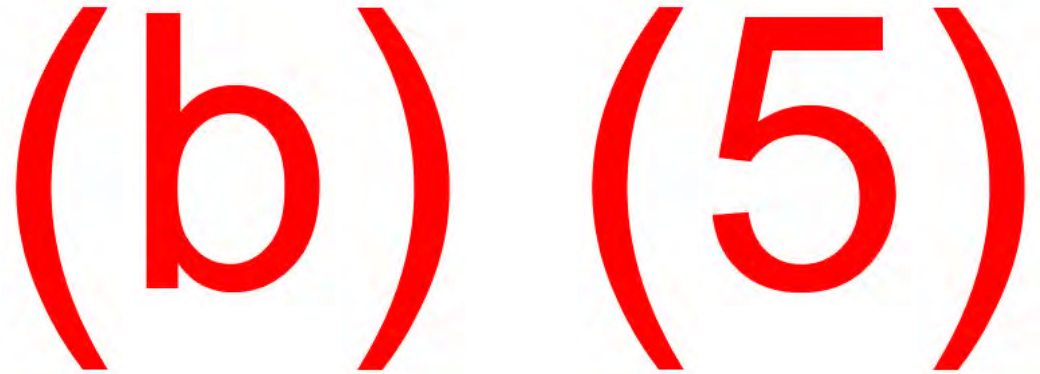

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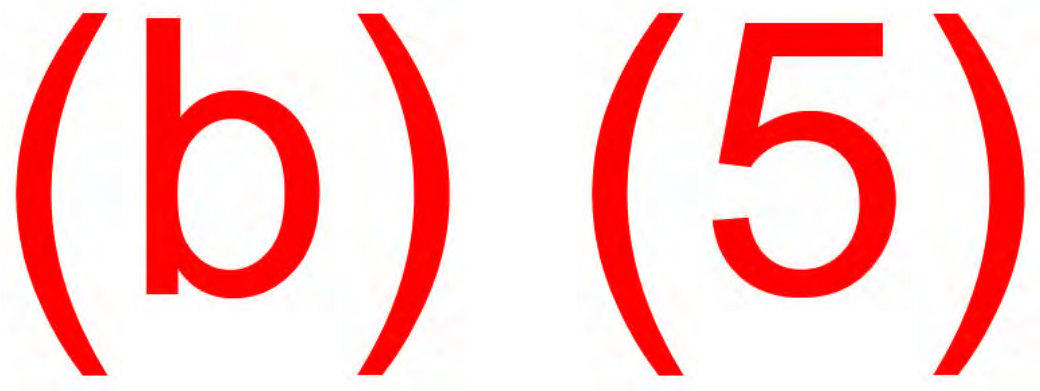

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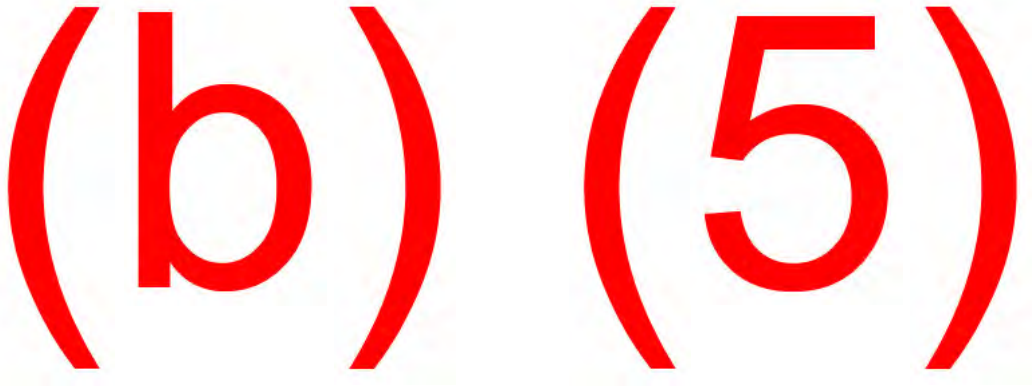

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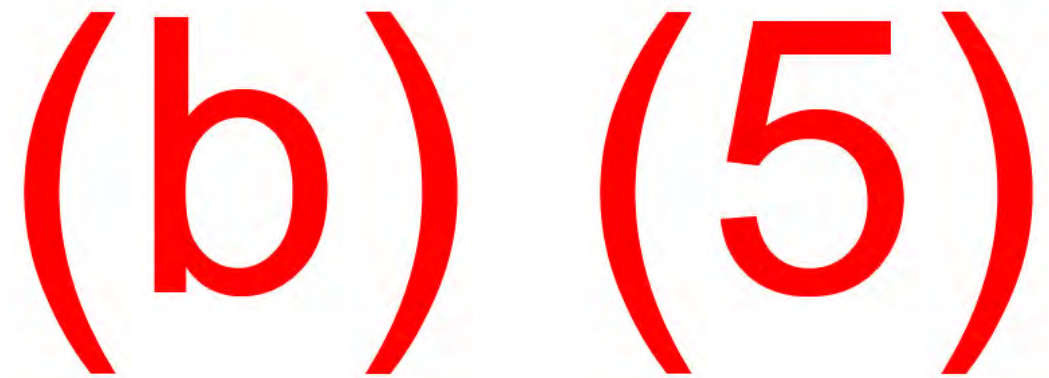
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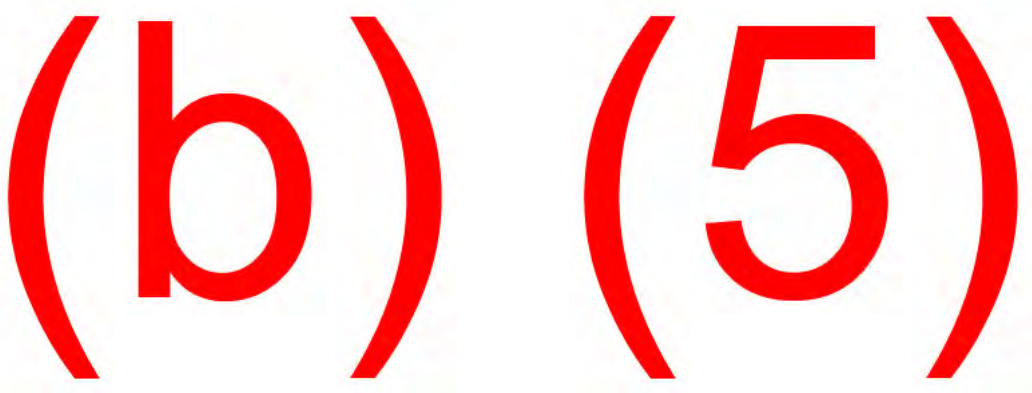
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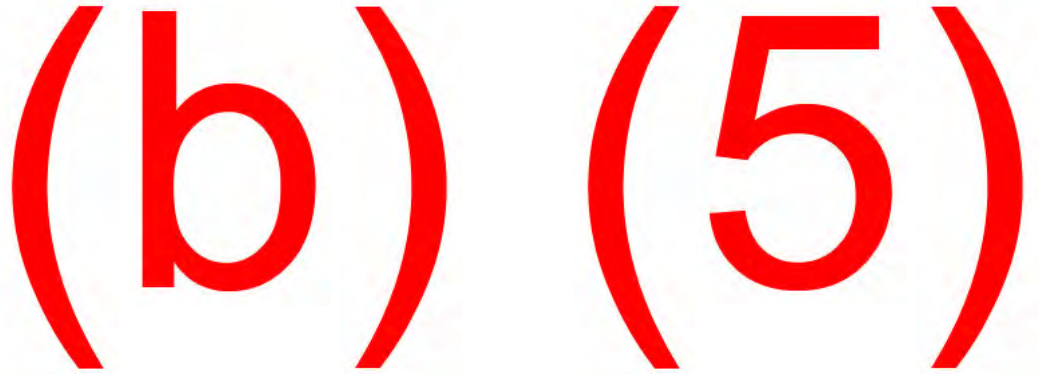

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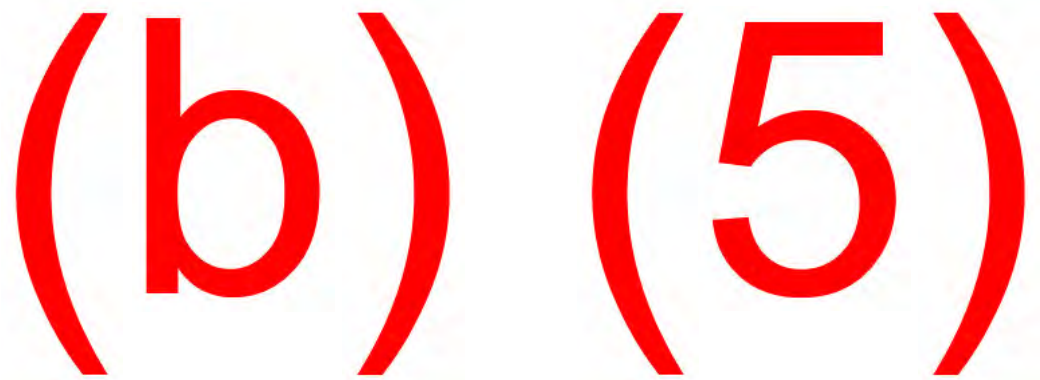

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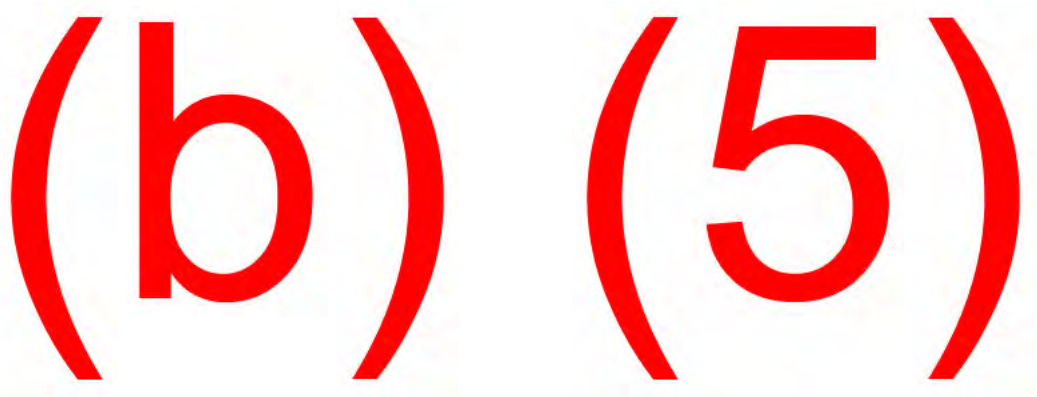

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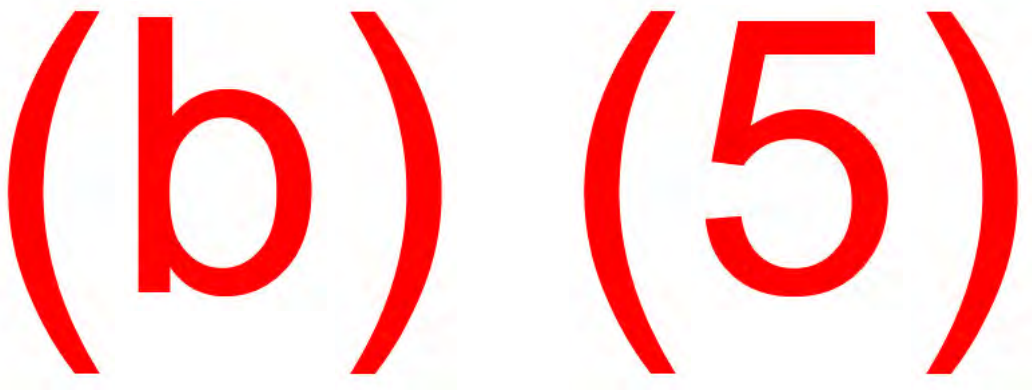
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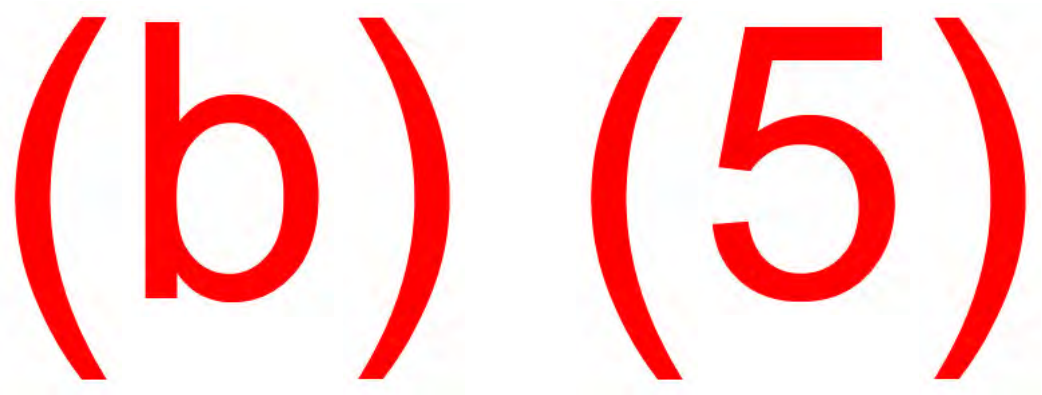

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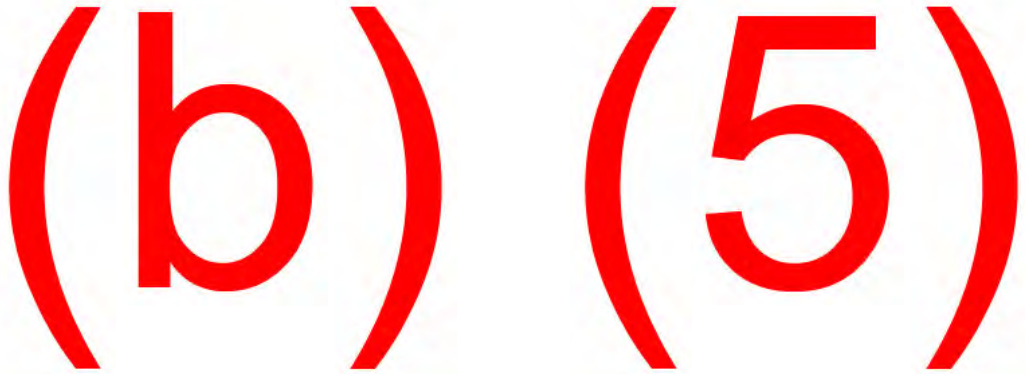

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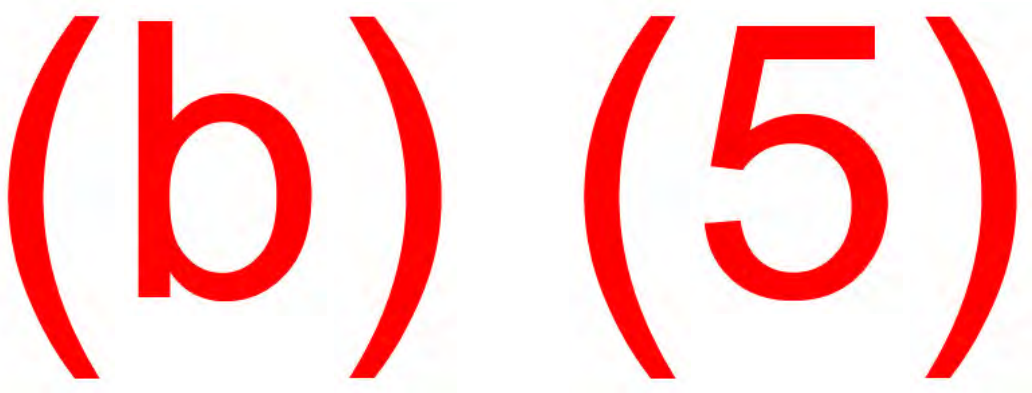

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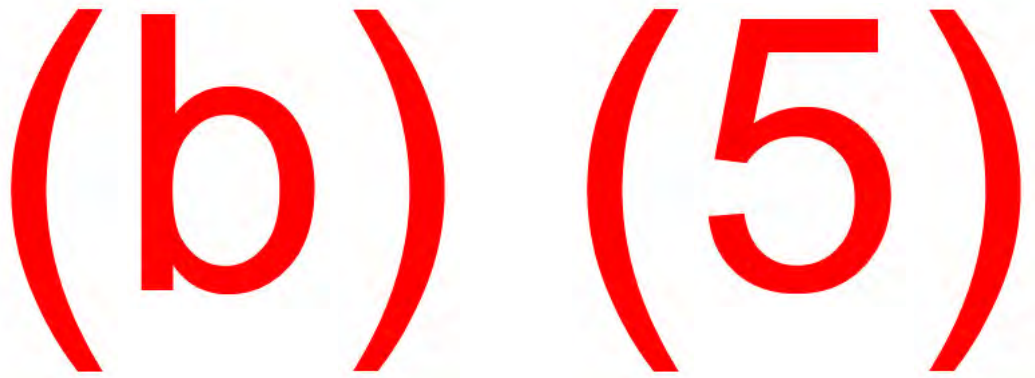

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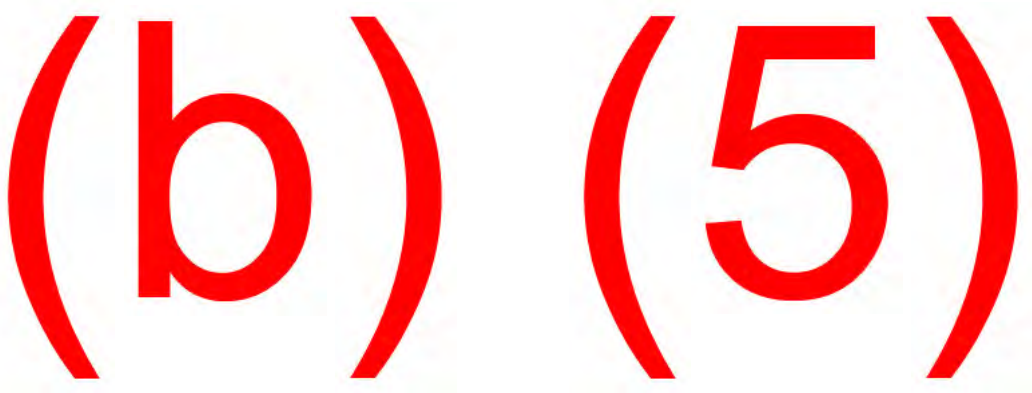
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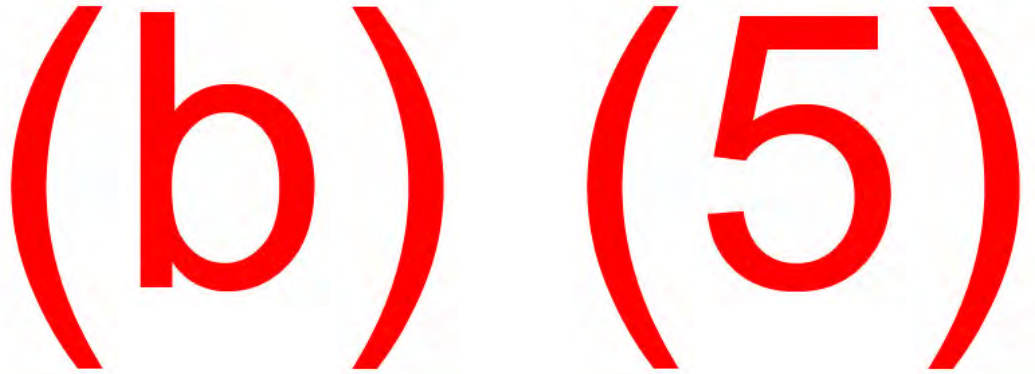

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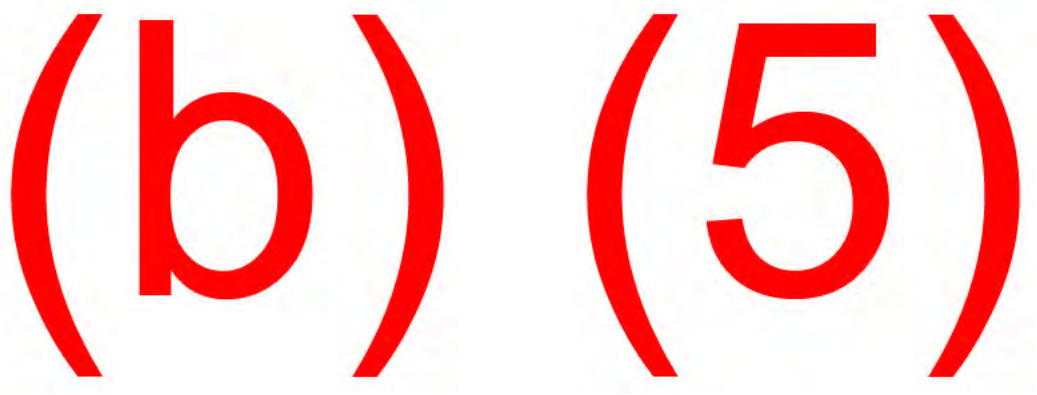

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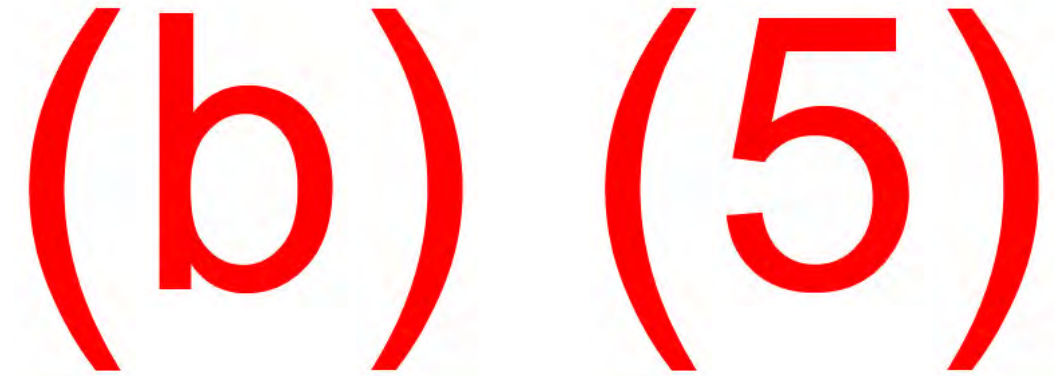

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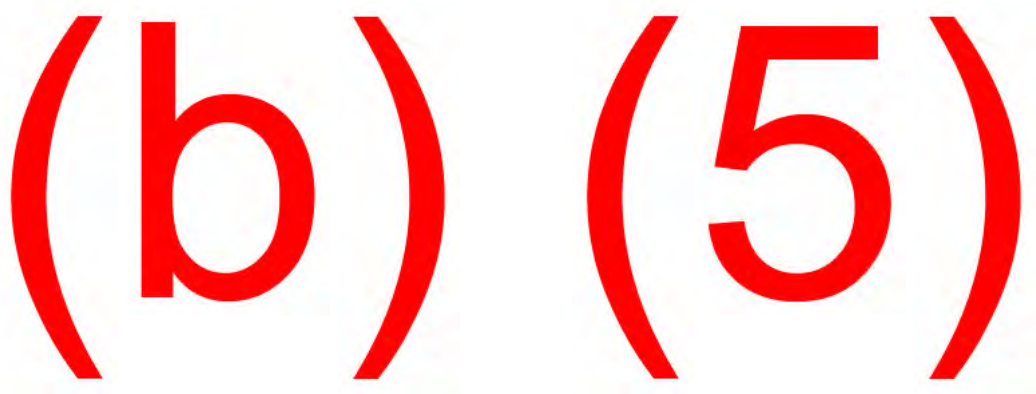

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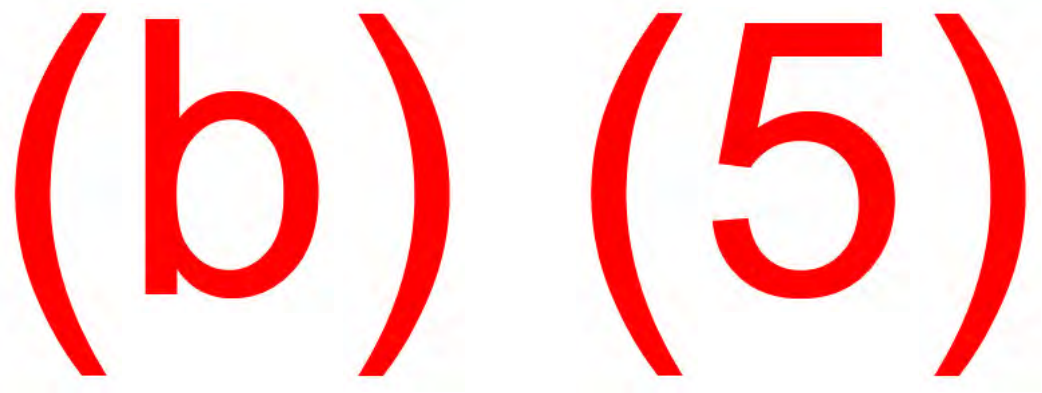

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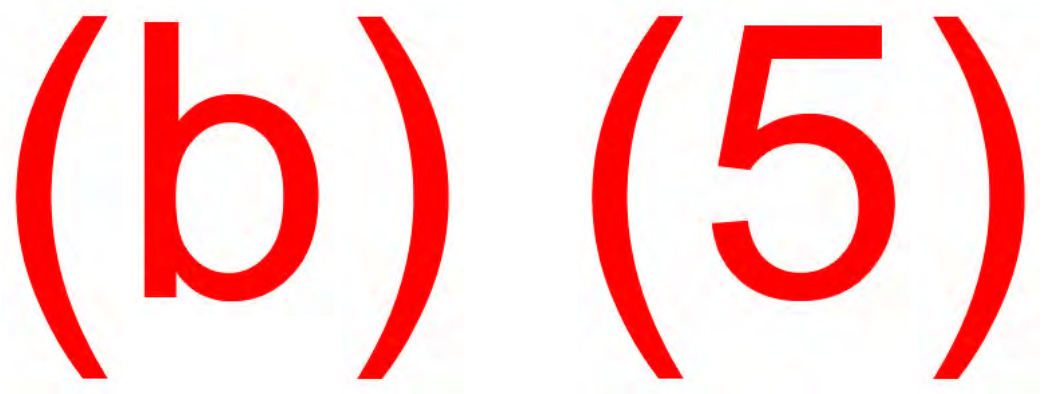

