Team Zaffre
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Section 2 - Background -Statutory, Regulatory, Litigation, and Notice/Guidance History

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0001
All Sections: 2 ,
(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:
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 of 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 marginalized identities can shape an individual's life course.

Comment Number: HHS-OS-2022-0012-DRAFT-35384-0001
All Sections: 2
(b)(5)

Organization: American College of Emergency Physicians

Excerpt Text:
As background, Section 1557 of the Affordable Care Act (ACA) prohibits discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity that receives federal financial assistance. In 2016, the U.S Department of Health and Human Services (HHS) finalized a regulation that defined "on the basis of sex" to include sex stereotyping, gender identity, and termination of pregnancy. However, in 2020, HHS removed gender identity and sexual orientation from the Section 1557 regulation. This proposed rule,

among other modifications to non-discrimination policies, proposes to revert back to the 2016 definition of "on the basis of sex," effectively rescinding the 2020 policy.

ACEP supports the rescission of the 2020 regulation. In 2019, ACEP and the Emergency Medicine Residents' Association (EMRA) issued a statement opposing the initial proposal to revise the regulation. ACEP stated that we strongly believe that discrimination in any form should be prohibited in health care. Both by law and by oath, emergency physicians must care for all patients seeking emergency medical treatment [Footnote 1: 42 U.S. Code § 1395dd - Examination and treatment for emergency medical conditions and women in labor]. Denial of emergency care or delay in providing emergency services on the basis of race, religion, sexual orientation, gender identity, ethnic background, social status, type of illness, or ability to pay, is unethical under our Code of Ethics as emergency physicians [Footnote 2: ACEP Code of Ethics for Emergency Physicians; Approved Jan 2017; https://www.acep.org/patient- care/policy-statements/code-of-ethics-for-emergency-physicians/].

Comment Number: HHS-OS-2022-0012-DRAFT-52236-0001
All Sections: 2
(b)(5)

Organization: Arkansas Department of Human Services

Excerpt Text:
The Department incorrectly interprets the U.S. Supreme Court's holding in Bostock v. Clayton County, 140 S. Ct. 1731 (2020) and improperly expands the scope of Section 1557 of the Affordable Care Act based on that incorrect interpretation. With the threat of losing federal healthcare funding, the Department attempts to coerce the states into adopting a federal policy that is contrary to their own law and policy.

Comment Number: HHS-OS-2022-0012-DRAFT-39385-0001
All Sections: 2
(b)(5)

Organization: American Hospital Association

Excerpt Text:
Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age or disability under any health program or activity that receives federal financial assistance, or under any program or activity that is administered by an executive agency or by an entity established under title I of the ACA (e.g., Health Insurance Marketplaces).

After the Department issued its second Section 1557 rule in June 2020, the AHA comments stated: "Hospitals and health systems value every individual we have the privilege of serving, regardless of race, religion, national origin, sexual orientation or gender identity. That is why we

urged the administration to not move forward with changes to non-discrimination protections. We are deeply disappointed that this rule weakens important protections for patients and could limit coverage. Treating all with dignity and respect will continue to guide us in everything we do."

Comment Number: HHS-OS-2022-0012-DRAFT-43142-0001
All Sections: 2

(b)(5)

Organization: American Psychological Association

Excerpt Text:
APA supported nondiscrimination protections in the ACA during the drafting process and consistently advocated for strong enforcement of Section 1557 since the law was enacted in 2010. We opposed the prior Administration's 2020 Section 1557 rule which undermined enforcement by rescinding substantial portions 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 identified and documented in comments submitted to the Department of Health and Human Services (HHS) in 2019 [Footnote 4: APA. (2019, August 19). Comment submitted to the U.S. Department of Health and Human Services Office for Civil Rights on Attention: Section 1557 NPRM, RIN 0495-AA11. Concerns documented included: limiting scope of coverage/applicability; eliminating regulatory provisions defining the prohibition on discrimination based on sex to include gender identity, sex stereotypes and pregnancy status; eliminating the provision preventing health insurers from varying benefits in ways that discriminate against certain groups; eliminating specific health insurance coverage protections for transgender individuals; weakening protections that provide access to interpretation and translation services for individuals with limited English proficiency; deleting or weakening sections of the current regulations prohibiting discrimination against people with disabilities; and adopting extremely broad religious freedom and conscience exemptions for health care providers]. The new proposed rule strengthens civil rights protections for patients and consumers in federally funded health programs and HHS programs. It affirms protections against discrimination on the basis of sex, including sexual orientation and gender identity consistent with the U.S. Supreme Court's holding in Bostock v. Clayton County, and reiterates protections from discrimination for seeking reproductive health care services. It requires covered entities to train staff in providing language assistance services for individuals with limited English proficiency (LEP), and effective communication and reasonable modifications to policies and procedures for people with disabilities.

Comment Number: HHS-OS-2022-0012-DRAFT-40175-0001
All Sections: 2

(b)(5)

Organization: California Department of Health Care Services

Excerpt Text:
[Bold/italics: Previous ACA 1557 Rulemakings and Existing California Law on Nondiscrimination in Public Programs]

DHCS, as the single state Medicaid agency for California, submitted comments in response to the 2019 Proposed Rule (84 Fed. Reg. 27846), which was finalized without substantive change in the 2020 Final Rule (85 Fed. Reg. 37160). To summarize, DHCS and its partners expressed concern with the rollback of federal nondiscrimination safeguards for historically marginalized and underserved populations, including those who are transgender, those with limited English proficiency (LEP), those with disabilities, and those seeking access to reproductive health care. Of particular concern was the narrow definition of discrimination on the basis of sex that excluded gender identity and sexual orientation, and the removal of the tagline and language access requirements for LEP individuals. This overly narrow framework presented several consequences for California's health care system and programs, including: the potential for wide-scale impediments to accessing care for some of our most vulnerable residents; the chilling effect on beneficiaries seeking, and health care professionals providing or referring for, essential health care services, particularly those of a sensitive nature like reproductive health; and the negative fiscal impacts borne by states and their systems as a result of health complications stemming from delayed or foregone care, the increased costs and reliance on state-funded programs to fill in and mitigate such gaps, and the potential jeopardizing of sizable federal financial participation where states exceeded these minimums in a manner that could be interpreted to conflict with federal law. Finally, in addition to the harms highlighted above, the 2019 and 2020 rulemakings presented serious legal flaws in the manner in which they were promulgated under the Administrative Procedure Act, and their departure from and inconsistency with the underlying federal statutes being implemented. Specifically, these rulemakings evinced an exceedingly narrow interpretation limited to the physiological distinction between male and female, in contravention to established precedent.

Despite the finalization of the 2020 rule, CalHHS and DHCS reiterated their commitments to abide by and further the higher standards for nondiscrimination and equitable access to public benefits embodied under California law, despite the relatively low, and in our view inadequate, federal floor included in the 2020 Final Rule. California statute prohibits any person from being unlawfully denied full and equal access to benefits of, or from being subjected to unlawful discrimination under, any program or activity funded directly or indirectly by the State on the basis of several enumerated classifications. [Footnote 1: California Government Code section 11135, subdivision (a).] This includes denial or discrimination on the basis of: sex, race, color, religion, ancestry, national origin, ethnic group identification, age, mental disability, physical disability, medical condition, genetic information, marital status, or sexual orientation. Of particular note for the immediate NPRM, these heightened protections for discrimination or denial on the basis of sex already extend in California to:

(1) Marital, parental, or family status; [Footnote 2: Id.]

(2) Sexual orientation; [Footnote 3: Id. See, also, California Government Code section 12926, subdivision (s).]

(3) Pregnancy, childbirth, and breastfeeding, or medical conditions related to pregnancy, childbirth, or breastfeeding; [Footnote 4: California Government Code section 12926, subdivision (r)(1).] and

(4) A person's gender, including gender identity and gender expression. [Footnote 5: California Government Code section 12926, subdivision (r)(2).]