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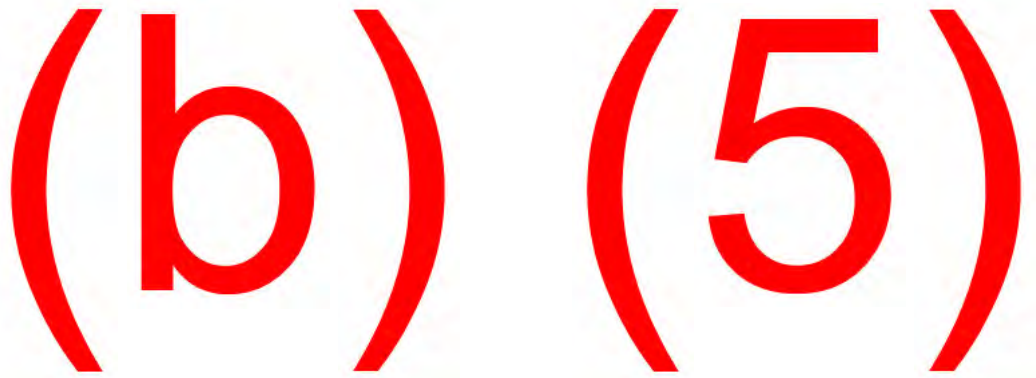
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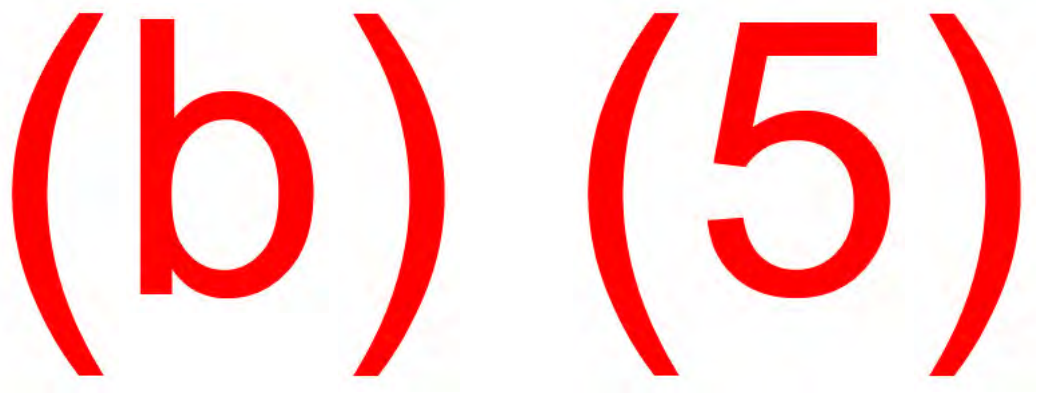
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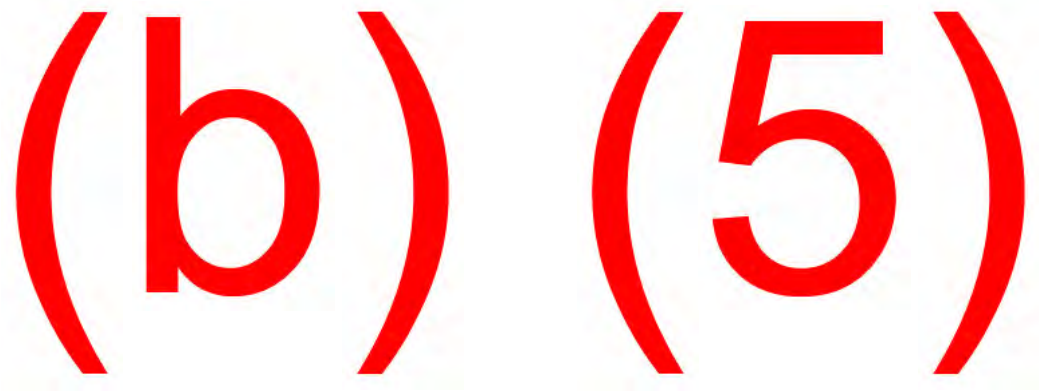

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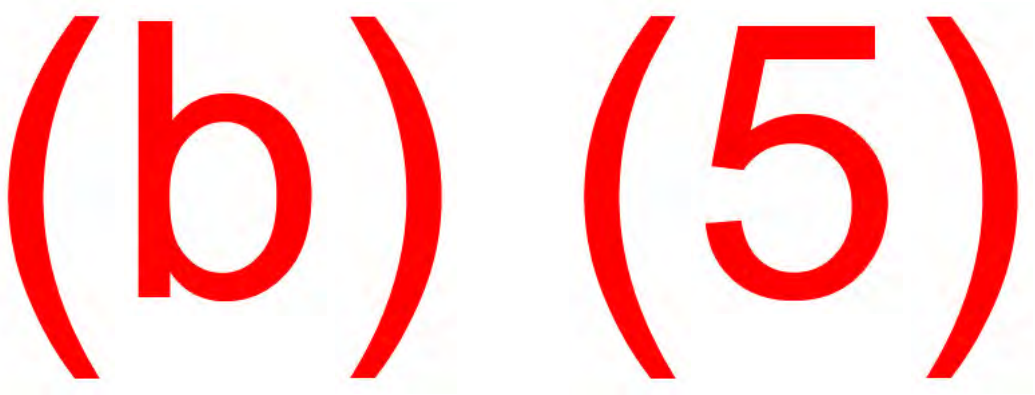

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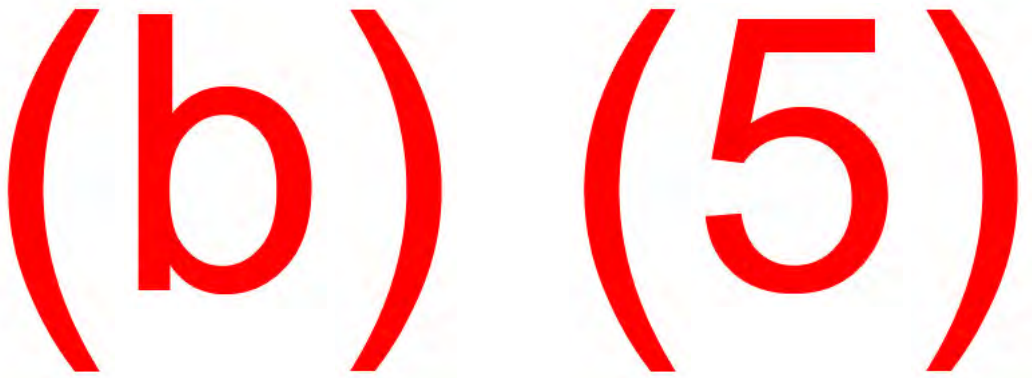

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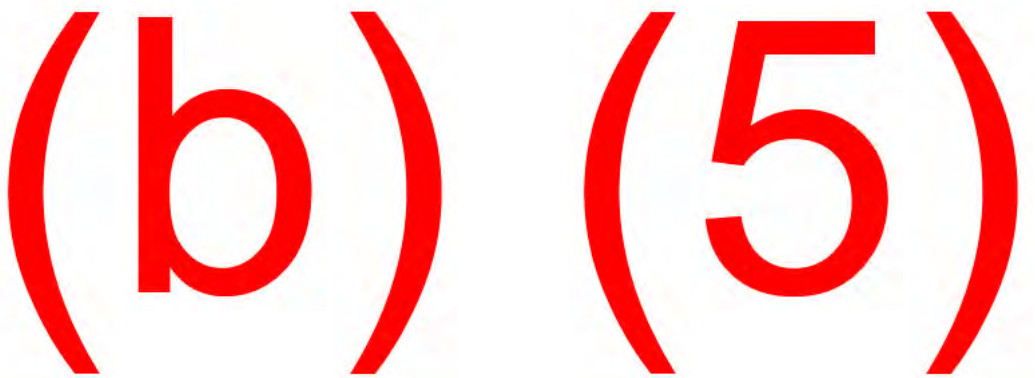

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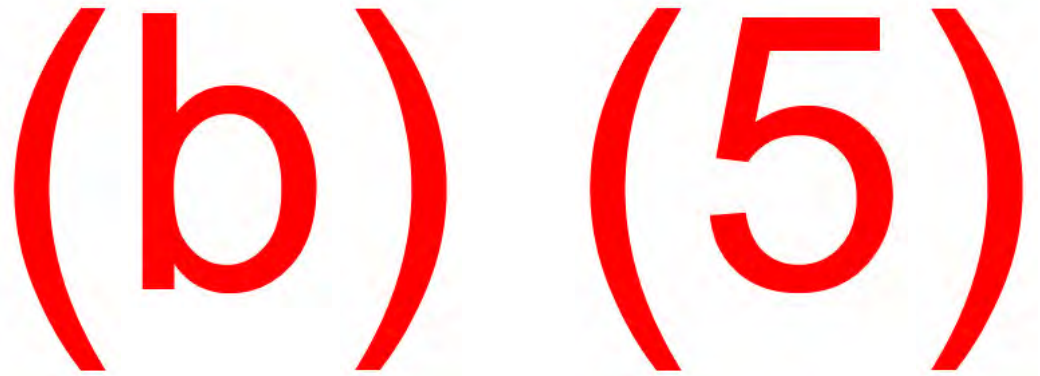
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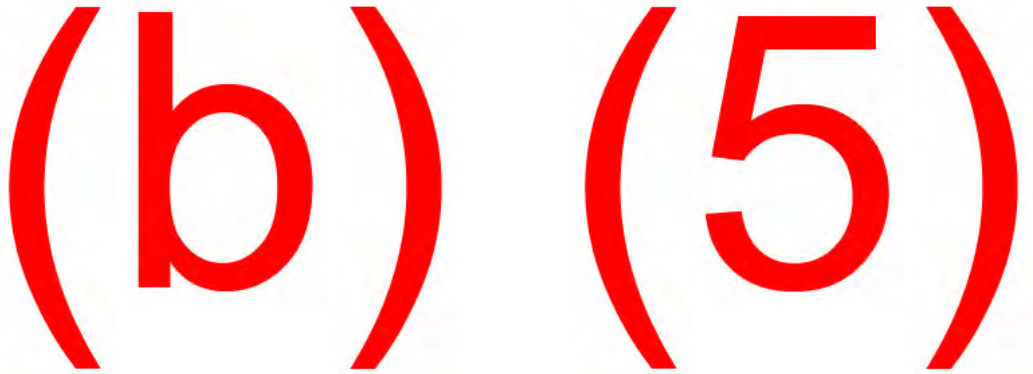

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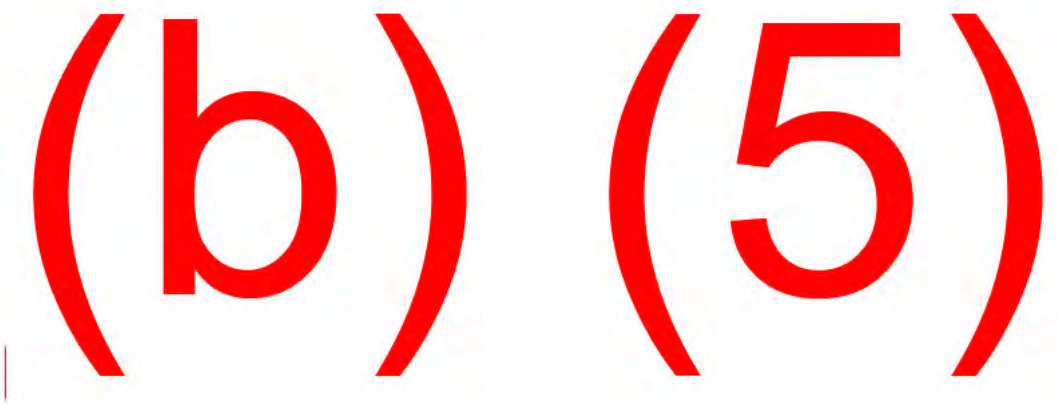

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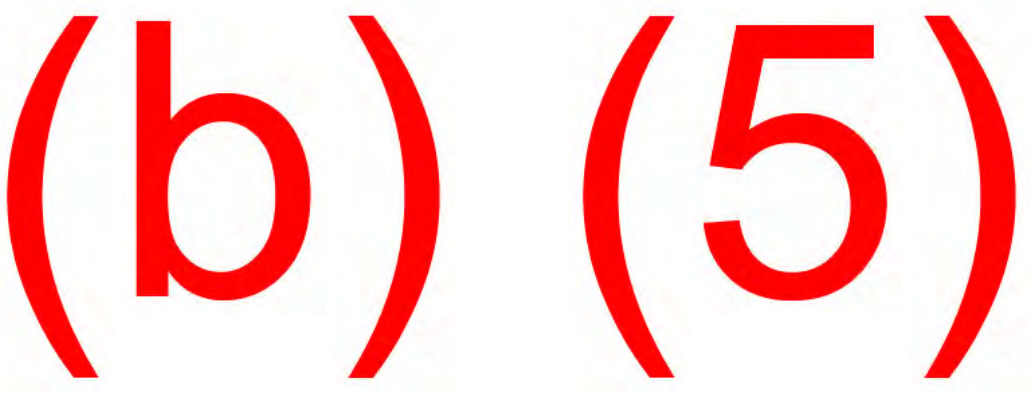

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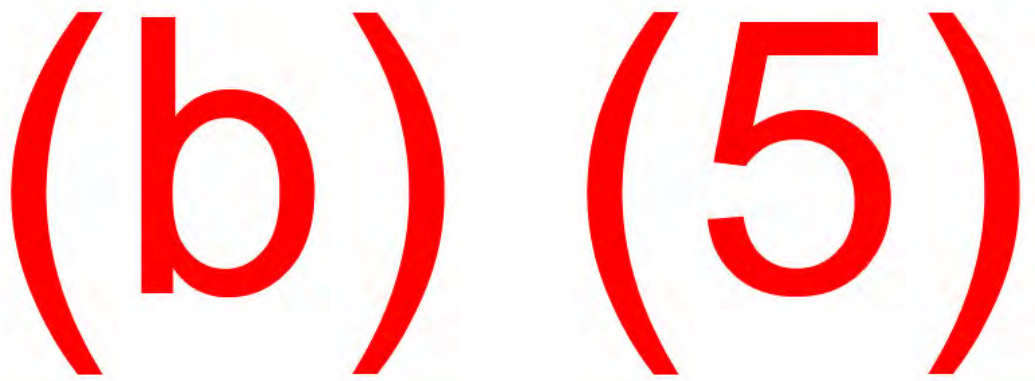

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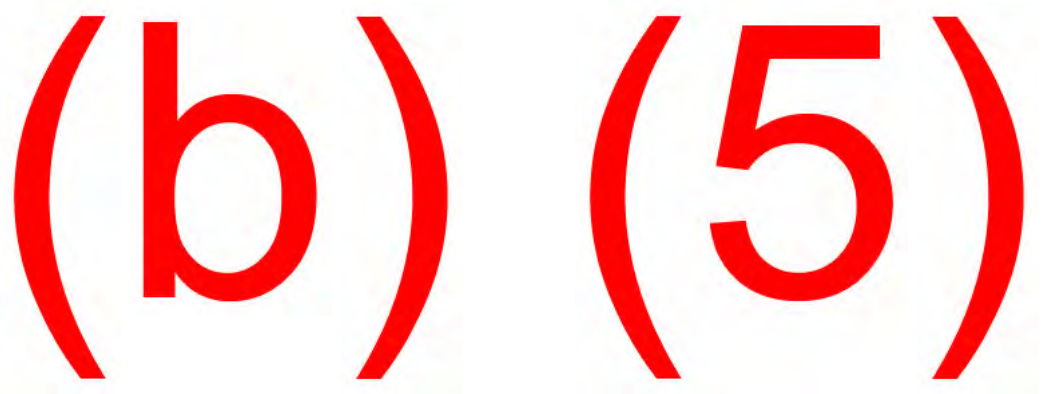

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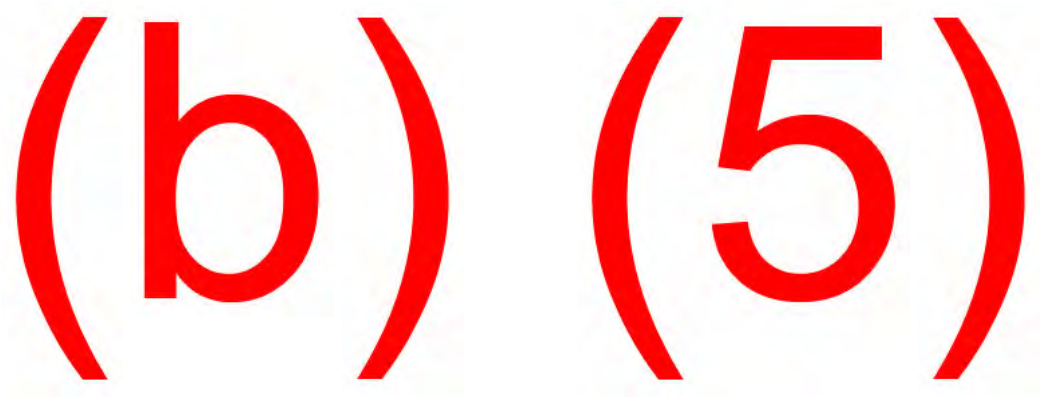

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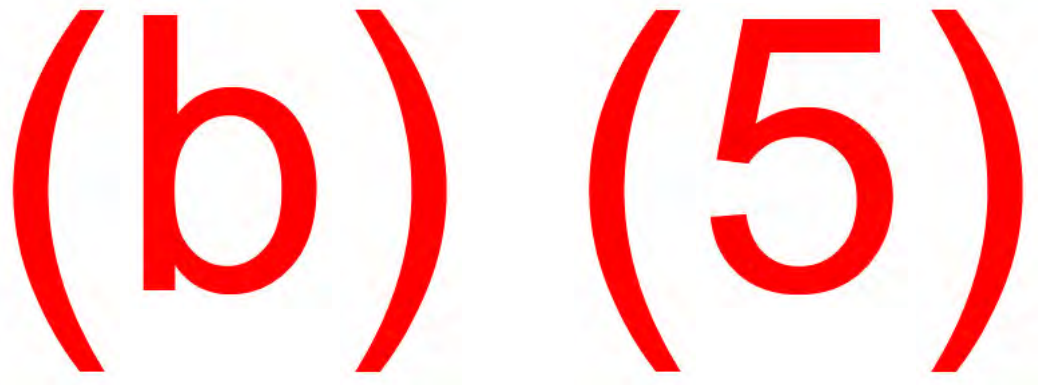

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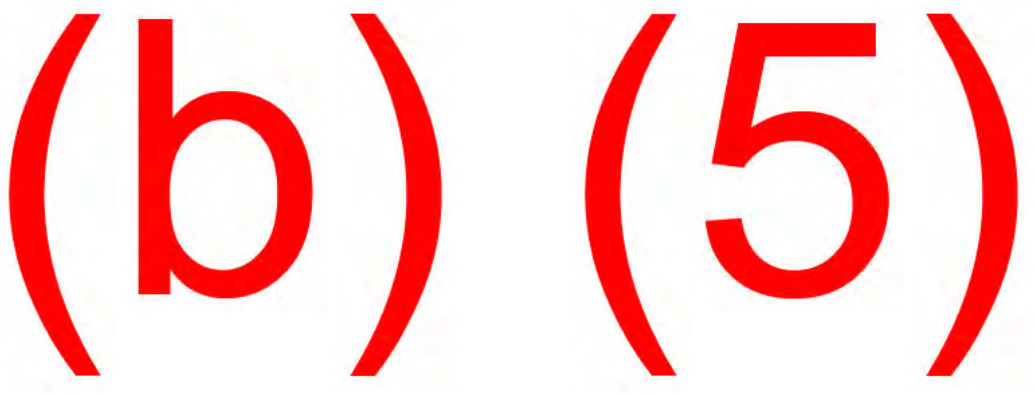

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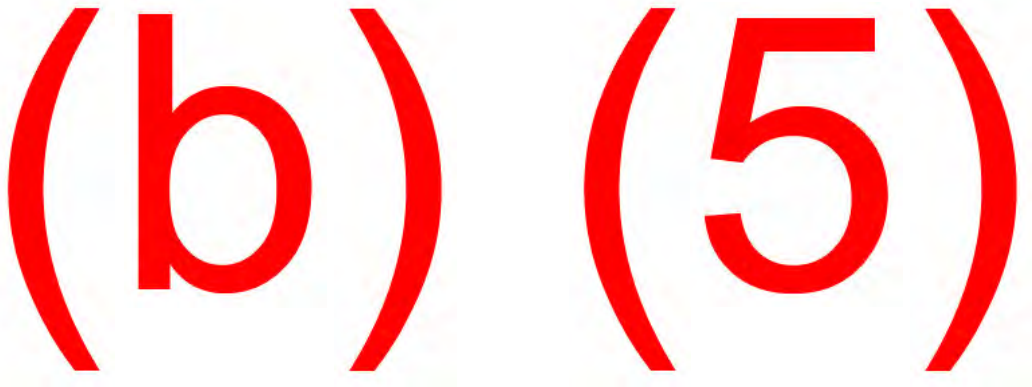

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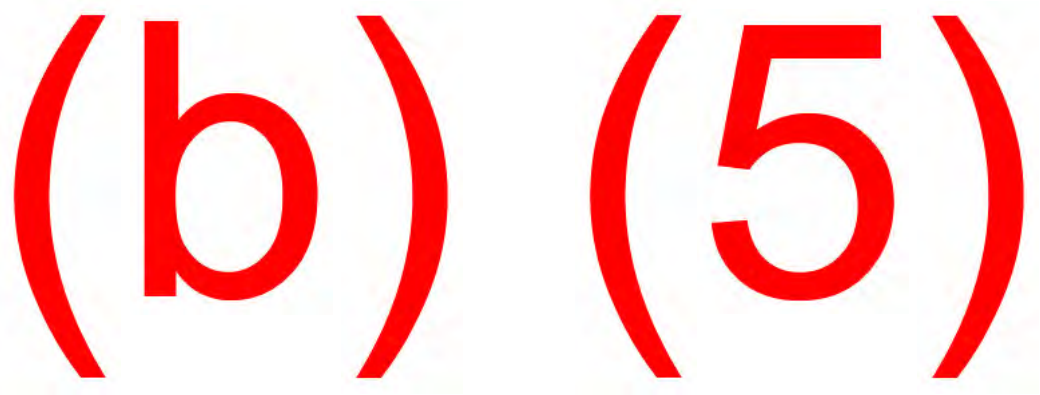

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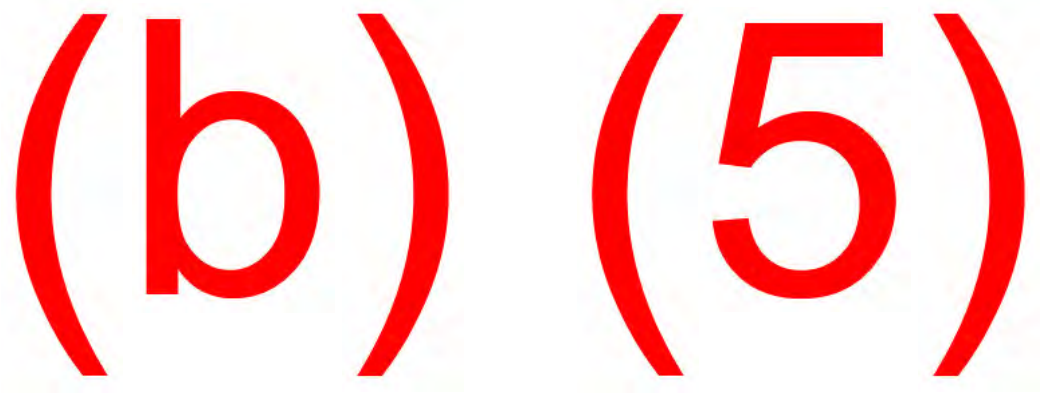

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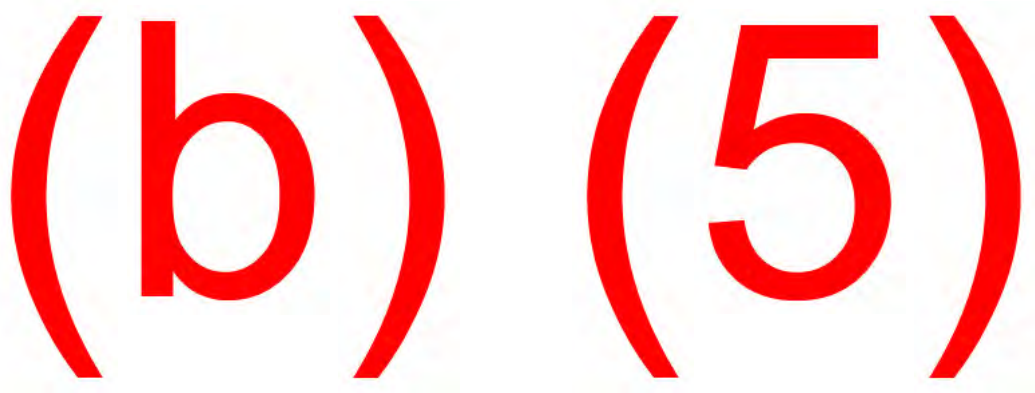

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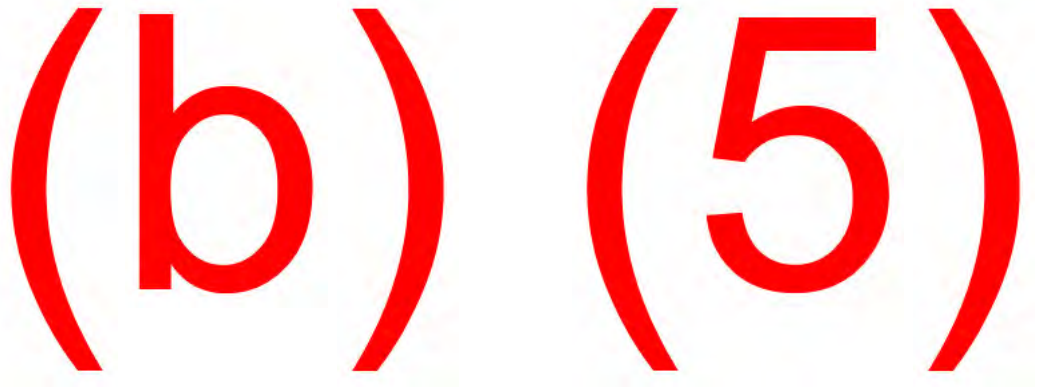

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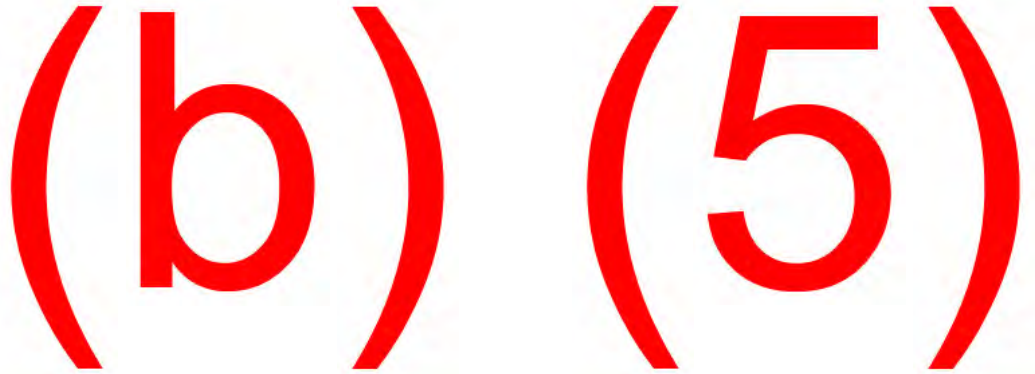

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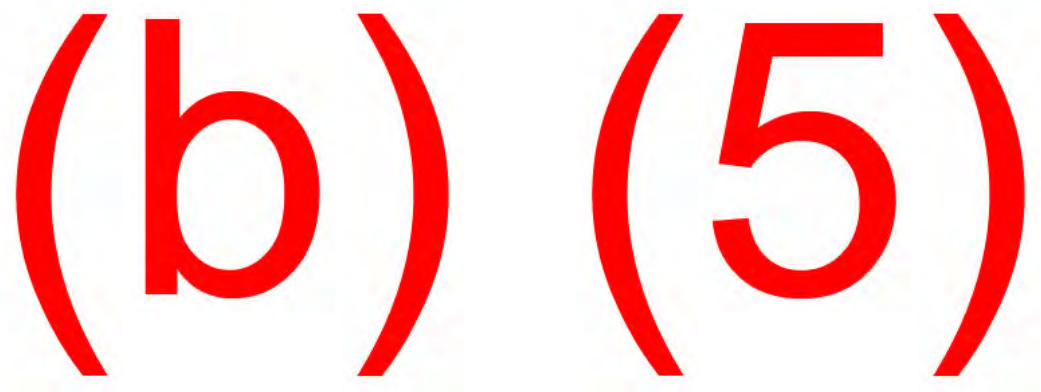

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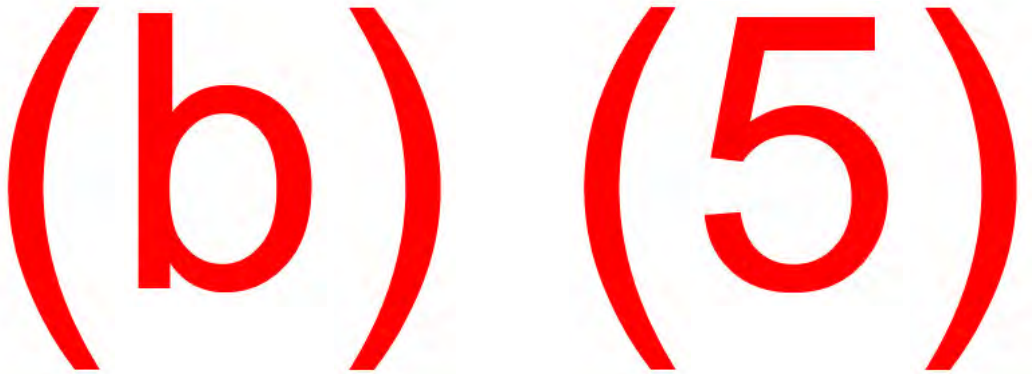
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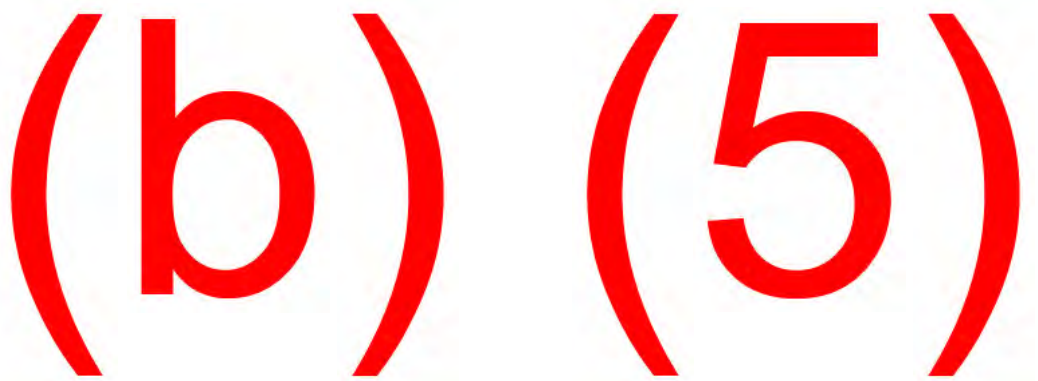

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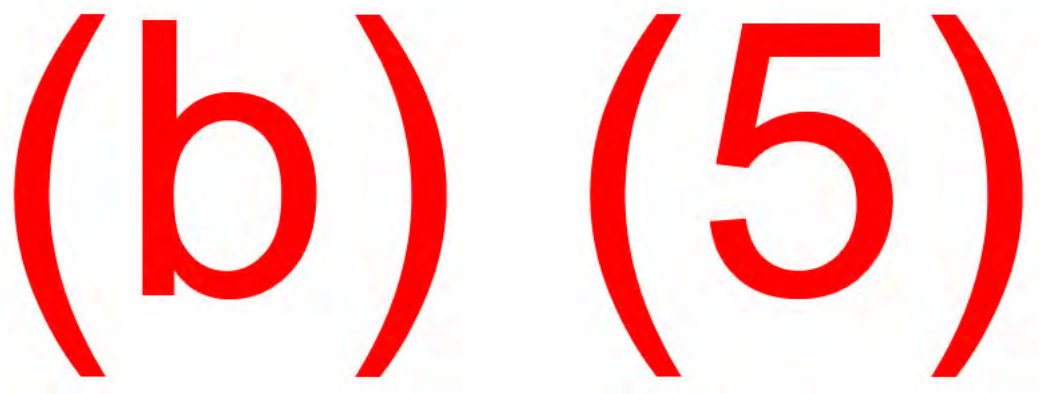

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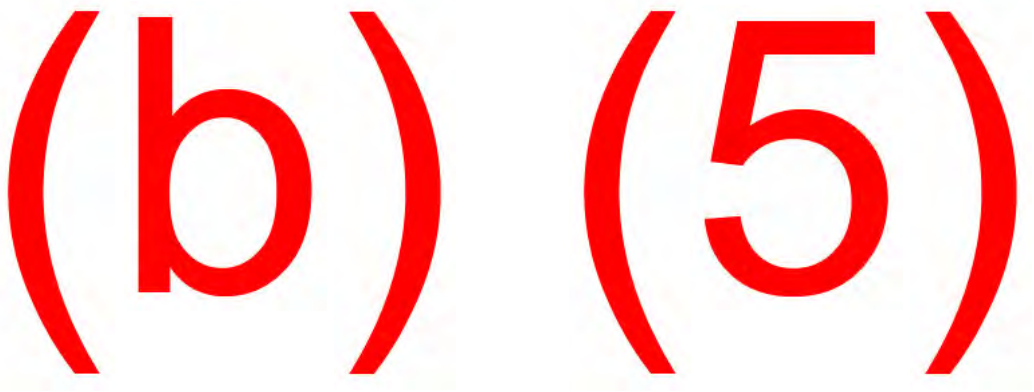
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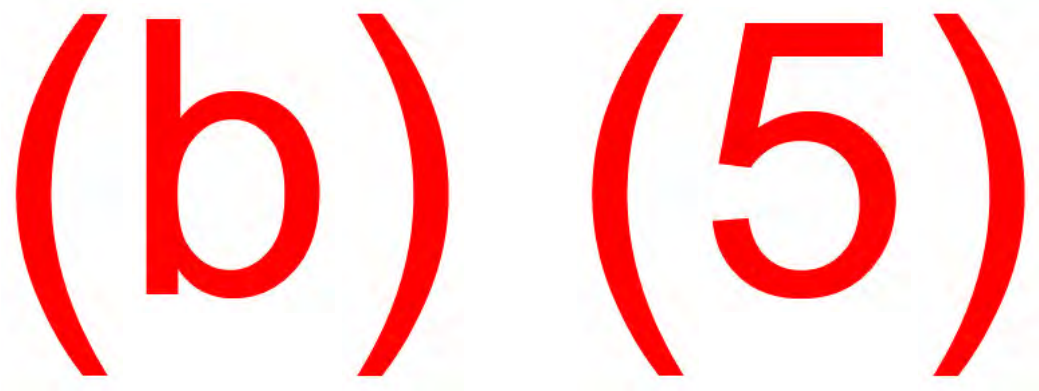
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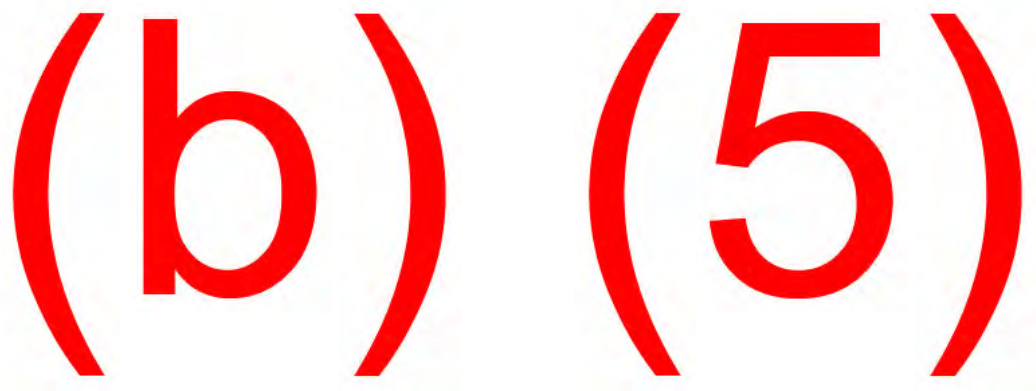
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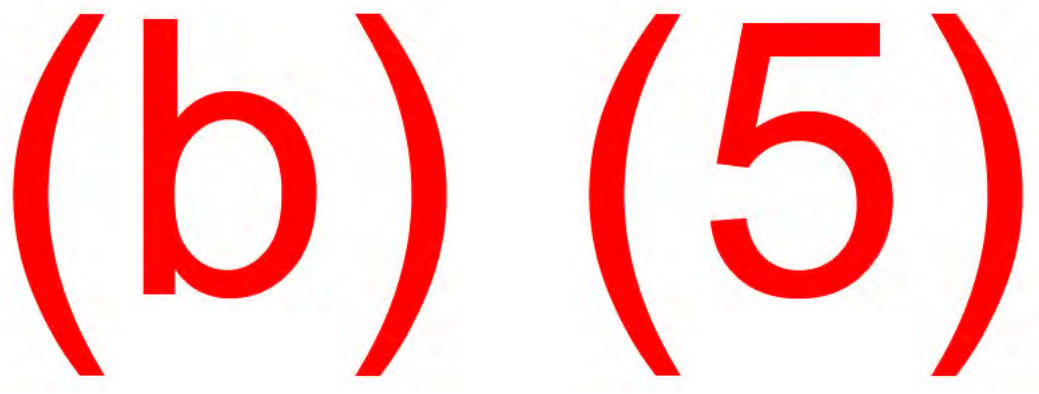

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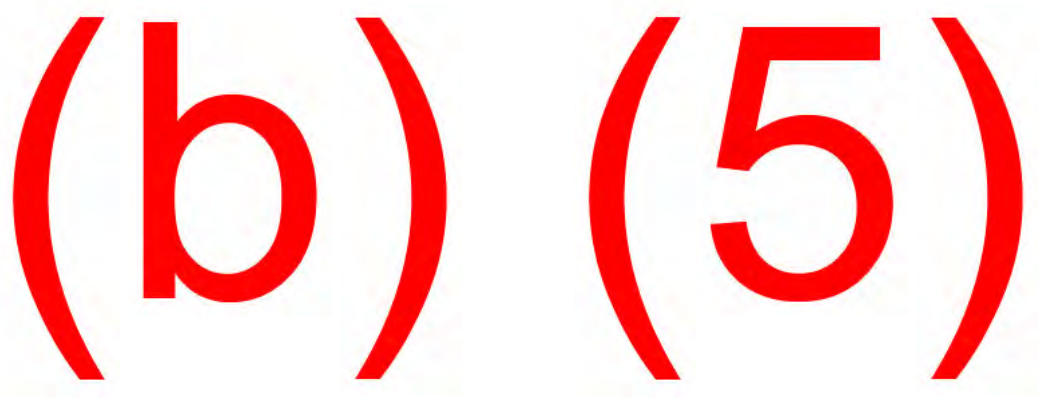

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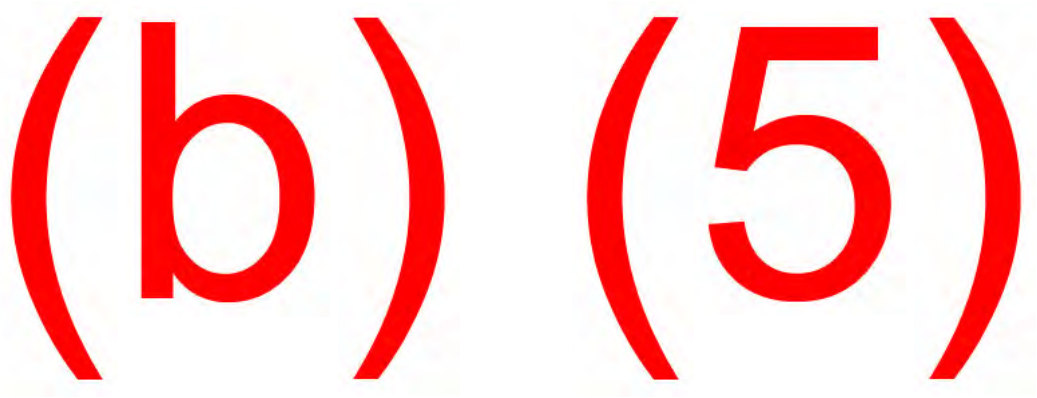

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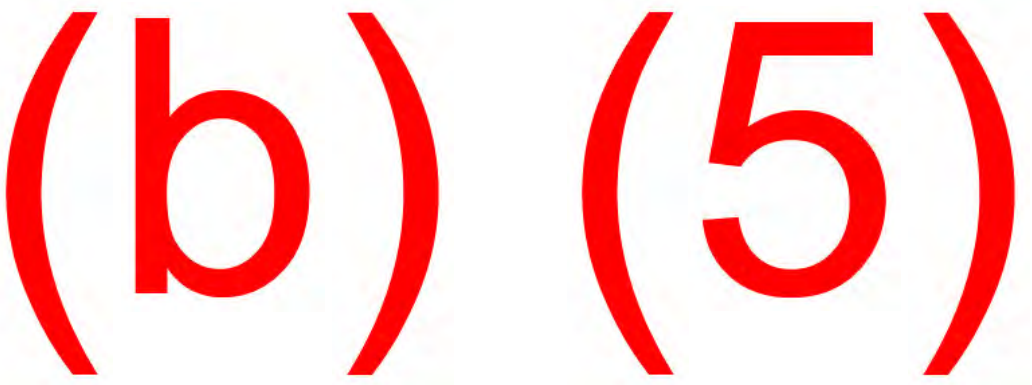

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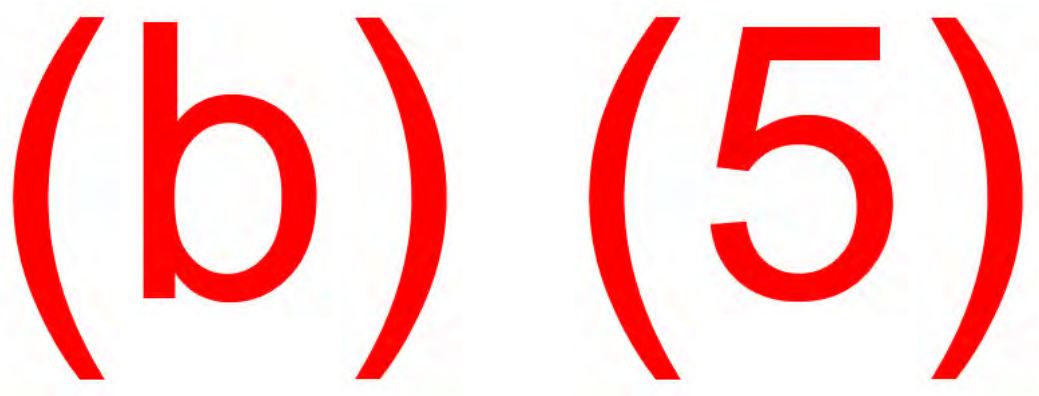

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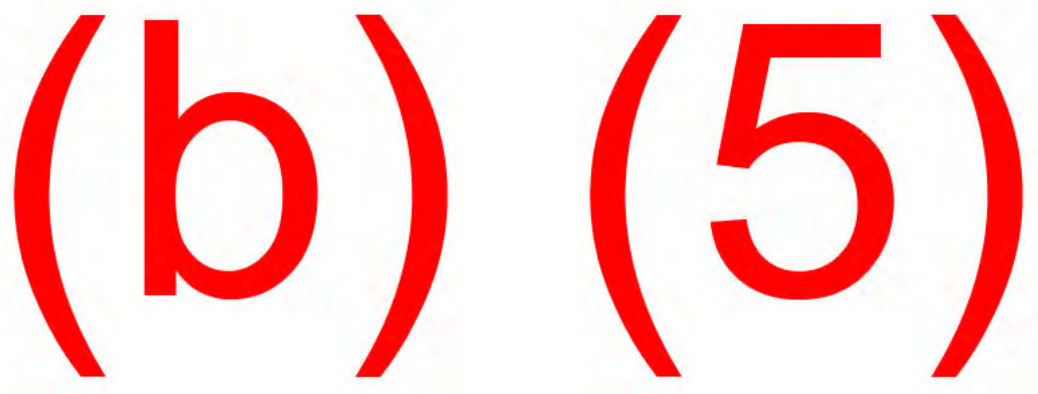

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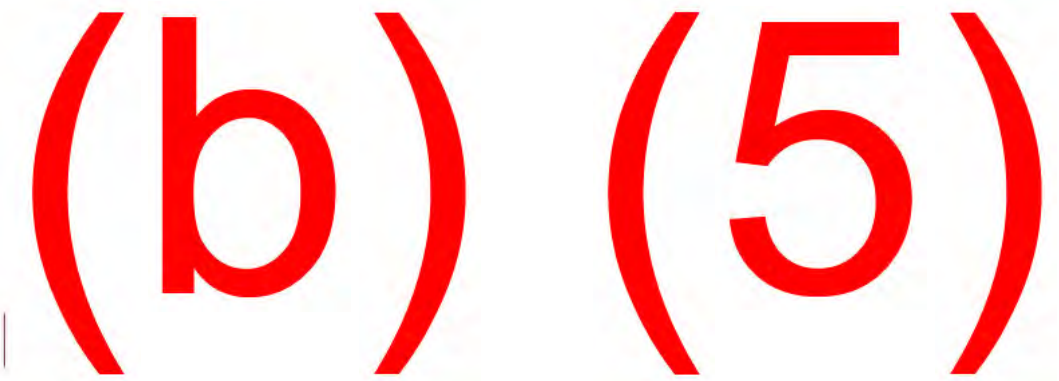

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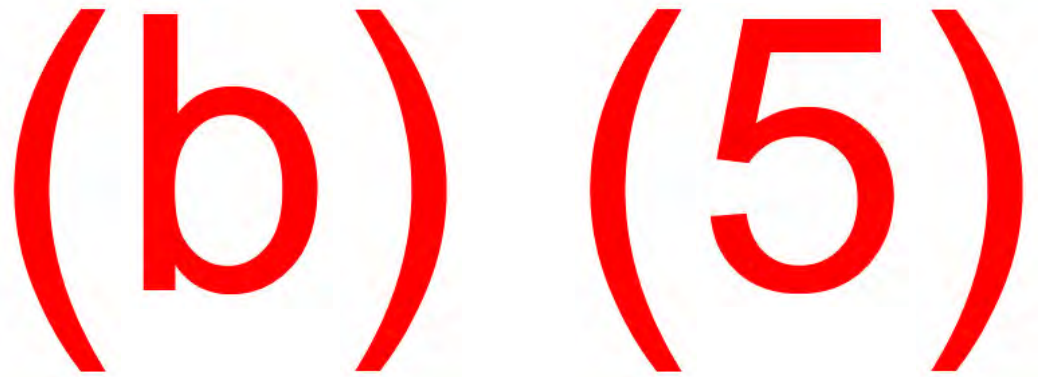
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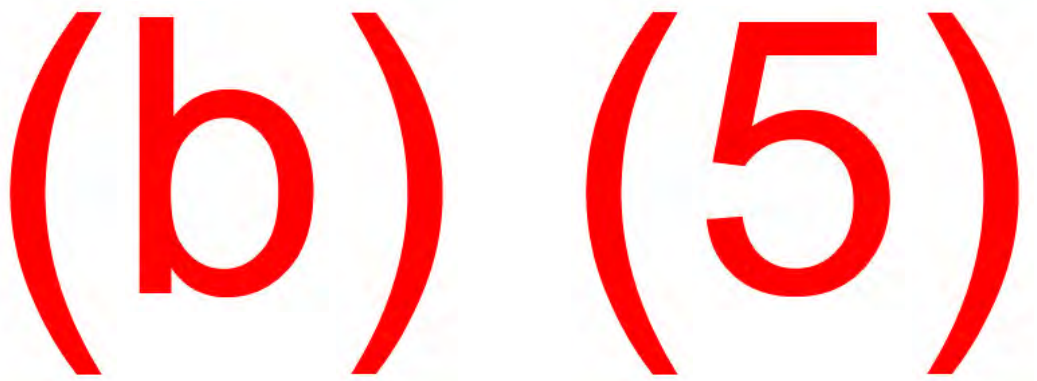

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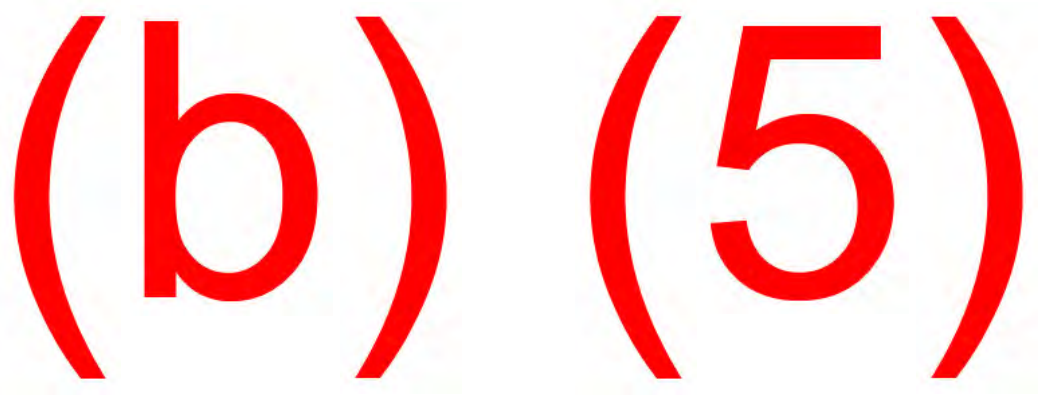