Existing California law also mandates that all protected bases, including those discussed above relating to sex, include a perception that a person has any of the enumerated characteristics or that the person is associated with someone who has, or is perceived to have, any such characteristics. [Footnote 6: California Government Code section 11135, subdivision (d).]

California also elected to codify the language and assistive services standards included in the 2016 Final Rule, despite the changes in the 2020 rulemaking to lessen or make these obligations more generalized. DHCS is required to notify Medi-Cal beneficiaries, prospective beneficiaries, and the general public of the availability of no-cost and timely language assistance services to individuals with LEP and appropriate auxiliary aids and services to individuals with disabilities, to facilitate meaningful access and equal opportunity to participate in Medi-Cal. [Footnote 7: California Welfare and Institutions Code section 14029.92, subdivision (a).] With respect to language assistance, written notice is required to be provided in English and in the top 15 languages spoken by LEP individuals in California. [Footnote 8: 8 California Welfare and Institutions Code section 14029.92, subdivision (b).] Within Medi-Cal managed care, the predominant delivery system utilized for Medicaid in California, plans are required to notify enrollees of the availability of no-cost and timely language assistance in those languages required for DHCS notices, alongside the requisite provision of oral interpretation services at key points of contact within 24 hours and in any language meeting numeric thresholds in a service area, and according to minimum qualification standards for interpreters. [Footnote 9: California Welfare and Institutions Code section 14029.91.]

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0001
All Sections: 4.3, 2

(b)(5)

Organization: Covered California

Excerpt Text:
Section 1557 of the ACA explicitly prohibits discrimination on the basis of race, sex, 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 utilize 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 their 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 buildings and services.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0001
All Sections: 2
(b)(5)
Organization: The Heritage Foundation

Excerpt Text:
[Bold: 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 their 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 are similar, 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 N. Morrison, "HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate in 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0001
All Sections: 2

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[Bold: I. BACKGROUND]

Congress enacted the ACA to expand access to healthcare, 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 included 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 in underserved communities, and leads to

ineffective distribution of healthcare resources. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376, 31,444 (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 31,467 (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, and pregnancy-related conditions, id.; (c) specifying covered entities' obligations to transgender individuals, id. at 31,471-72 (codified at 45 C.F.R. §§ 92.206, 92.207); (d) establishing detailed language access requirements to ensure nondiscriminatory access to health services for people of all national origins, including those with LEP, id. at 31,410-11 (codified at 45 C.F.R. § 92.201); and (e) establishing a uniform enforcement scheme for all forms of discrimination prohibited by the statute, id. at 31,439-40.

Although the 2016 Rule unquestionably improved access to healthcare services and programs by vulnerable groups, HHS reversed course just three years later and adopted a new rule that, contrary to the text of the ACA, attempted to undermine many of Section 1557's core protections. In particular, the 2020 Rule arbitrarily and unlawfully stripped healthcare rights statutorily guaranteed by Section 1557 from transgender people, women and other individuals seeking reproductive healthcare or with pregnancy-related conditions, LEP individuals, individuals with disabilities, and other individuals experiencing discrimination. Remarkably, HHS published the 2020 Rule in the midst of the COVID-19 pandemic and just days after the Supreme Court confirmed in Bostock that the prohibition on sex discrimination under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., prohibits discrimination based on sexual orientation or transgender status. The 2020 Rule ignored Bostock, redefined discrimination "on the basis of sex" to exclude express regulatory protections against gender identity discrimination, removed the specific protections for transgender people contained in the 2016 Rule, and struck the express prohibitions on sexual orientation and gender identity discrimination from other HHS regulations.

Furthermore, the 2020 Rule, without sufficient justification, redefined covered "health program or activity" to newly exclude many health insurers not "principally engaged in the business of providing healthcare." 85 Fed. Reg. at 37,244. This redefinition conflicted with the statute by arbitrarily and narrowly defining "healthcare" to exclude health insurance, thus removing many private employer-based plans, Medicare Part B providers, and the Federal Employee Health Benefits program from the Rule's scope. The 2020 Rule also gutted the 2016 Rule's language access provisions, and sowed unnecessary confusion by deleting the uniform Section 1557 enforcement standards contained in the 2016 Rule. Finally, the 2020 Rule created a broad religious exemption that had no statutory basis in Section 1557 and gave religiously affiliated providers and insurers license to deny care and coverage for discriminatory reasons.