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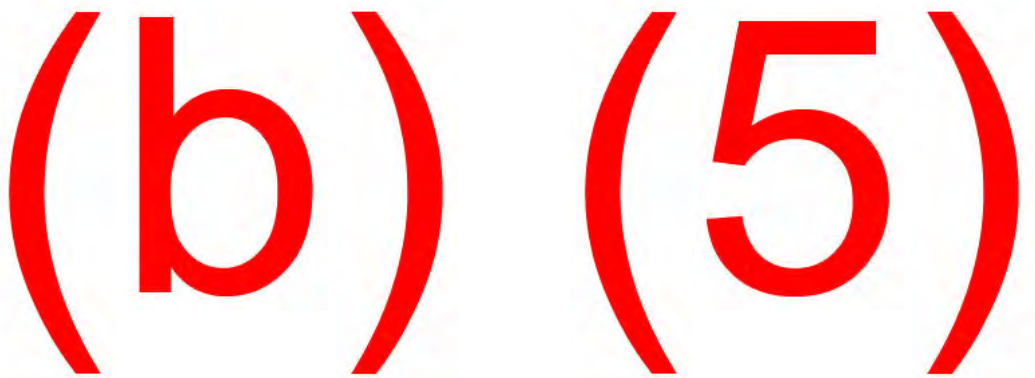
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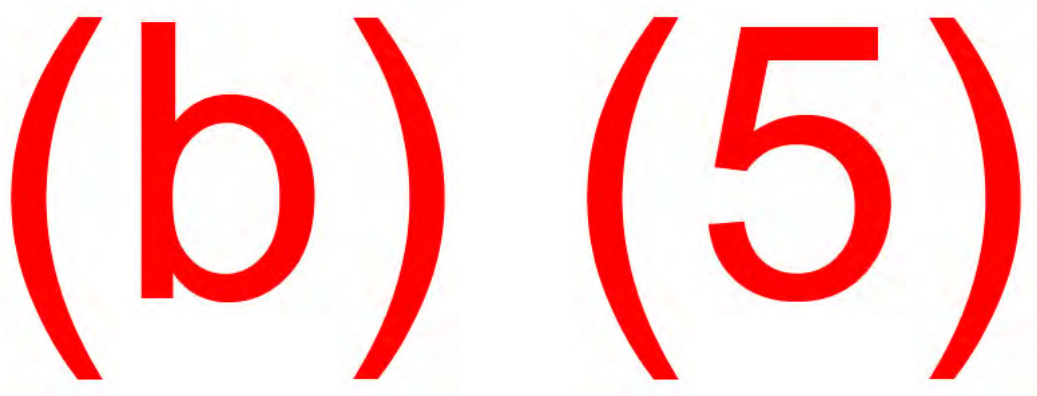
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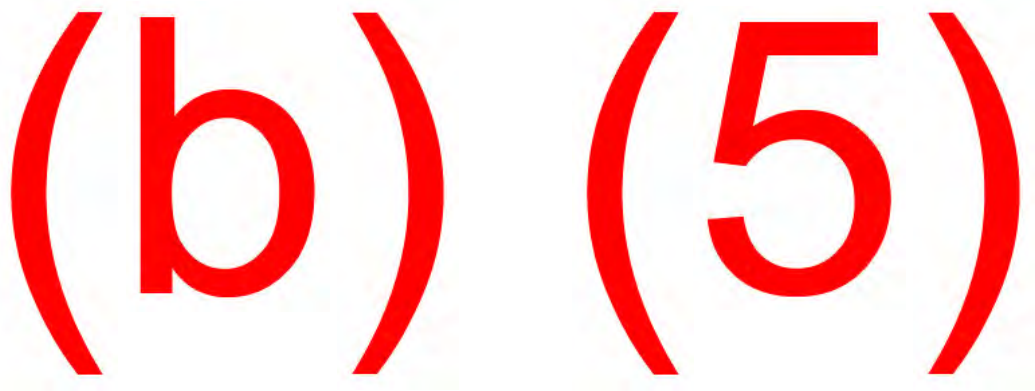

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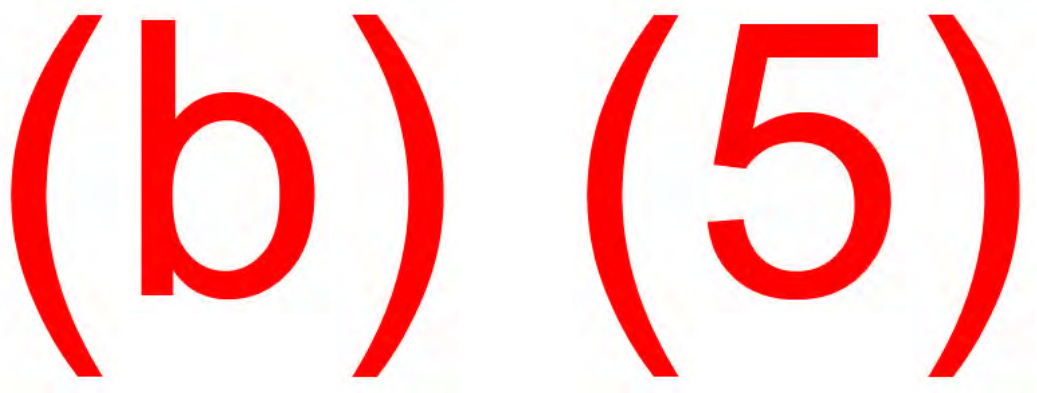
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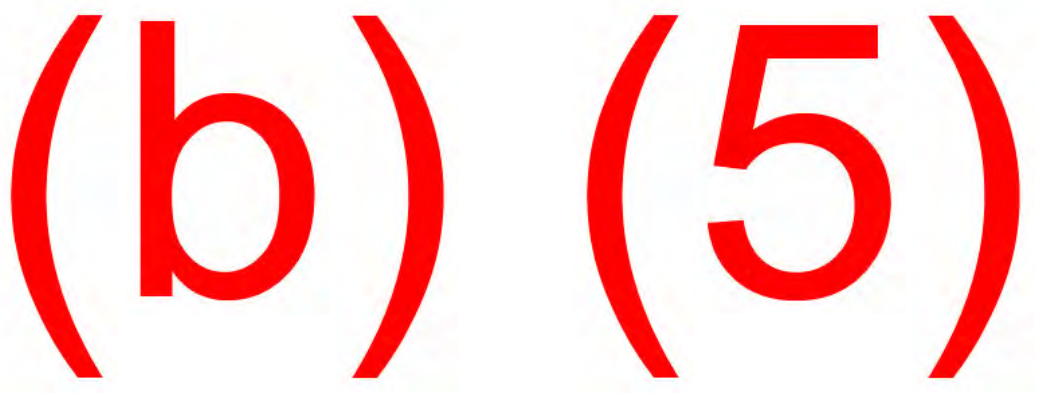
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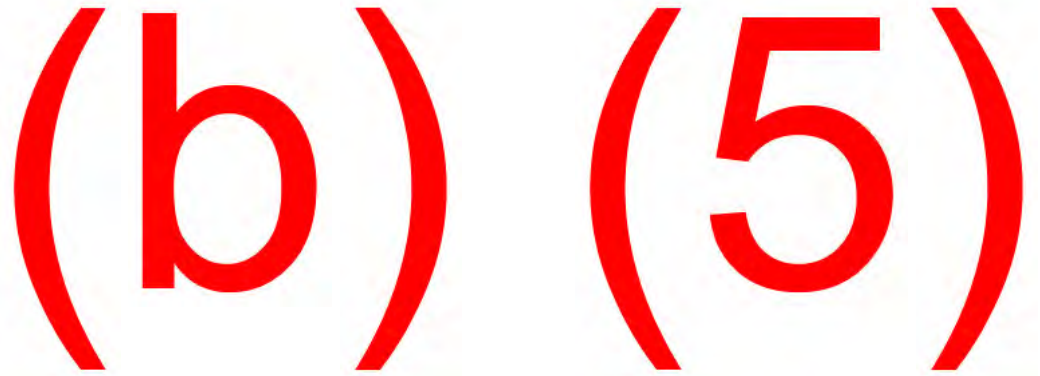

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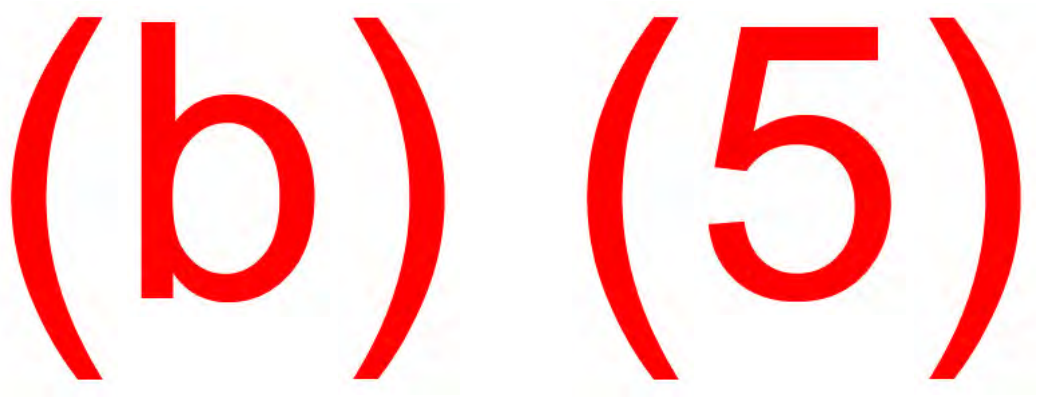

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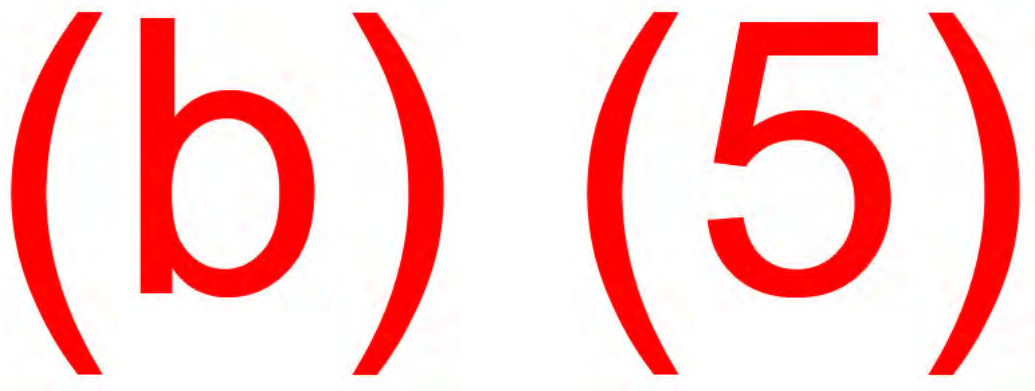

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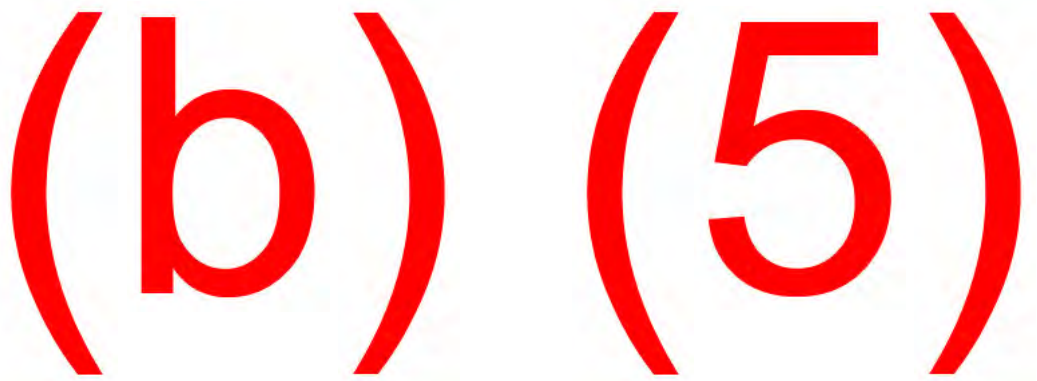

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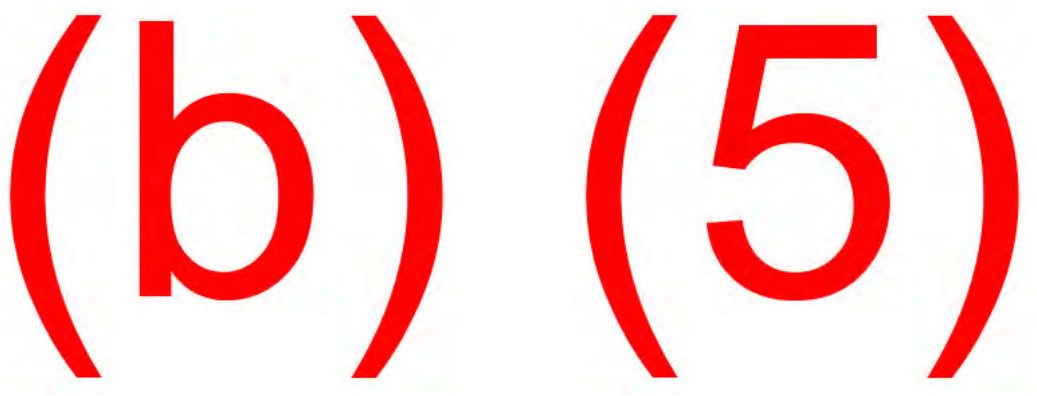

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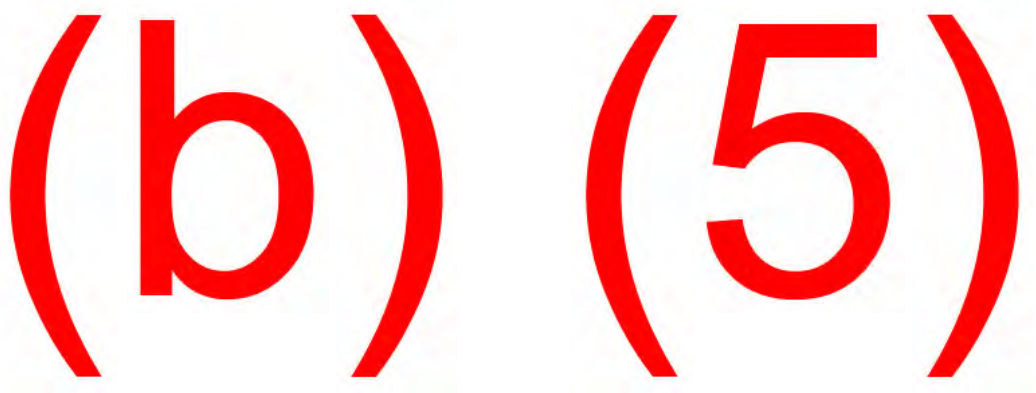

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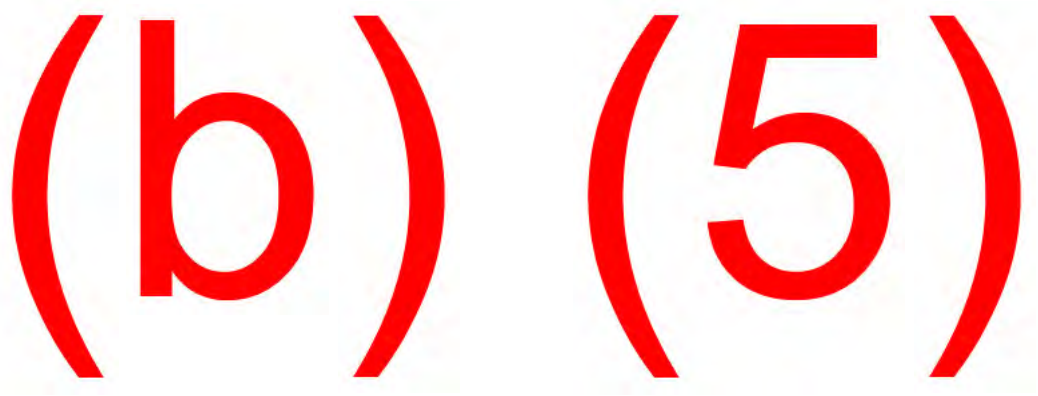

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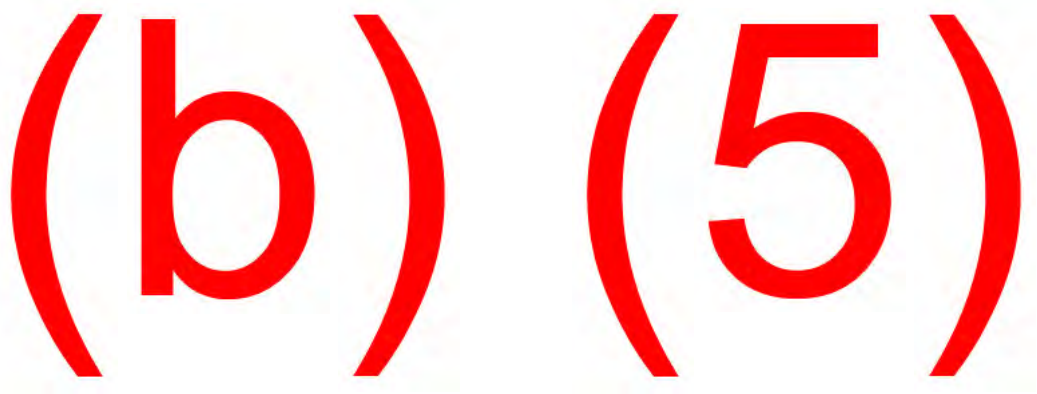

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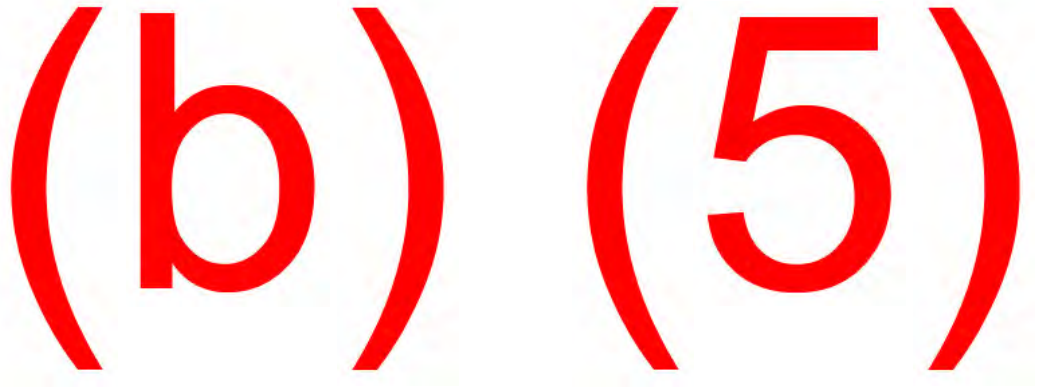

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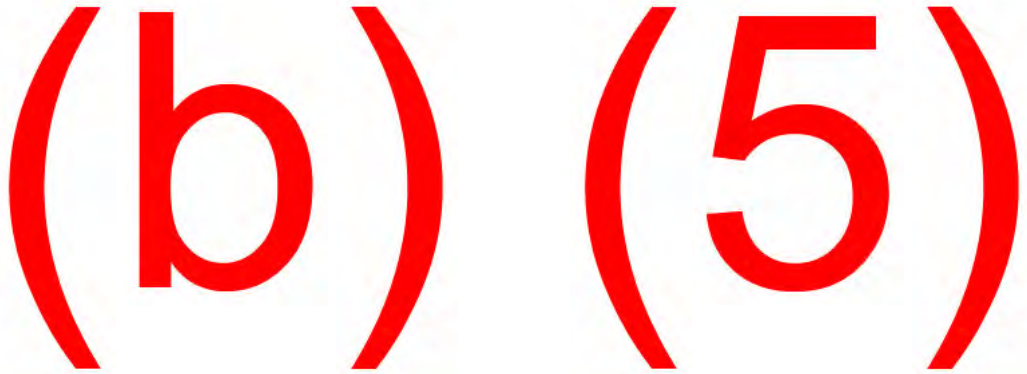

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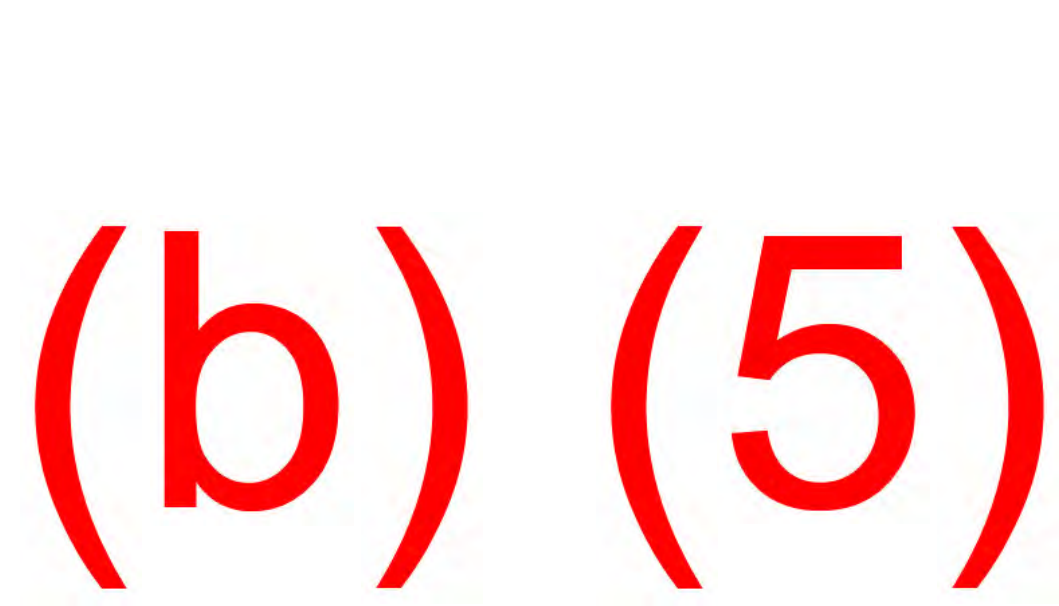

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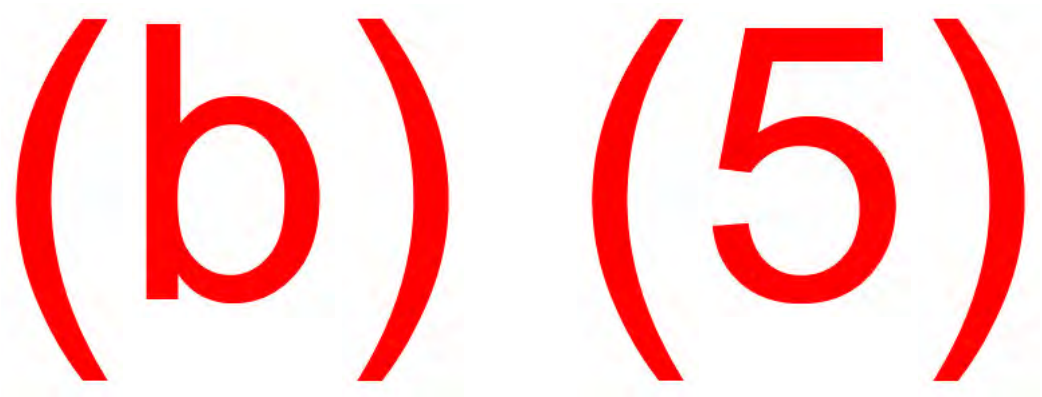
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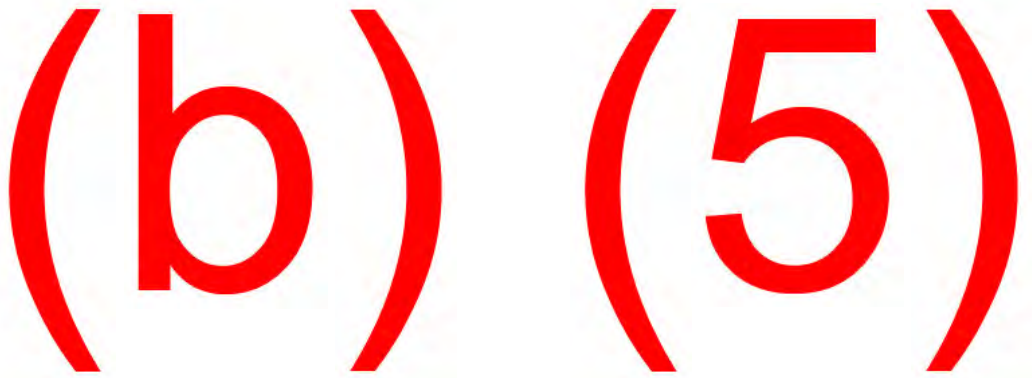

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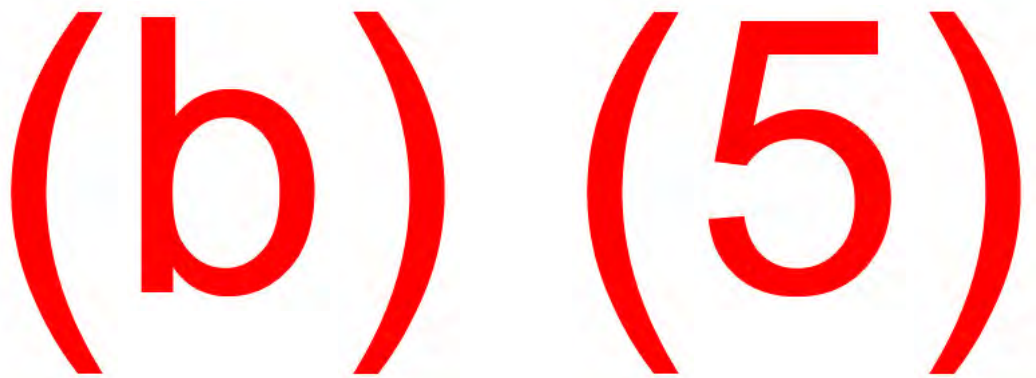

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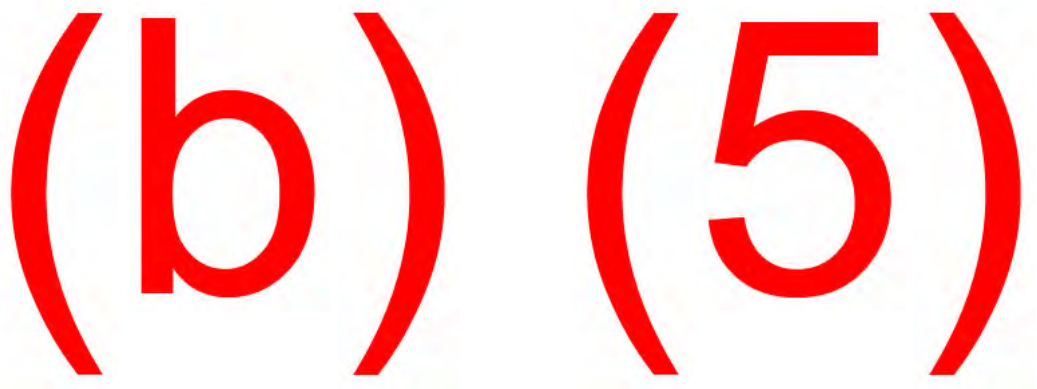