Myriad lawsuits were quickly filed to enjoin the 2020 Rule based on its arbitrary and unlawful revisions to the 2016 Rule. Several States challenged the 2020 Rule in [Italics: New York v U.S. Department of Health & Human Services,] which is currently stayed pending rulemaking. Two

other cases—[Italics: Whitman-Walker Clinic v. HHS] and [Italics: Walker v. Azar]—resulted in nationwide preliminary injunctions that enjoined various parts of the rule. [Footnote 6: Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs., 485 F. Supp. 3d 1 (D.D.C. 2020) (enjoining enforcement of the repeal of the 2016 Rule's definition of discrimination "[o]n the basis of sex" insofar as it includes "discrimination on the basis of . . . sex stereotyping) and enforcement of the incorporation of Title IX's religious exemptions); Walker v. Azar, 480 F. Supp. 3d 417 (E.D.N.Y. 2020) (enjoining enforcement of the repeal of the definition of discrimination on the basis of sex). Both cases are stayed pending rulemaking.] In a fourth lawsuit—[Italics: Boston Alliance of Gay, Lesbian, & Bisexual Youth (BAGLY) v. HHS]—a federal district court denied the federal government's motion to dismiss claims related to the incorporation of Title IX's abortion exemption, the narrowing of the scope of covered entities, and the elimination on categorical coverage exclusions for gender affirming care. [Footnote 7: Boston Alliance of Gay, Lesbian, Bisexual and Transgender Youth (BAGLY) v. U.S. Dep't of Health & Human Servs., 557 F. Supp. 3d 224 (D. Mass. 2021)(stayed pending rulemaking).] And a fifth suit has also been filed specifically challenging the 2020 Rule's rollback of the LEP provisions in the 2016 Rule. [Footnote 8: Chinatown Serv. Center v. U.S. Dep't of Health & Human Servs., No. 21-331 (JEB), 2021 WL 8316490 at *3 (D.D.C. filed on Feb 5, 2021) (stayed pending rulemaking).]

Comment Number: HHS-OS-2022-0012-DRAFT-69547-0001
All Sections: 2

(b)(5)

Organization: Congressman Mike Quigley

Excerpt Text:
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 in 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 LGBTQI+ individuals face in particular, the same 1557 protections should apply to other individuals who also face discrimination in accessing AR services.

Comment Number: HHS-OS-2022-0012-DRAFT-67830-0001
All Sections: 2

(b)(5)

Organization: U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Excerpt Text:
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 while receiving health care services.

Simultaneously, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0001
All Sections: 2

(b)(5)

Organization: Concerned Women for America

Excerpt Text:
Under your leadership, the Department and this Administration are losing in court on 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 [Italics: Religious Sisters of Mercy et al. v. Becerra et al., Franciscan All., 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 disregarding our concerns in order to appease some small, radical supporters.

Thumbing your nose at the court only underscores this Rule is nothing short of an executive power grab. Like the illegitimate 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 [Italics: 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.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0001
All Sections: 2
(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
The Patient Protection and Affordable Care Act's core purpose was to protect patients and ensure patient access to affordable health care. The Section 1557 nondiscrimination policy clearly embodied this core purpose by protecting patients from discrimination in accordance with multiple different Civil Rights laws dating back decades, including protections based on race, sex, age, and disability. In addition, the statute created an administrative remedy through the Office of Civil Rights for patients who faced discrimination. As a result, in 2016 HHS promulgated regulations ("the Initial Rule") interpreting and implementing this nondiscrimination policy to clarify and ensure uniform application of the ACA's promise.