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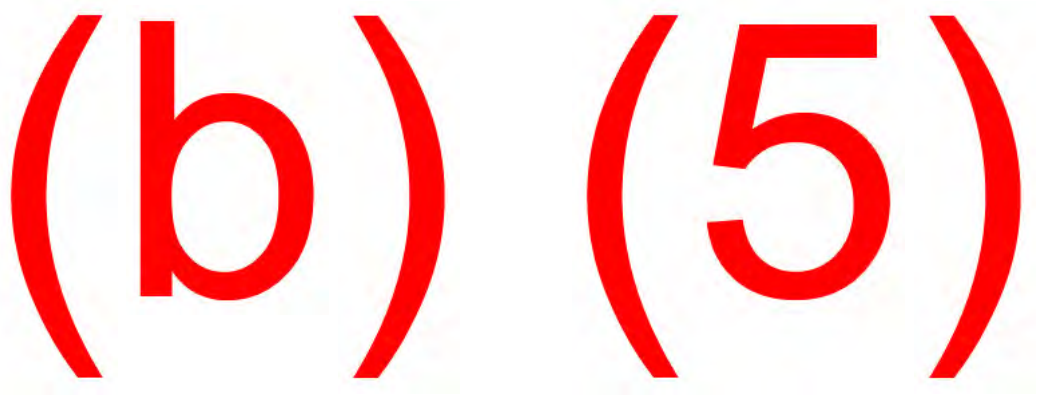

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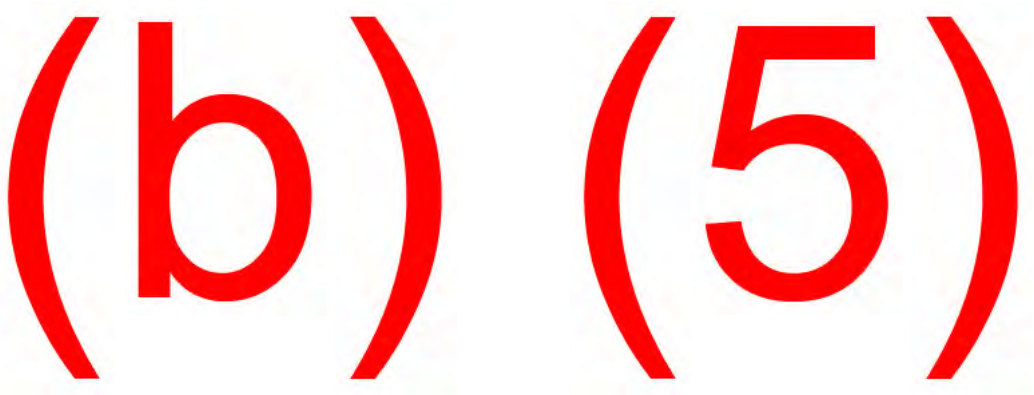
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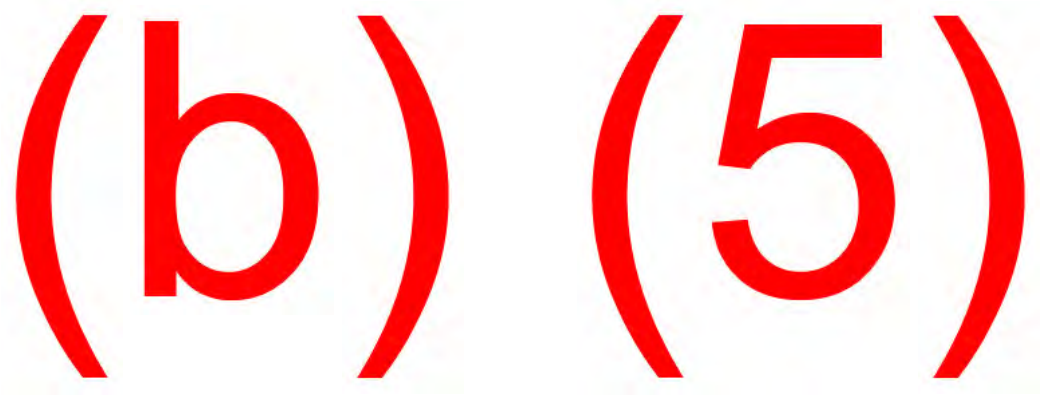
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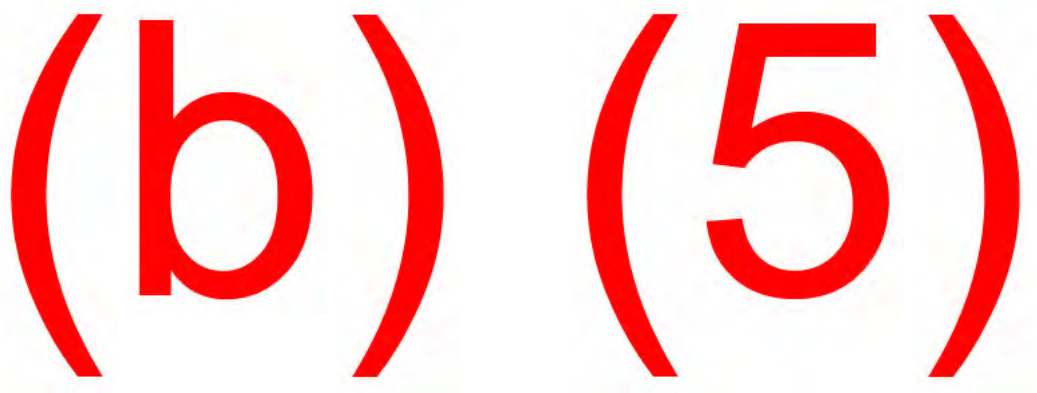

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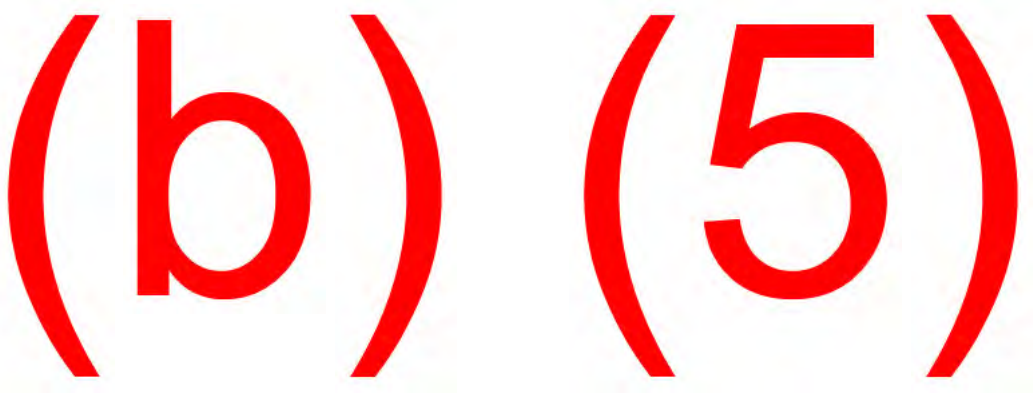

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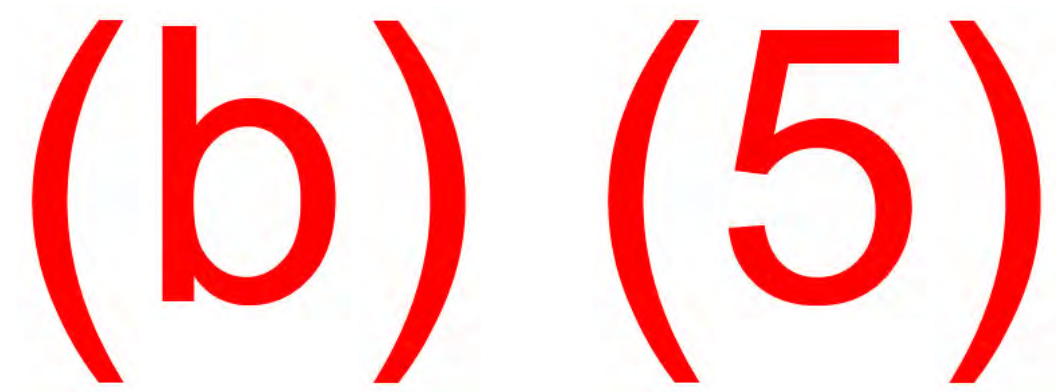

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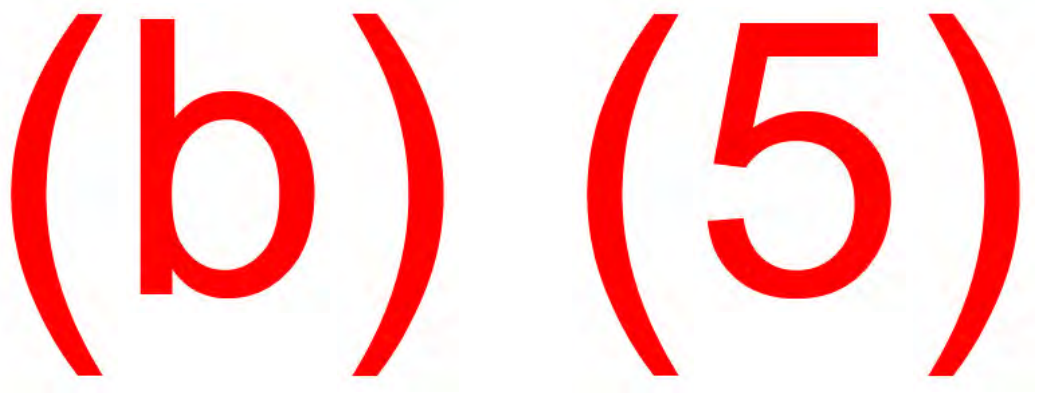

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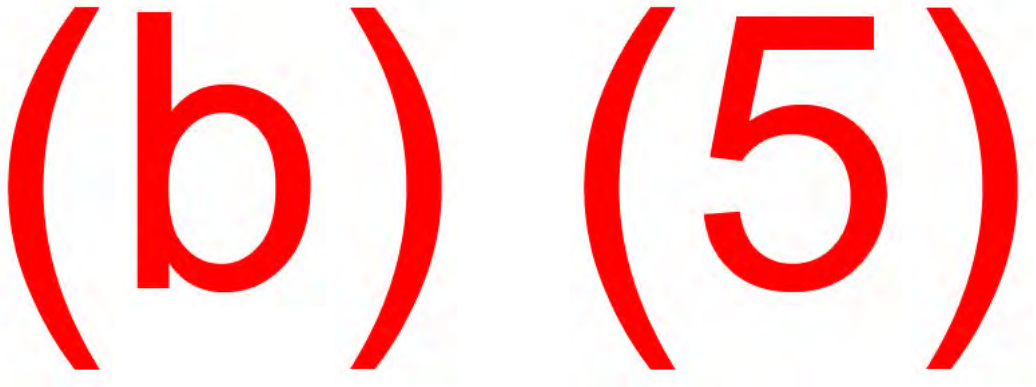
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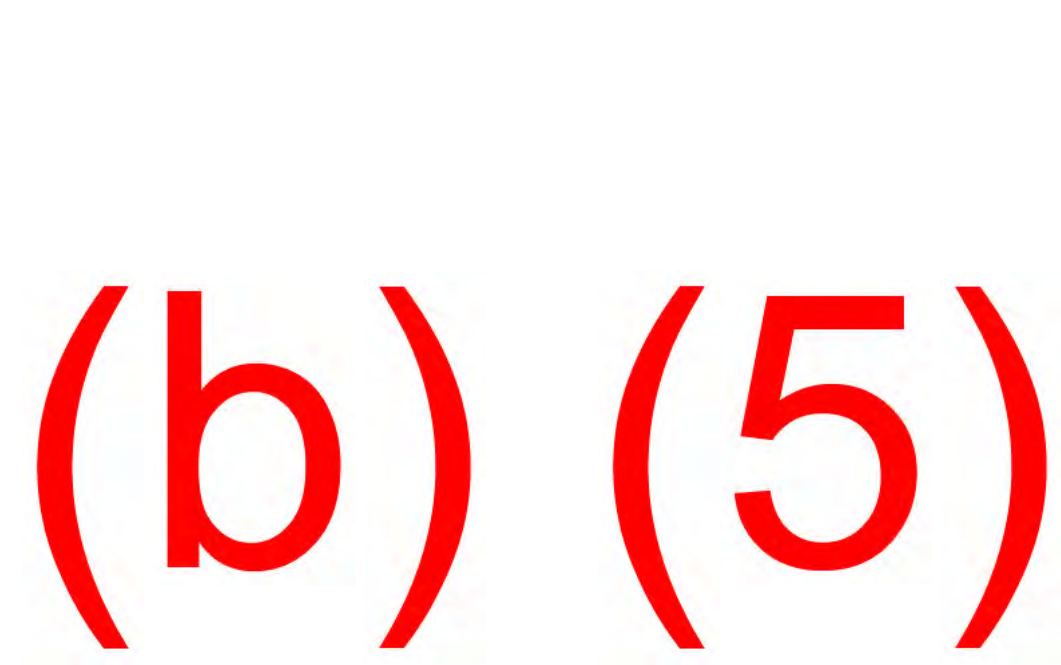

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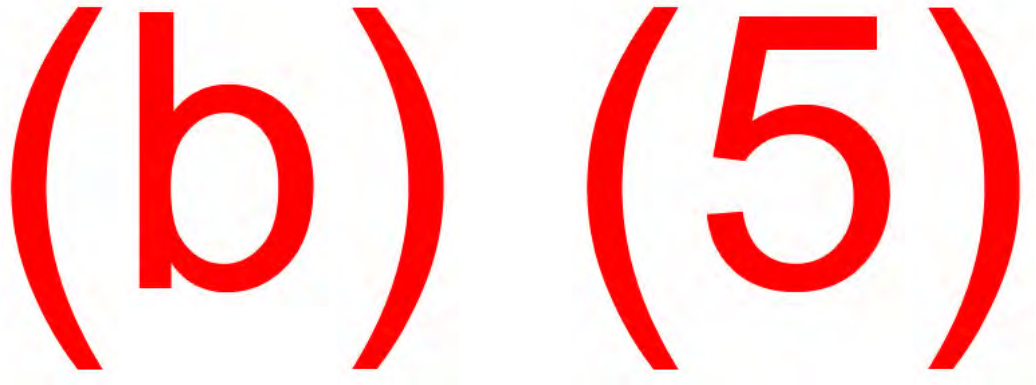
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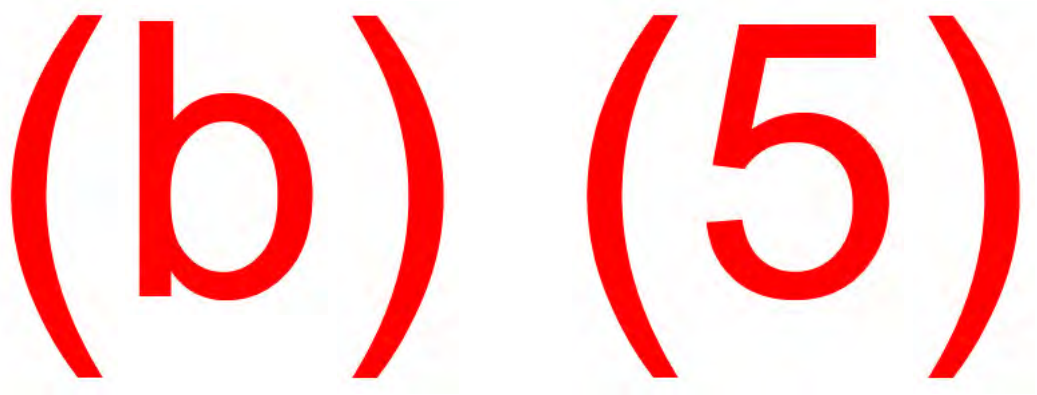

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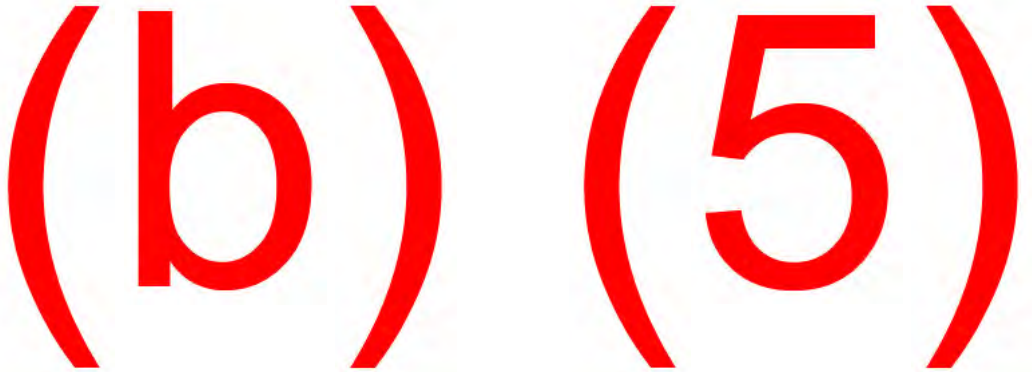
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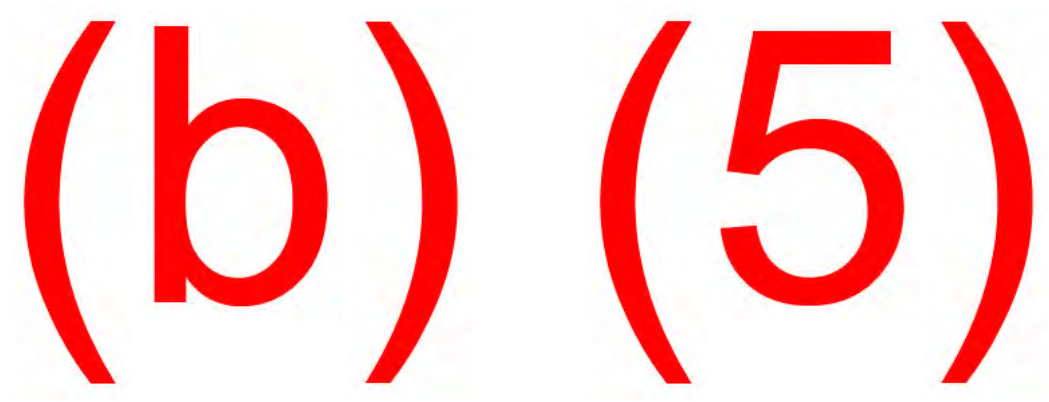

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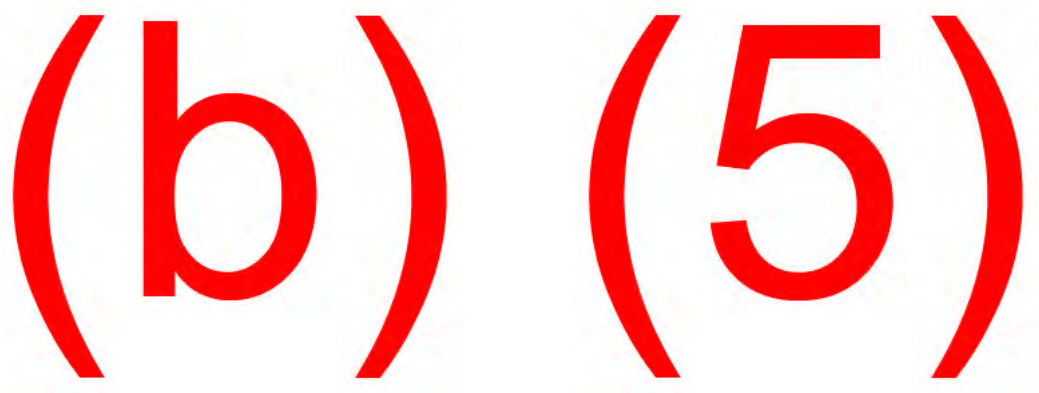
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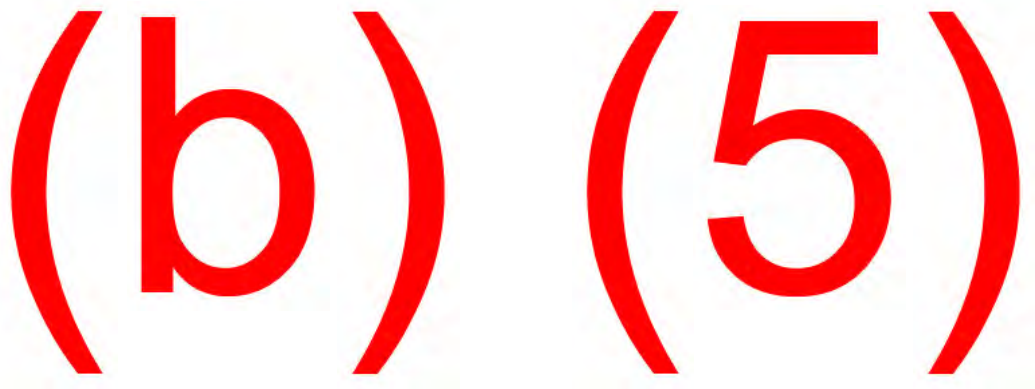

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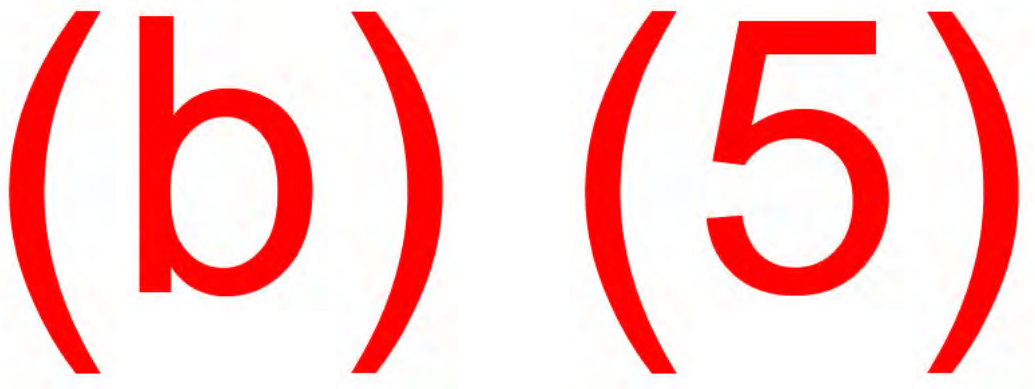
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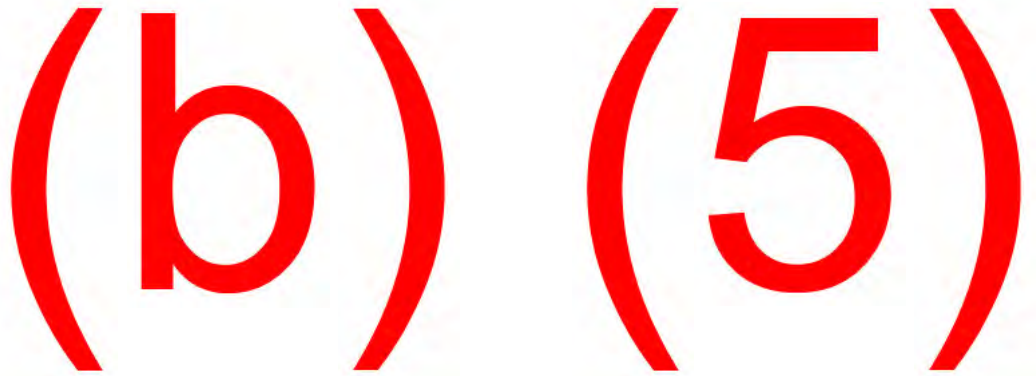

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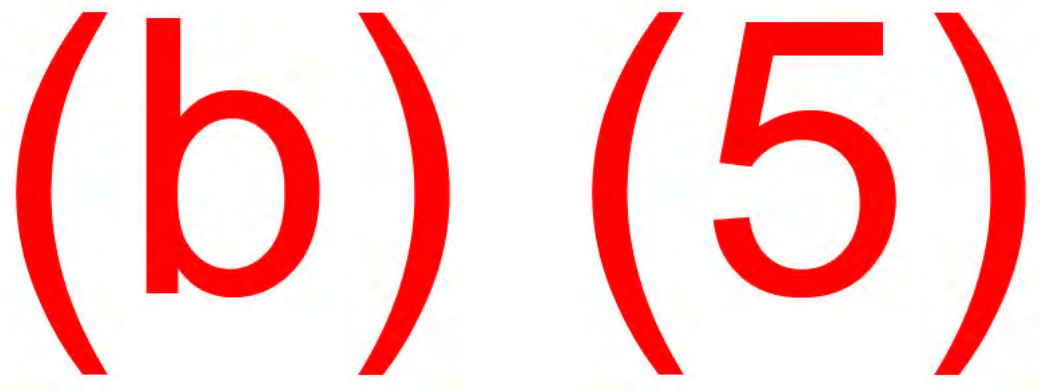

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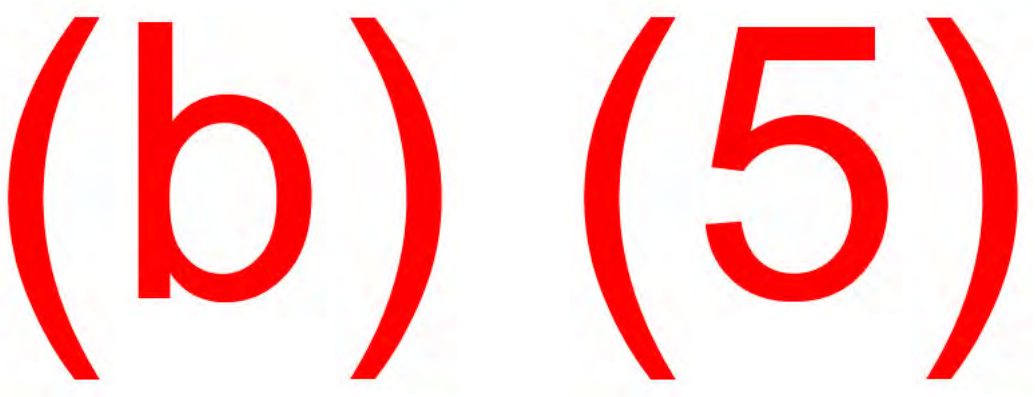
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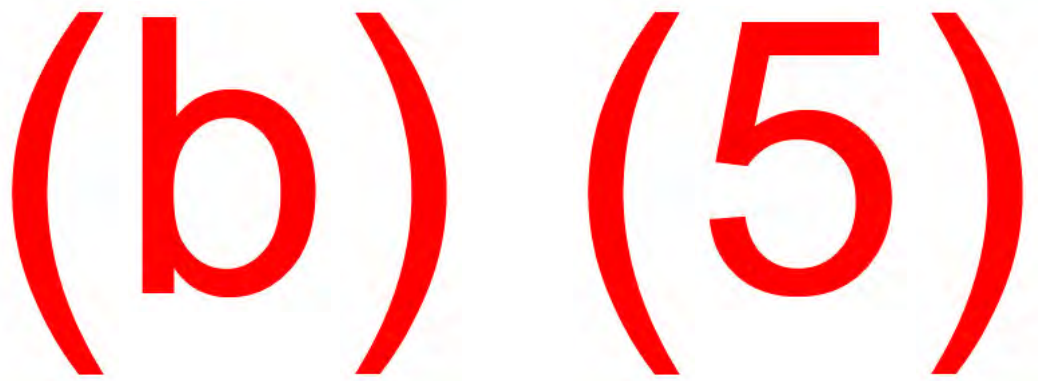

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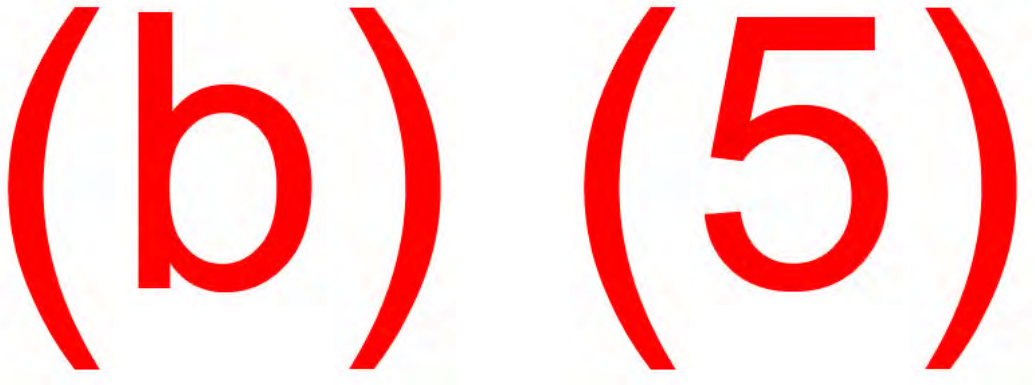

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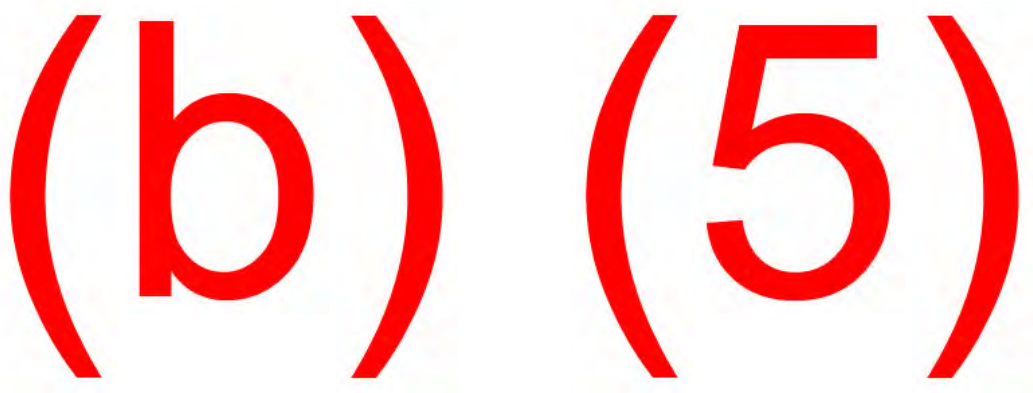

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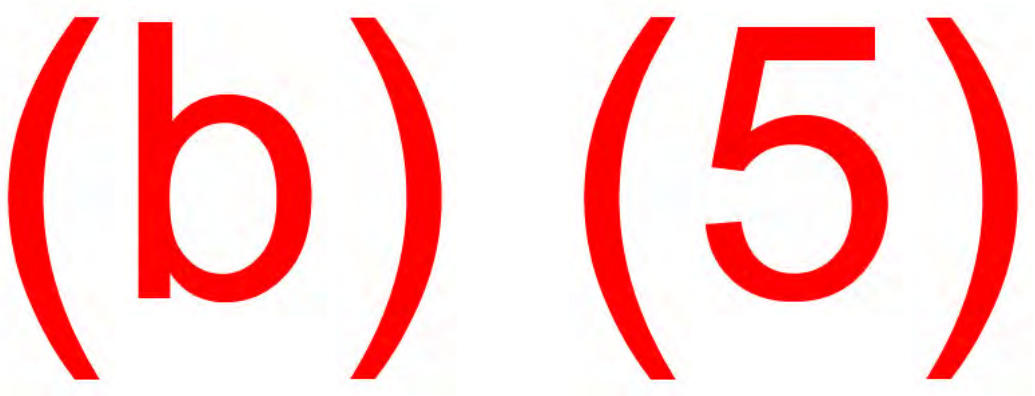

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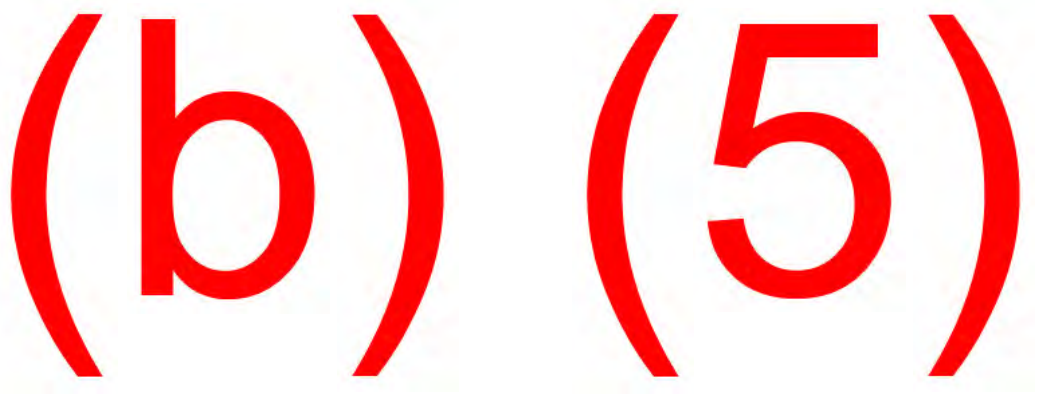

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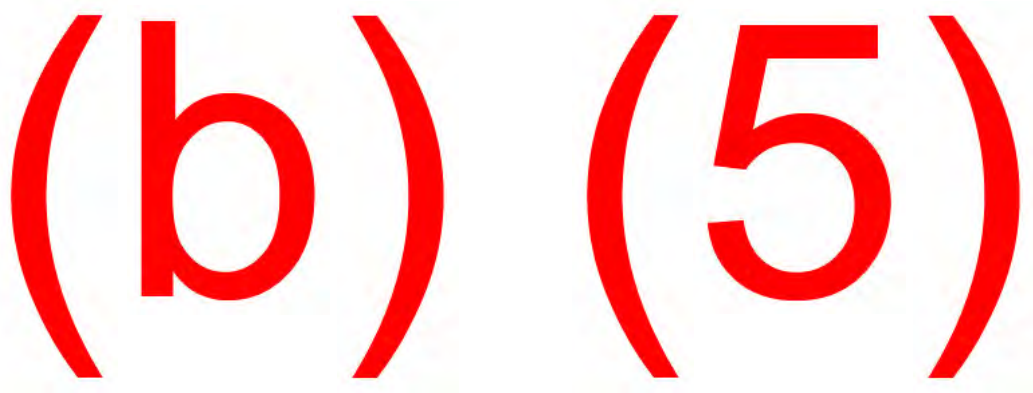

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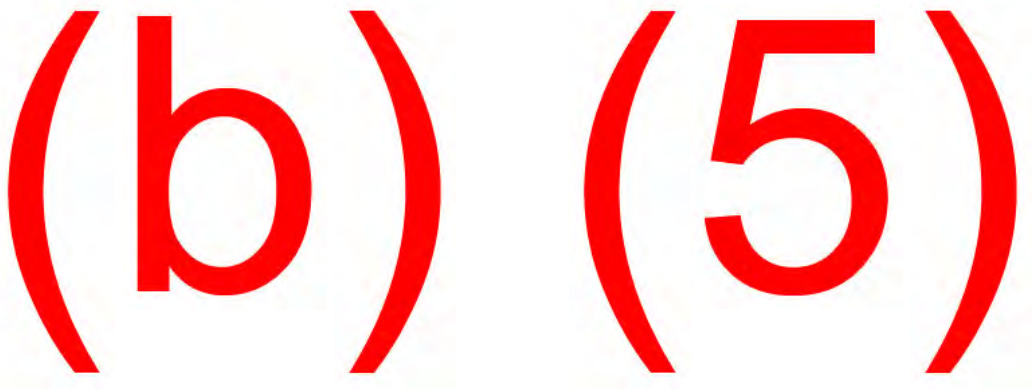

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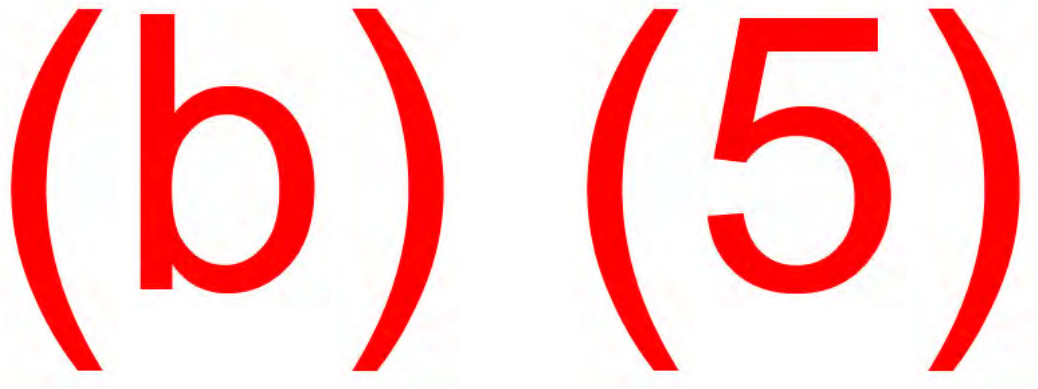

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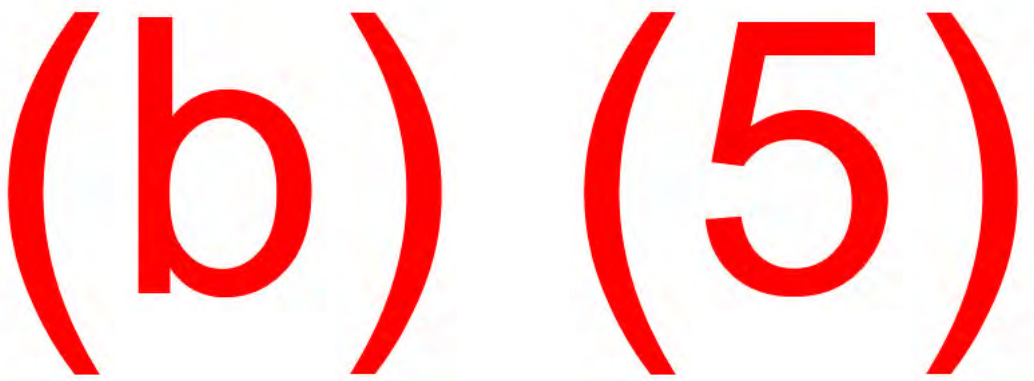

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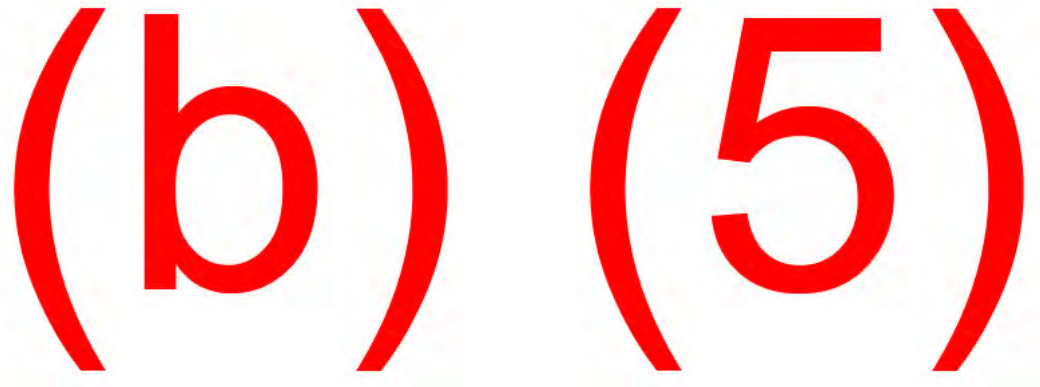

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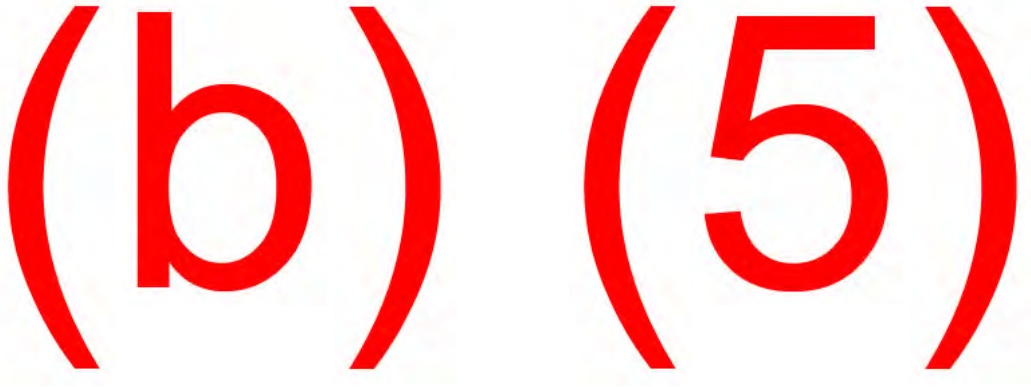

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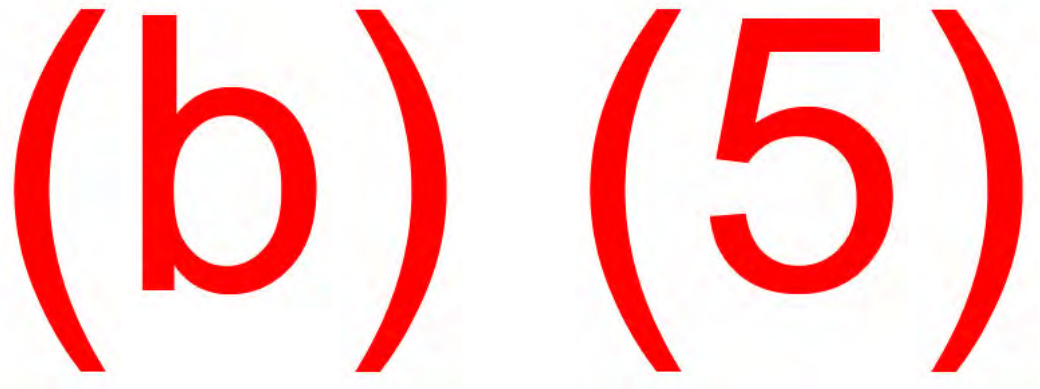
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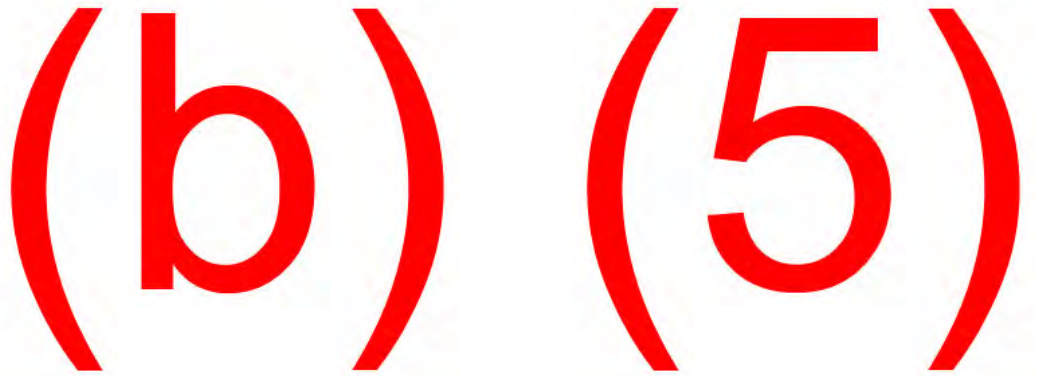

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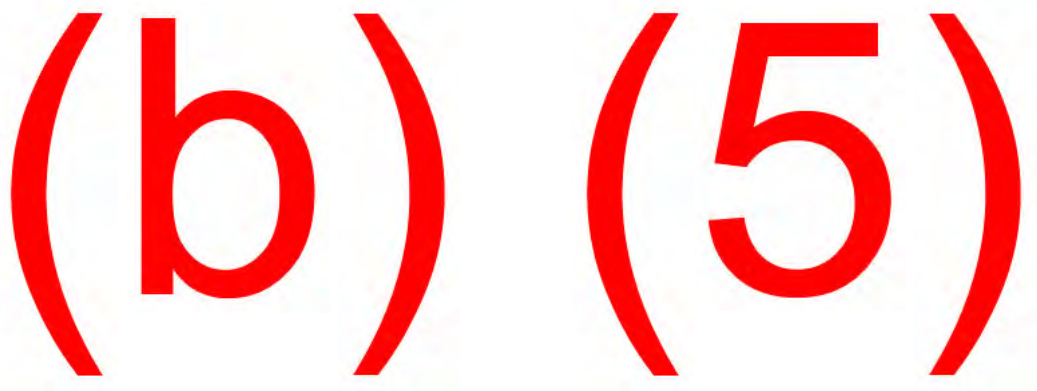
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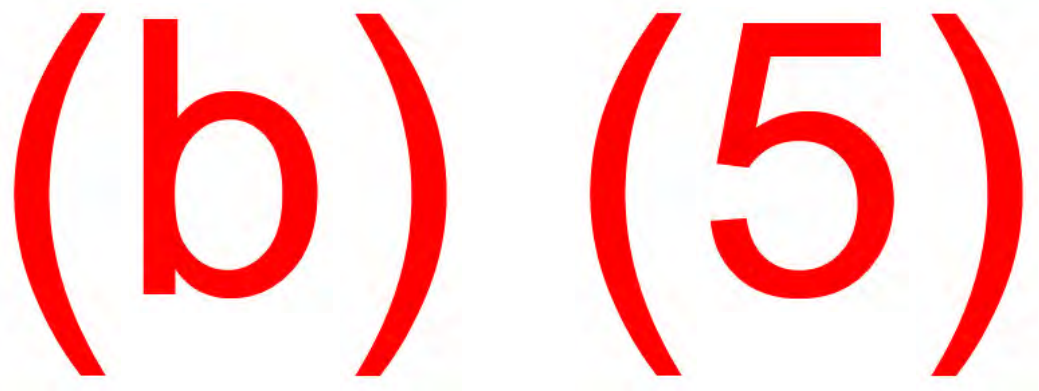

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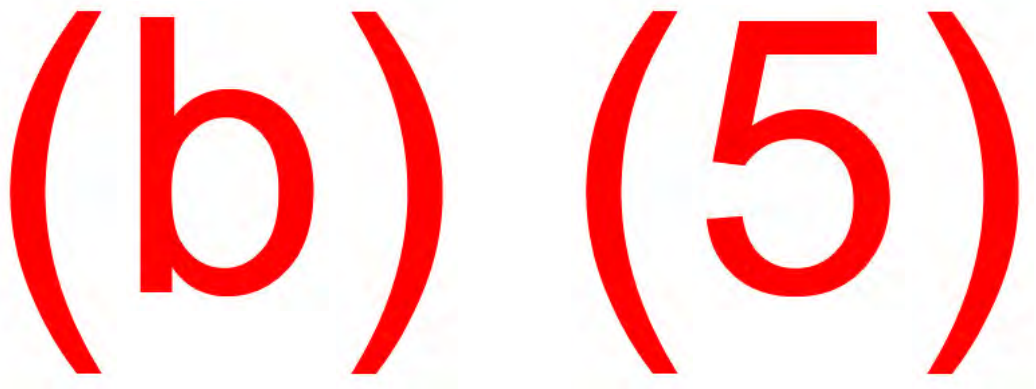

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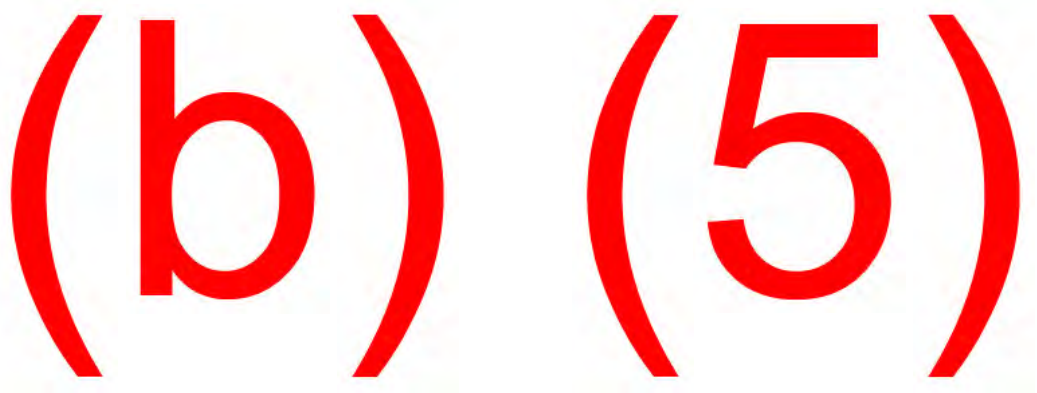
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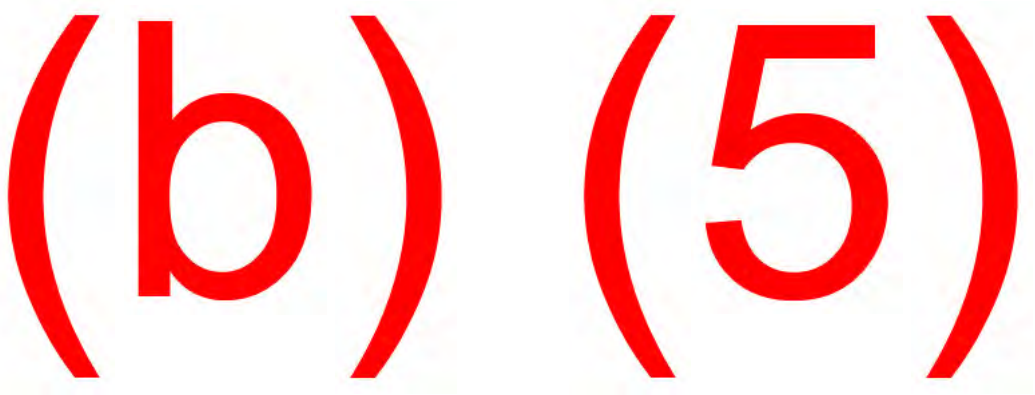

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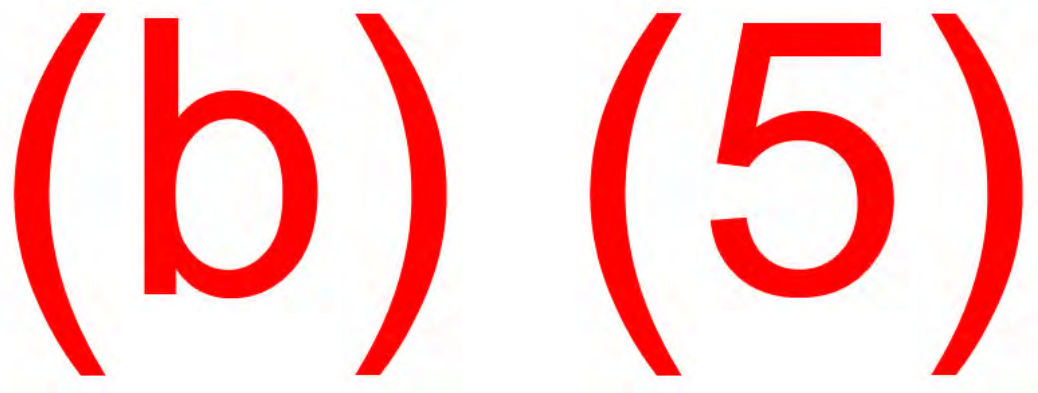

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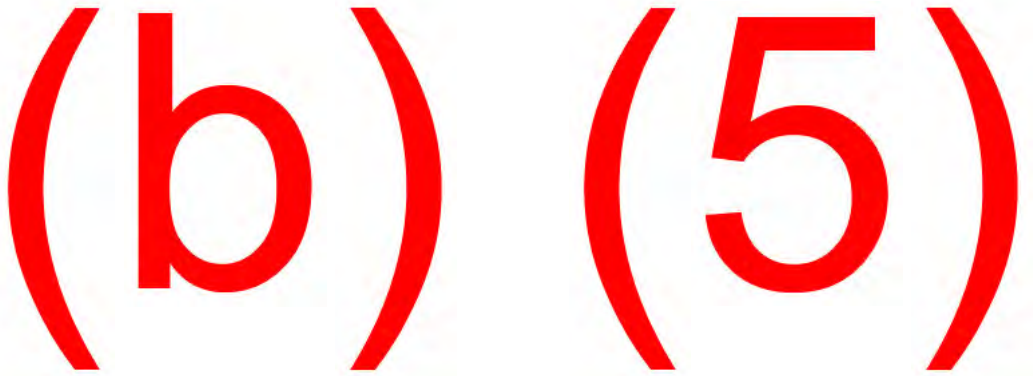