In 2019, the Department published revised regulations ("Current Rule") that failed to uphold the vision and promise of the law. Rather, the Current Rule attempts to undermine Section 1557 by mis-stating the law, and creating confusion on a question that has been consistently decided by courts for over two decades. While the Department then claimed that the change would prevent confusion by removing the definitions and clarifying regulations for the coverage of gender identity, the wholesale removal of definitions and clarifications in fact have the opposite effect and impact on implementation and access. The vague rule fostered deep uncertainty and confusion among patients and providers. It undermined the core mission of nondiscrimination provisions generally – which is to create a universal threshold of security for vulnerable populations so that they will have access to the care they need free from harassment, intimidation, or unwarranted refusal. In the absence of these explicit protections, many patients avoid seeking care altogether.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0011
All Sections: 4.3.1.2.5, 4.3.1.2.4, 2
(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
[Italics: D. Impact of Discrimination on LGBTQ+ People.]

Discrimination in healthcare settings remains a significant problem for LGBTQ+ individuals. Such discrimination adversely affects the mental and physical health of LGBTQ+ individuals and engenders the individuals' avoidance behavior, delays, or denials of care. [Footnote 9: Caroline Medina & Lindsay Mahowald, Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities, (Sept. 8, 2022), https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/.] In 2021, roughly ten percent of the LGBTQ+ survey respondents reported experiencing refusals of care by doctors and other healthcare providers. [Footnote 10: Id.] Finally, such discrimination deters LGBTQ+ people from seeking care. The 2021 survey revealed that LGBTQ+ individuals were three times more likely to postpone or avoid healthcare due to discrimination by providers than non-LGBTQ+ individuals. [Footnote 11: Id.]

Under the current iteration of the rule, LGBTQ+ individuals are more likely to avoid seeking medical care out of fear of discrimination. [Footnote 12: See, Shabab Ahmen Mirza & Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care, Ctr. for Am. Progress (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.] For example, thirty percent of LGBTQ+ Americans reported difficulty accessing healthcare services and fifteen percent reported postponing or foregoing healthcare services due to the current rule. [Footnote 13: Sharita Gruberg et al, The State of the LGBTQ Community in 2020, Ctr. for Am. Progress (Oct. 6, 2020), https://www.americanprogress.org/article/state-lgbtq-community-2020/.] This inability to access healthcare flies directly in the face of the spirit and intent of the [Italics: Patient Protection] and Affordable Care Act, specifically Section 1557: "[A]n individual shall not, on the ground prohibited under [various Civil Rights laws], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity." [Footnote 14: 111 P.L. 148, Sec. 1557.]

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0012
All Sections: 2

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
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]qual access for all individuals without discrimination is essential to achieving this goal." 81 Fed. Reg. 31,379, 31,444. HHS expressly acknowledged the seriousness of continuing discrimination against LGBTQ individuals and the healthcare disparities caused by discrimination. Id. at 31,460. Accordingly, 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 31,471–72. Further, if an insurance company covers a particular treatment of 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 their gender identity. Id. at 31,435.

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 200,000 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 40–41, 64; Walker, 480 F. Supp. 3d at 429–30.]

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0013
All Sections: 4.3.1.1, 2

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
[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 antidiscrimination 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 recommend 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0015
All Sections: 4.3.1.2.5, 4.3.1.2.6, 2
(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[Bold: a. Impacts on Transgender Youth]