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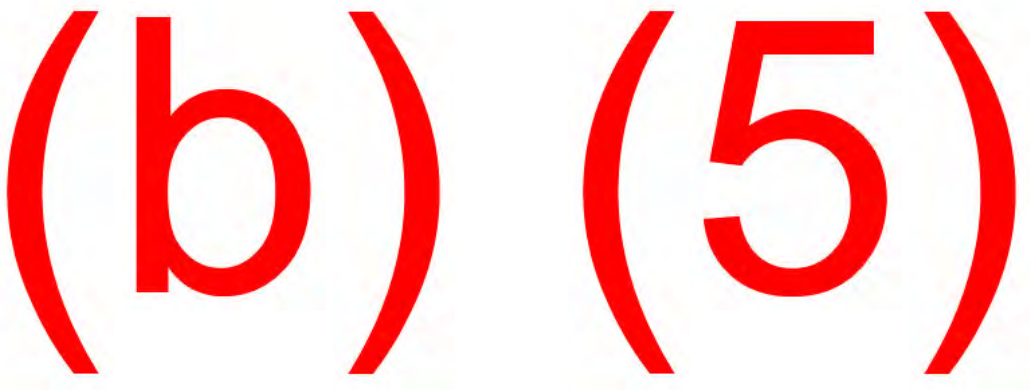

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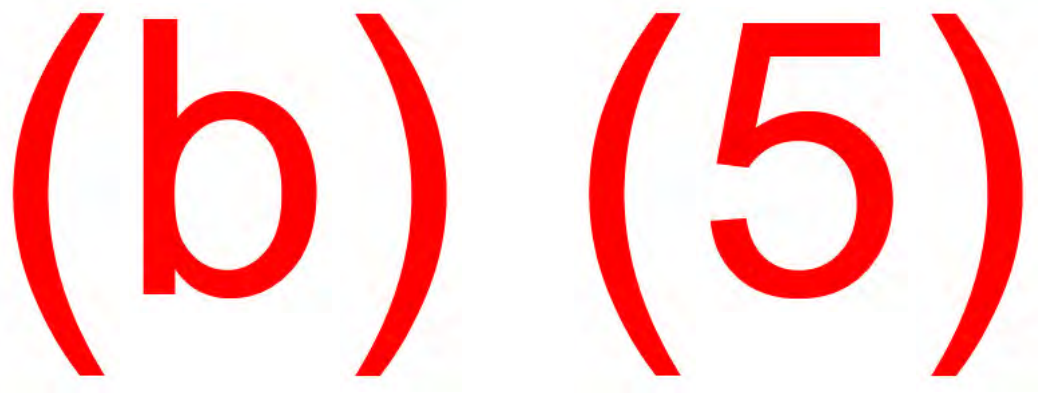

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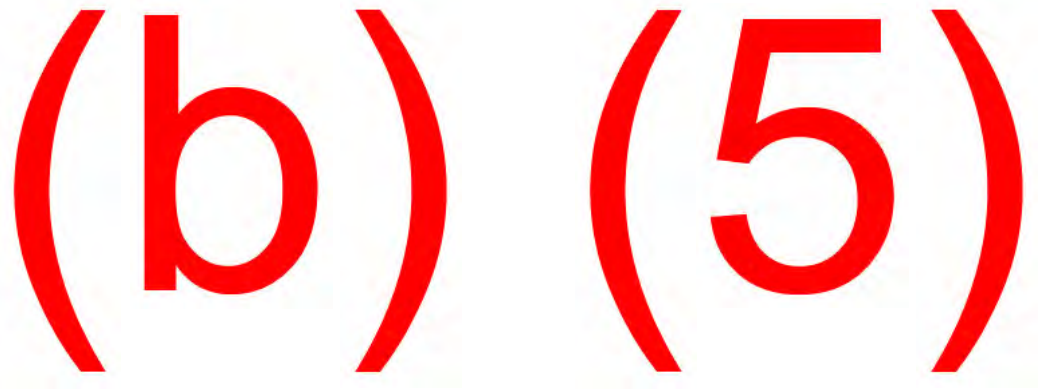

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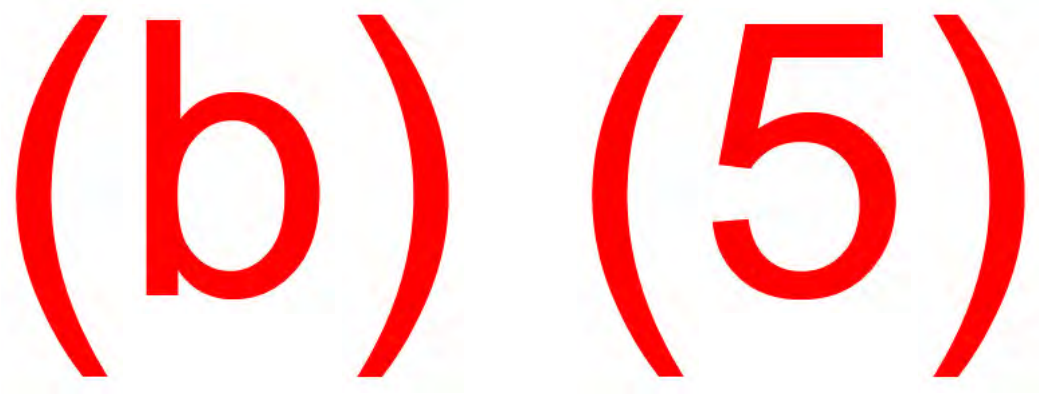

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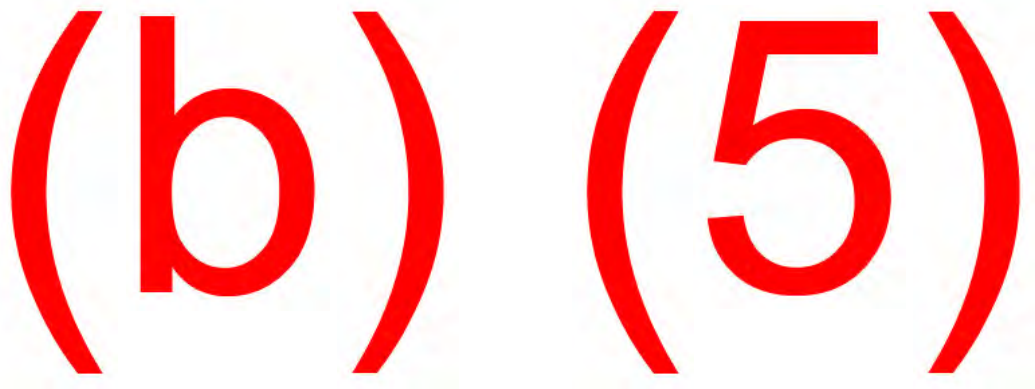
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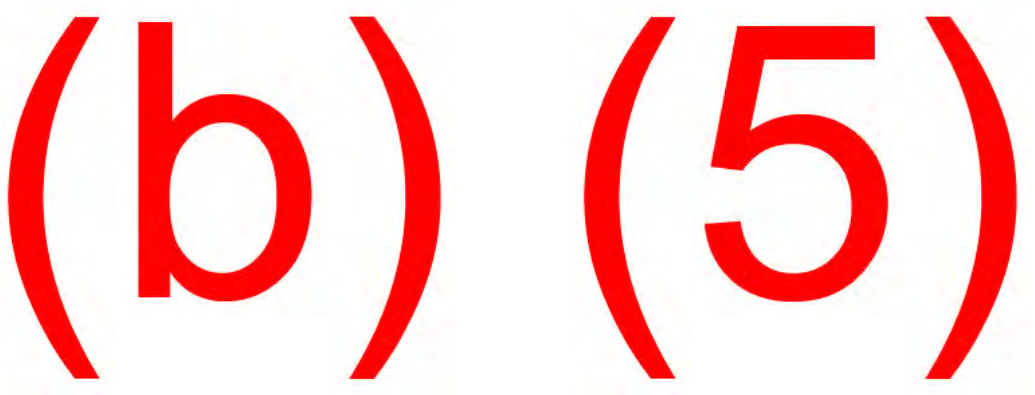
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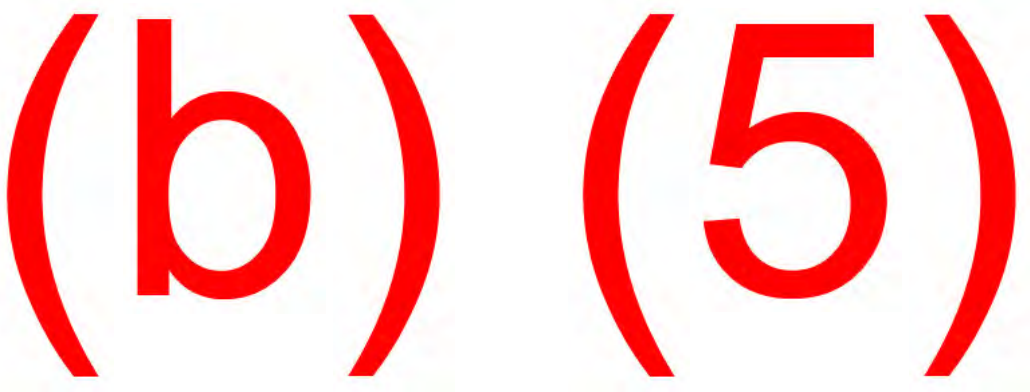

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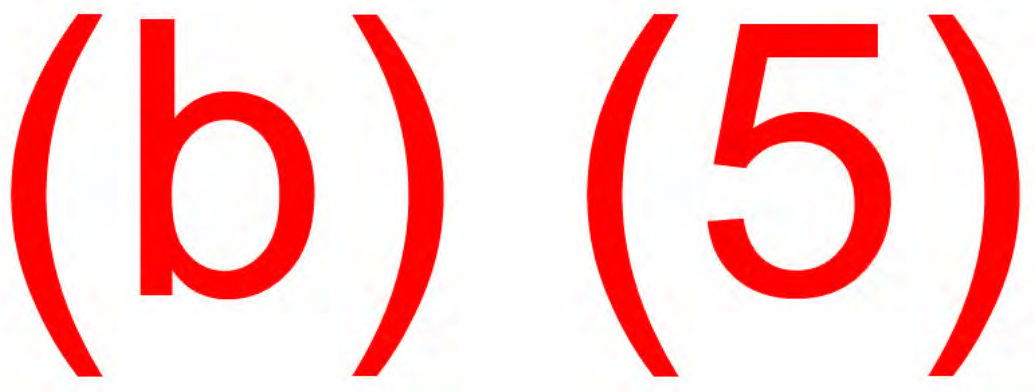
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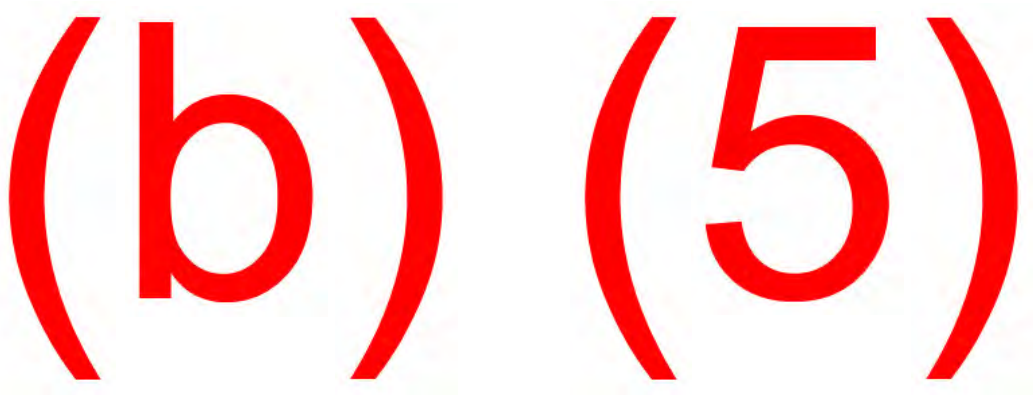

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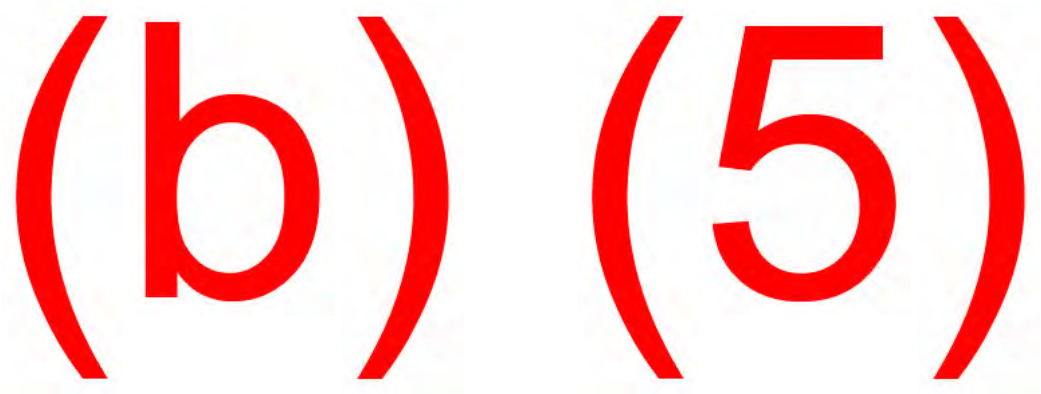
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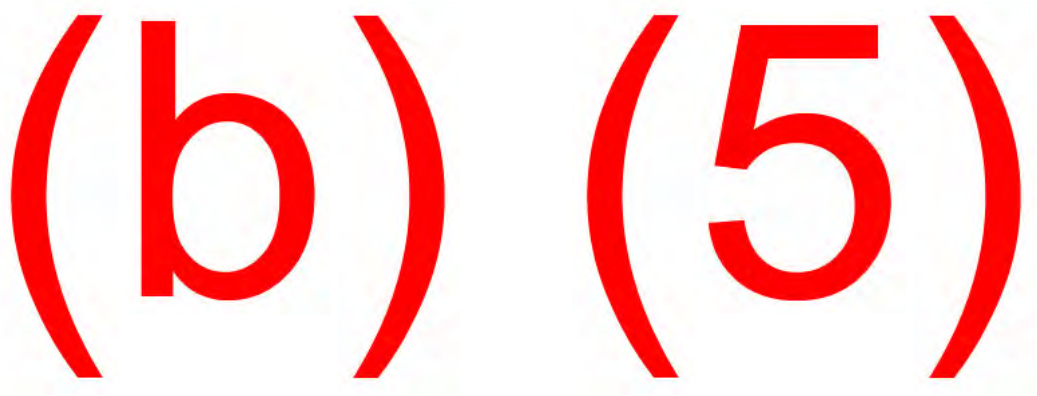

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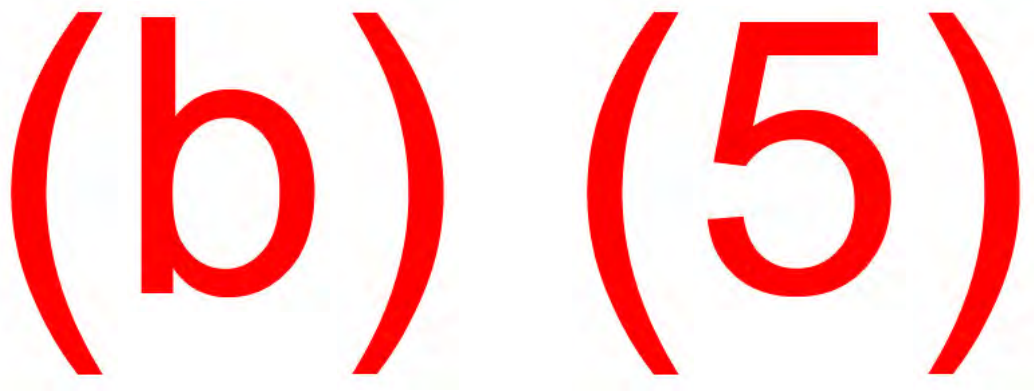
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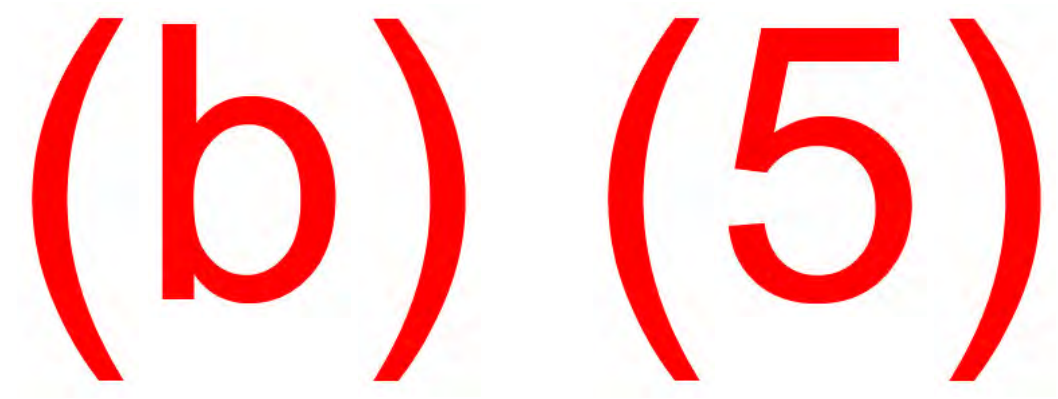

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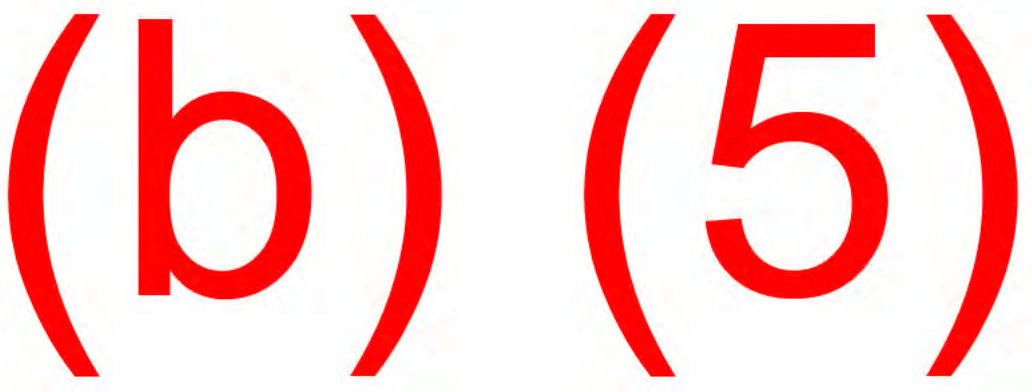

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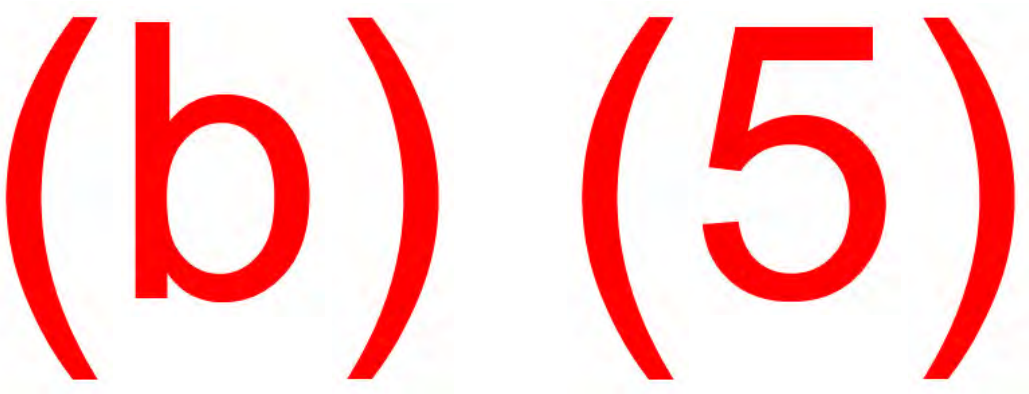

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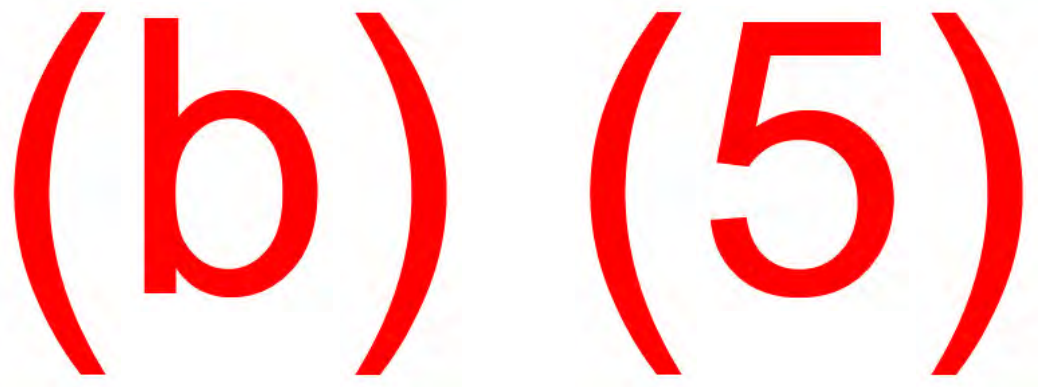

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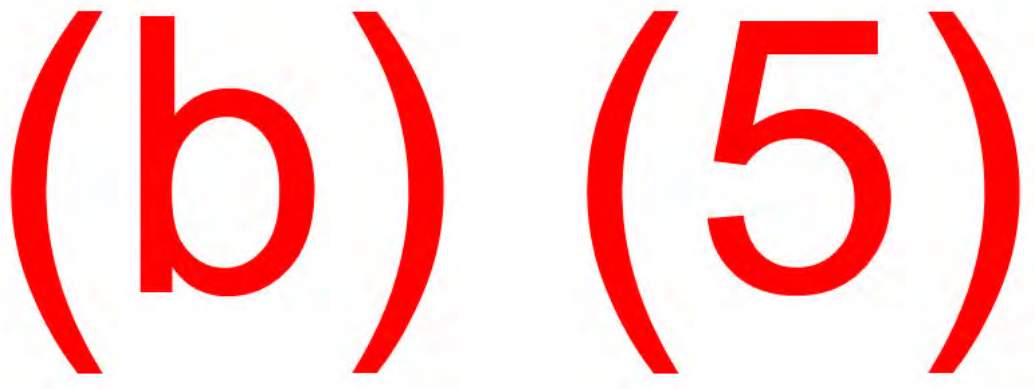
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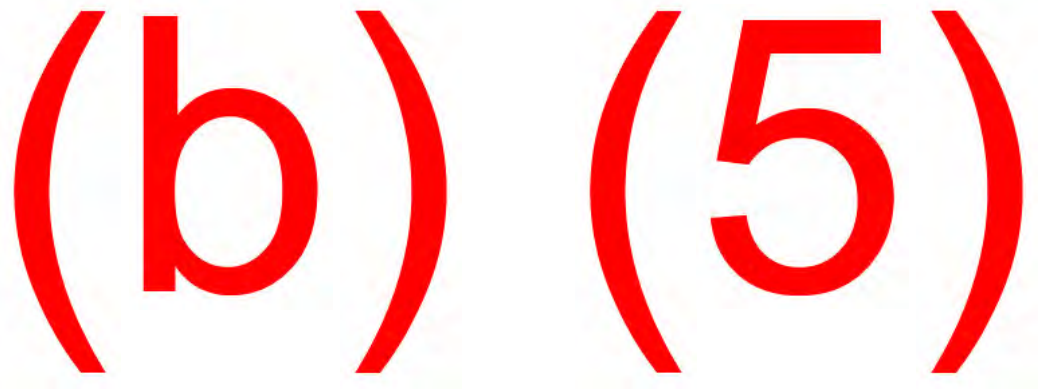
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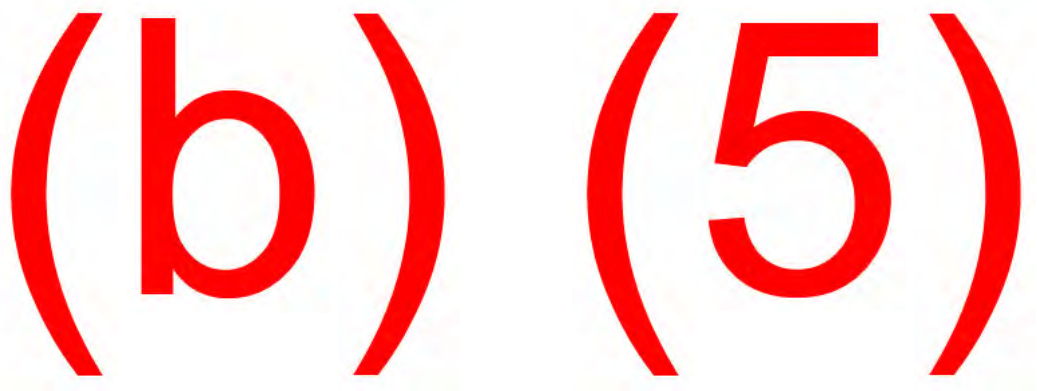
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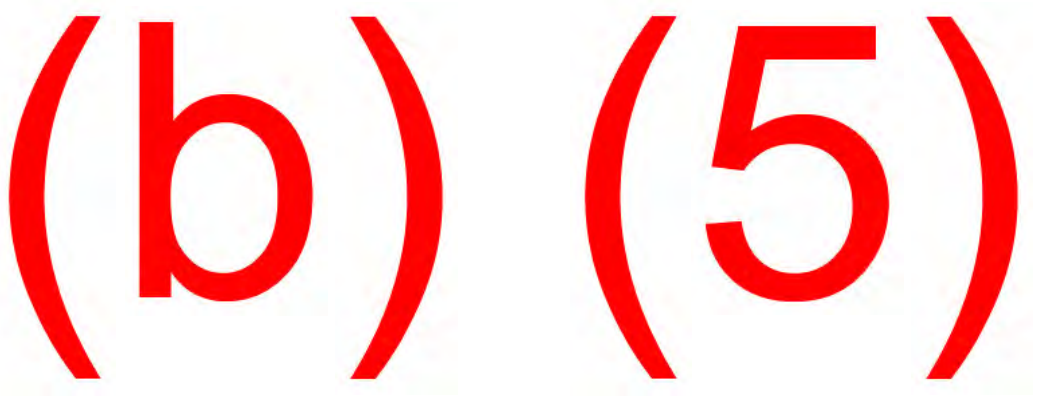

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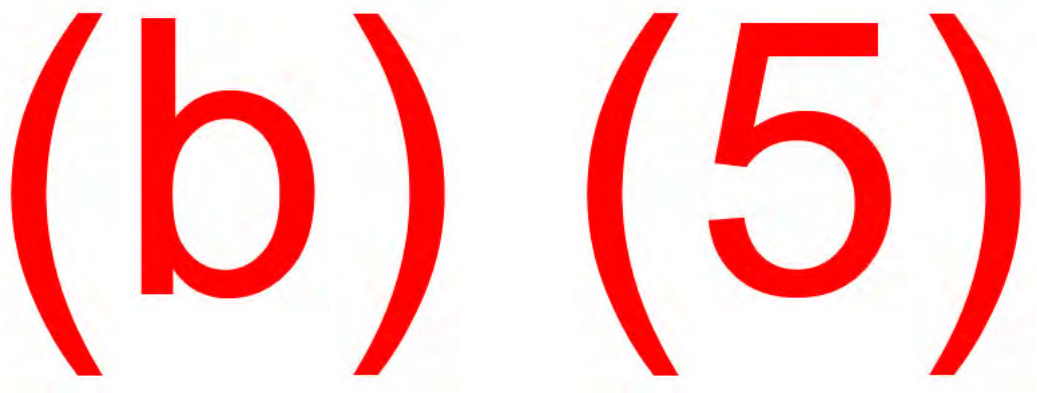

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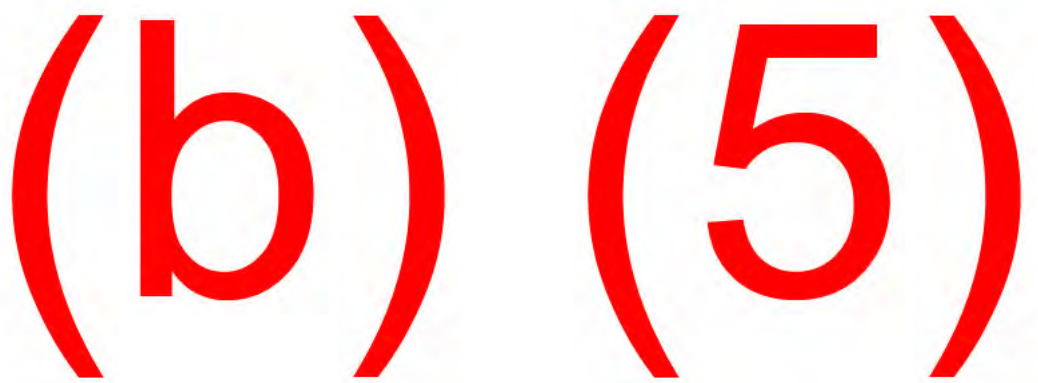

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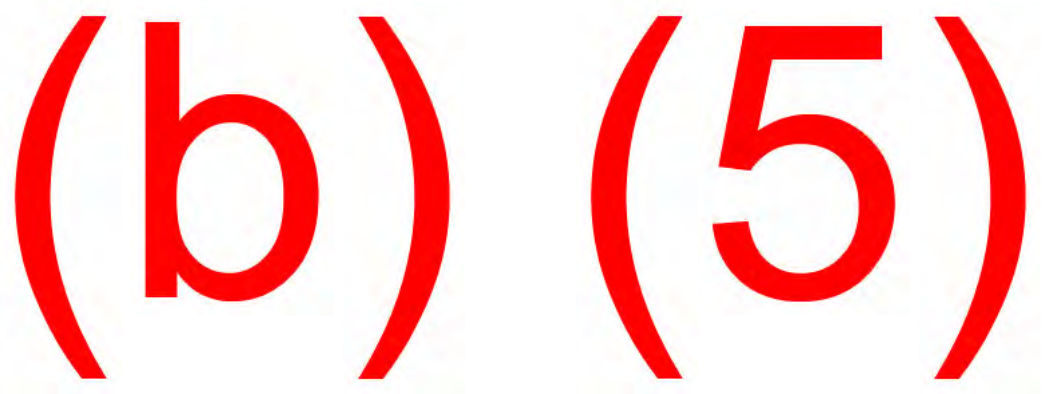
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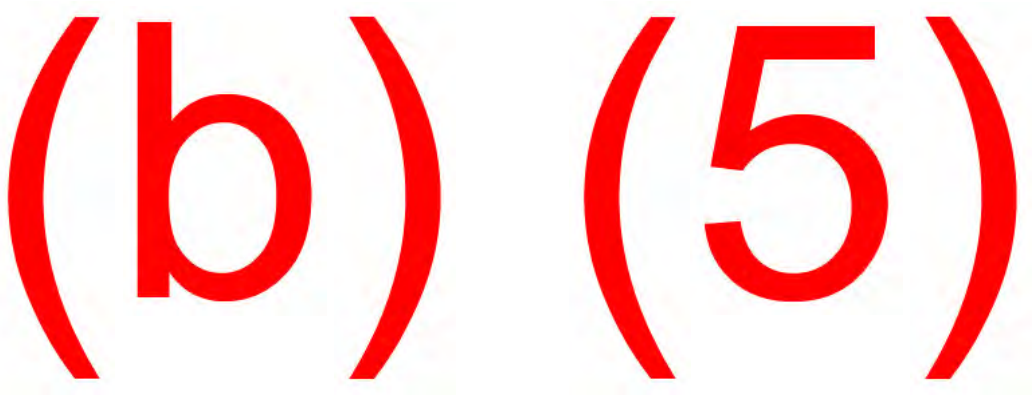
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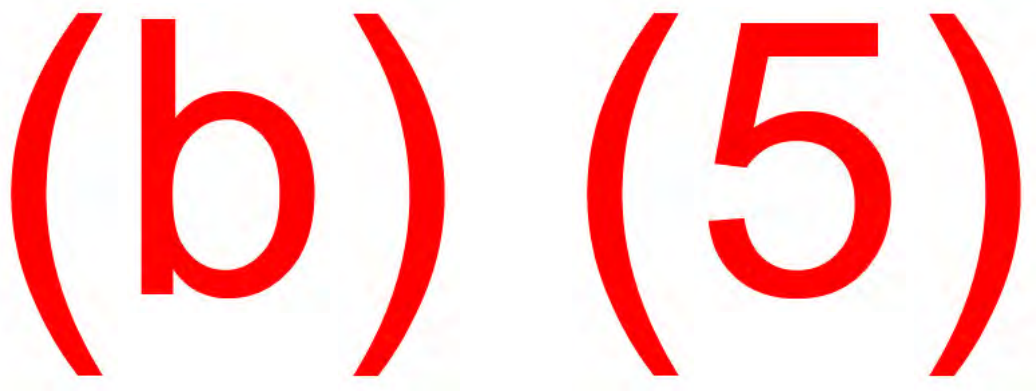

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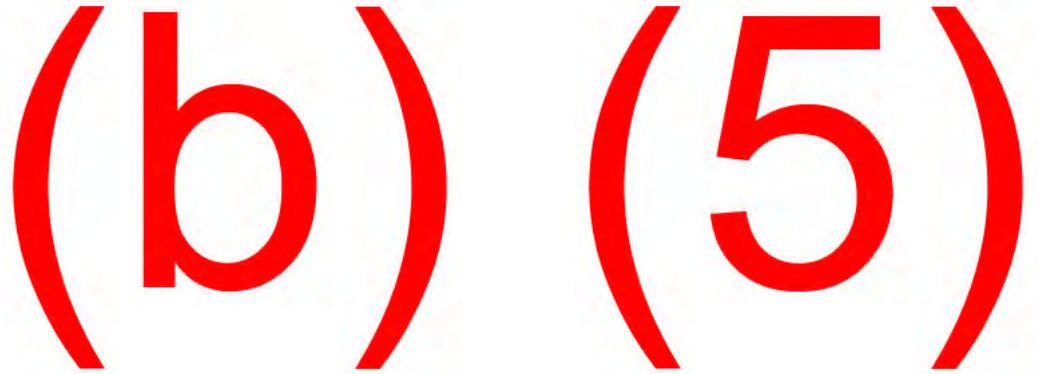

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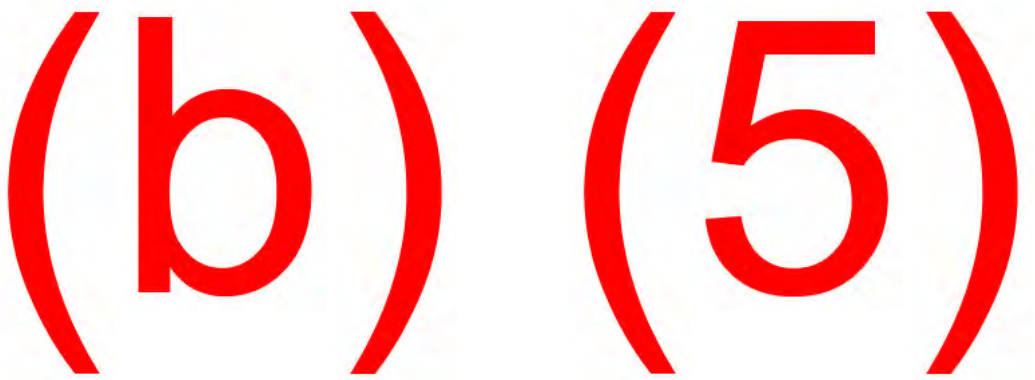

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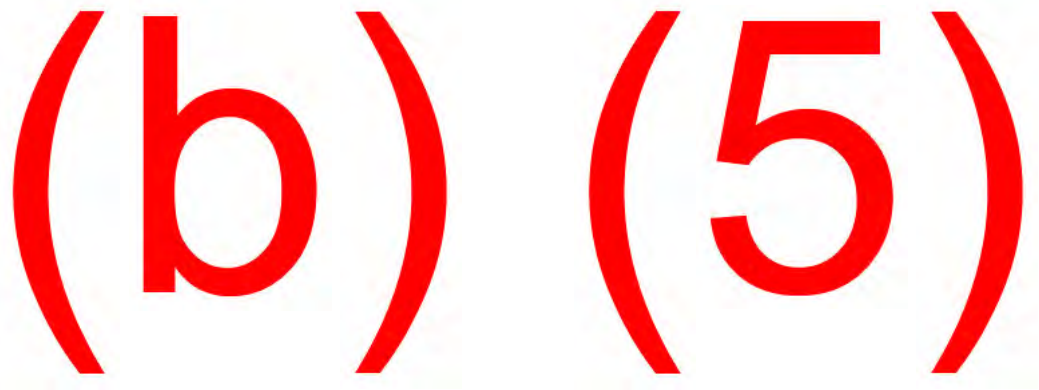

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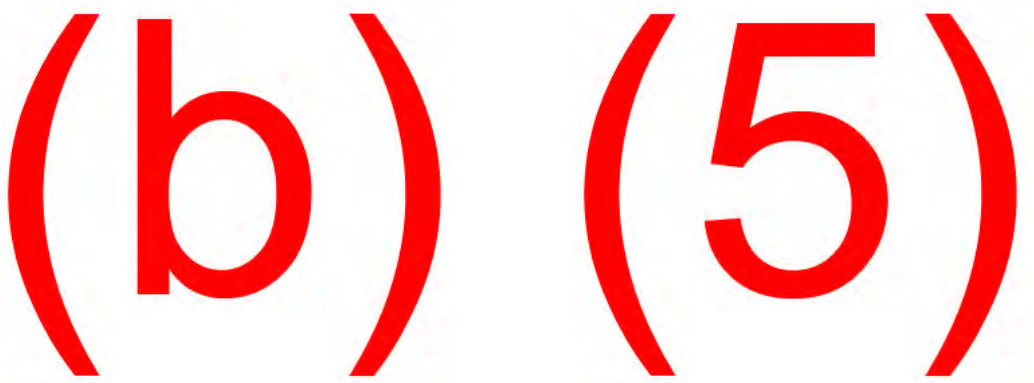

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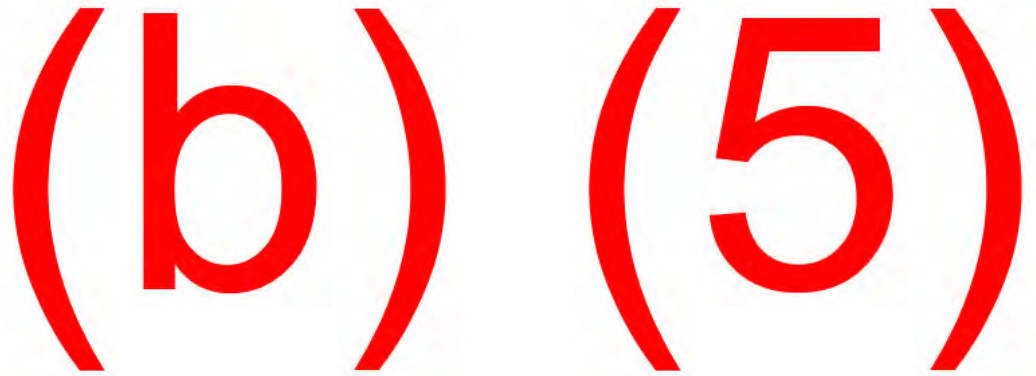

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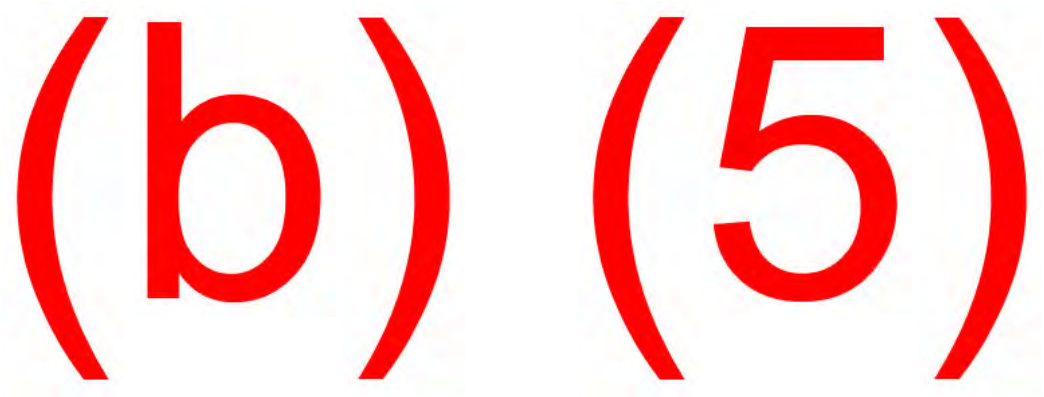

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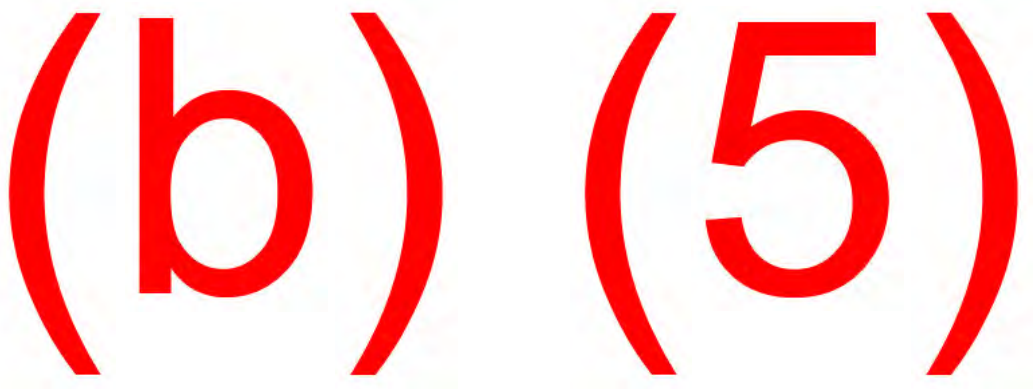

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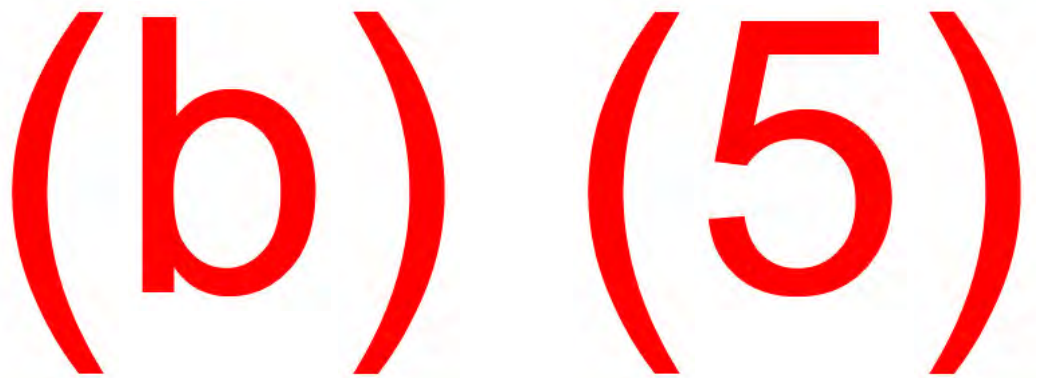

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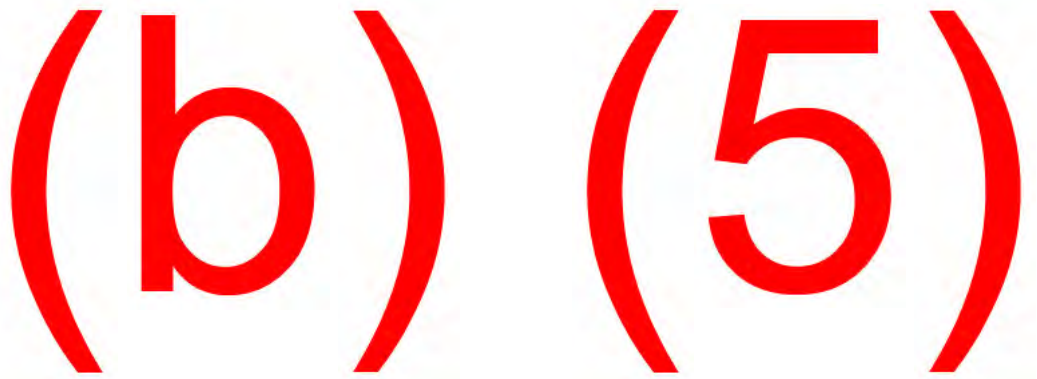
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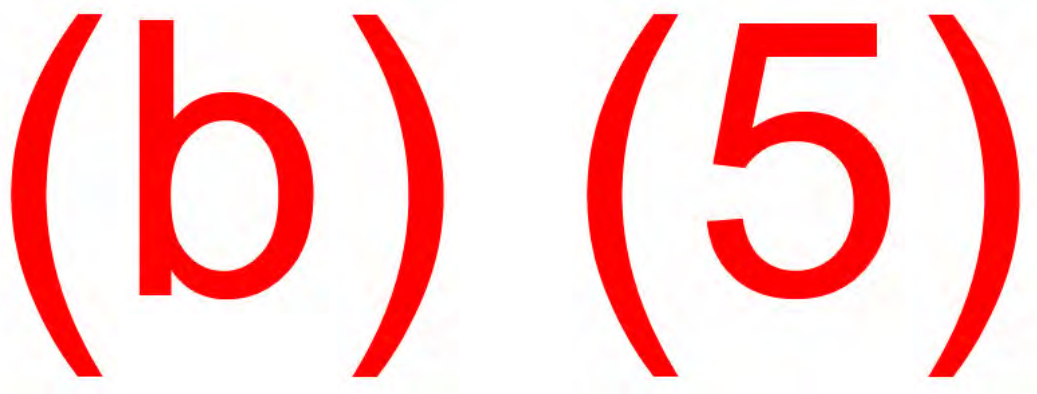

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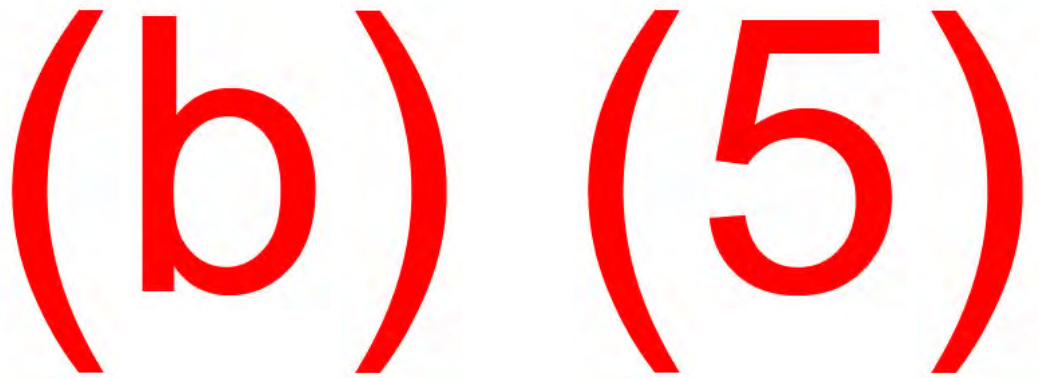

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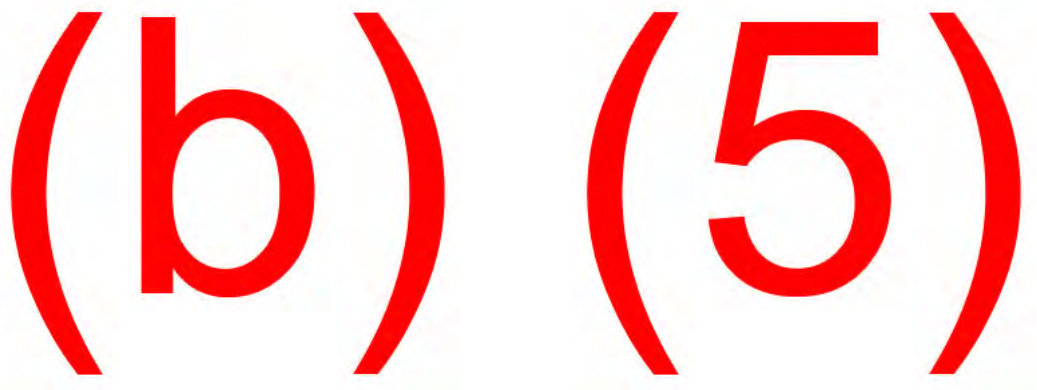

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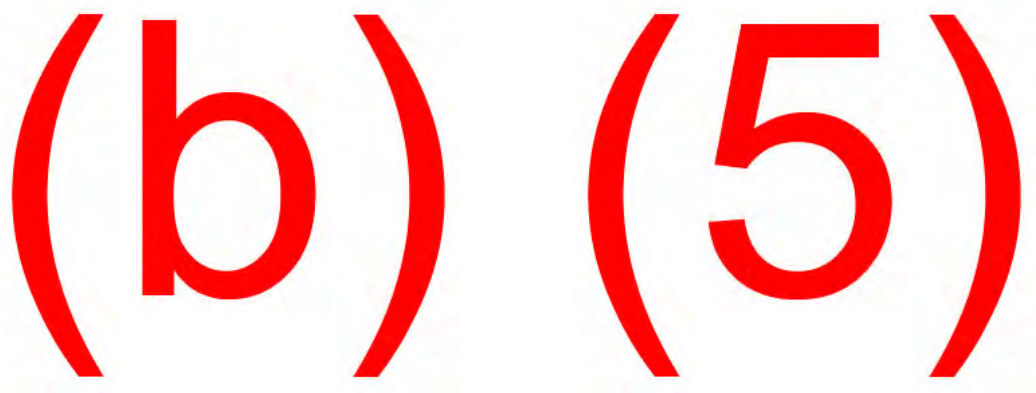

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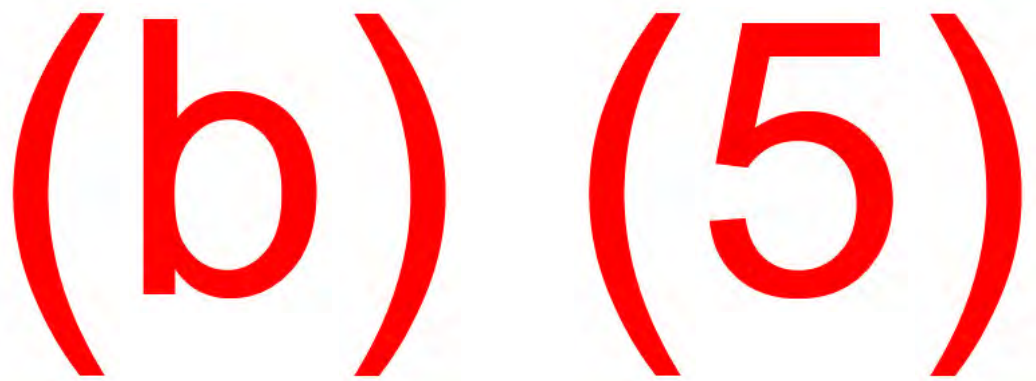

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Office of the Secretary

2021