LGBTQ youth are especially vulnerable. 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/PMC5478215.] 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/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 M. 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 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: Ximena 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 social support and gender-affirming healthcare experience mental health outcomes equivalent to their cisgender peers. [Footnote 29: Dominic J. Gibson et al., Evaluation of Anxiety and Depression in a Community Sample of Transgender Youth, 4(4) J. Am. Med. Ass'n Open 1, 1–2 (Apr. 7, 2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2778206 (finding no significant group differences in self and parent reported depressive and anxiety symptoms among "socially transitioned transgender youth, their siblings, and age- and gender-matched control participants"); Lily Durwood et al., Social Support and Internalizing Psychopathology in Transgender Youth, 50 J. of Youth and Adolescence 841 (2021), https://link.springer.com/article/10.1007%2Fs10964-020-01391-y ("Parents who reported higher levels of family, peer, and school support for their child's gender identity also reported fewer internalizing symptoms."); Kristina R Olson et al., Mental Health of Transgender Children Who Are Supported in Their Identities, 137(3) Pediatrics 1, 1 (2016), https://pubmed.ncbi.nlm.nih.gov/26921285 (similar); Anna I. R. van der Miesen et al., Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender General Population Peers, 66 J. Adolescent Health 699, 703 (2020), https://pubmed.ncbi.nlm.nih.gov/32273193 (similar); see also Jack L. Turban et al., Access To Gender- Affirming Hormones During Adolescence and Mental Health Outcomes Among Transgender Adults 17 PLOS One 1, 8 (2022), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0261039 (access to gender-affirming hormones during adolescence was associated with lower rates of past-month severe psychological distress, past-year suicidal ideation, past month binge drinking, and lifetime illicit drug use when compared to access to gender-affirming hormones during adulthood).] And for teens under the age of eighteen, use of gender-affirming hormone therapy was associated with 39% lower odds of recent depression and 38% lower odds of attempting suicide compared to adolescents who wanted, but did not receive, such therapy. [Footnote 30: Amy E. Green et al., Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth, 70 J. Adolescent Health 643, 647–48 (2022), https://doi.org/10.1016/j.jadohealth.2021.10.036; see also Diana M. Tordoff, et al., Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care, 5 J. Am. Med. Ass'n Network Open 1, 1 (2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789423 (access to gender affirming care associated with improved mental health outcomes in youths).] Adolescents who begin gender-affirming treatment at later stages of puberty are over five times more likely to have been diagnosed with depression and over four times more likely to have anxiety disorders than adolescents who seek treatment in early puberty. [Footnote 31: Julia C. Sorbara et al., Mental Health and Timing of Gender-Affirming Care, 146 Pediatrics 1, 5 (2020), https://publications.aap.org/pediatrics/article/146/4/e20193600/79683/Mental-Health-and-Timing- of-Gender-Affirming-Care.]

In addition to improved mental health outcomes, access to gender-affirming treatment improves overall well-being in transgender teenagers and young adults. A longitudinal study that followed transgender adolescents from their intake at a gender clinic into young adulthood found that gender-affirming treatment resulted in significant improvement in global functioning and psychological wellbeing. [Footnote 32: Annelou L.C. de Vries et al., Young Adult Psychological

Outcome After Puberty Suppression and Gender Reassignment, 134 Pediatrics 696, 702 (2014), https://doi.org/10.1542/peds.2013-2958.] The study reported that post-treatment, participants had "rates of clinical problems that are indistinguishable from general population samples," and that their life satisfaction, quality of life, and subjective happiness were comparable to their same-age cisgender peers. [Footnote 33: Id.] Another study found significant improvement in teens' self-worth and perceived physical appearance after starting hormone replacement therapy. [Footnote 34: Marijn Arnoldussen et al., Self-Perception of Transgender Adolescents After Gender-Affirming Treatment: A Follow-Up Study Into Young Adulthood, 9 LGBT Health 238 (2022), https://www.liebertpub.com/doi/epdf/10.1089/lgbt.2020.0494; see also Mona Ascha et al., Top Surgery and Chest Dysphoria Among Transmasculine and Nonbinary Adolescents and Young Adults, JAMA Pediatr. (forthcoming 2022), doi:10.1001/jamapediatrics.2022.3424 (reconstructive chest surgery associated with statistically significant improvement in chest dysphoria, gender congruence, and body image at three months follow-up).]

[Bold: b. Impacts on Transgender Elders]

LGBTQ elders are also particularly vulnerable to discrimination. In a survey of 2,560 LGBTQ older adults in the United States, nearly half of respondents were living at or below 200 percent of the federal poverty line. [Footnote 35: Karen I. Fredriksen-Goldsen et al., The Aging and Health Report: Disparities and Resilience Among Lesbian, Gay, Bisexual, and Transgender Older Adults Institute for Multigenerational Health 4 (2011), https://www.lgbtagingcenter.org/resources/pdfs/LGBT%20Aging%20and%20Health%20Report_final.pdf; see also Karen I. Fredriksen-Goldsen et al., Iridescent Life Course: LGBTQ Aging Research and Blueprint for the Future: A Systematic Review 65 Gerontology 253 (2019), https://pubmed.ncbi.nlm.nih.gov/30826811 (discussing state of literature).] More than one in ten LGBTQ older adults (13%) who participated in the project have been denied healthcare or provided with inferior care. [Footnote 36: Fredriksen-Goldsen et al. (2011), supra note 35, at 4.] Fifteen percent of LGBTQ older adults fear accessing healthcare outside the LGBTQ community, and 8% fear accessing healthcare inside the community. [Footnote 37: Id.] More than 21% of LGBTQ older adults have not revealed their sexual orientation or gender identity to their primary physician, and bisexual older women and men are less likely to disclose than lesbian and gay older adults. [Footnote 38: Id. at 4–5.]

Nationally, 40% of transgender seniors reported being denied healthcare or facing discrimination by healthcare providers. [Footnote 39: Id. at 31; see also Annie Snow et al., Barriers to Mental Health Care for Transgender and Gender-Nonconforming Adults: A Systematic Literature Review 44 Health & Social Work 149–55 (2019), https://pubmed.ncbi.nlm.nih.gov/31359065.] Transgender older adults are at significantly higher risk of poor physical health, disability, depressive symptomatology, and perceived stress, and suffer from fear of accessing health services, lack of physical activity, internalized stigma, victimization, and lack of social support. [Footnote 40: Karen I. Fredriksen-Goldsen et al., The Physical and Mental Health of Transgender Older Adults: An At-Risk and Underserved Population 54 The Gerontologist 488 (2014), https://pubmed.ncbi.nlm.nih.gov/23535500; see also Vanessa D. Fabbre & Eleni Gaveras, The Manifestation of Multilevel Stigma in the Lived Experiences of Transgender and Gender Nonconforming Older Adults 90 Am. J. of Orthopsychiatry 350 (2020), https://pubmed.ncbi.nlm.nih.gov/31971406; Kristen E. Porter et al., Providing Competent and

Affirming Services for Transgender and Gender Nonconforming Older Adults 39 Clinical Gerontologist 366 (2016), https://pubmed.ncbi.nlm.nih.gov/29471769 Charles P. Hoy-Ellis & Karen I. Fredriksen-Goldsen, Depression Among Transgender Older Adults: General and Minority Stress 59 Am. J. of Cmty. Psychology 295 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5474152.] Discrimination in a long-term care setting and the related anxiety anticipating it are associated with negative health outcomes. [Footnote 41: Jaclyn White Hughto & Sari Reisner, Social Context of Depressive Distress in Aging Transgender Adults 37 J. of Applied Gerontology 1517 (2018), https://pubmed.ncbi.nlm.nih.gov/28380703; see also Dagfinn Nåden et al., Aspects of Indignity in Nursing Home Residences as Experienced by Family Caregivers 20 Nursing Ethics 748 (2013), https://pubmed.ncbi.nlm.nih.gov/23462504.] At least one recent study has shown that LGBTQ older adults reported a higher likelihood of moving to a long-term care facility, as compared to heterosexual older adults. [Footnote 42: Mekiayla Singleton et al., Anticipated Need for Future Nursing Home Placement by Sexual Orientation: Early Findings from the Health and Retirement Study 19 Sexuality Research & Soc. Policy 656 (2022), https://doi.org/10.1007/s13178-021-00581-y.] A survey of LGBTQ elders and their families by Justice in Aging also found that 89% of respondents predicted that staff would discriminate against an openly LGBTQ elder. [Footnote 43: Justice in Aging, Stories from the Field: LGBT Older Adults in Long-Term Care Facilities 8 (2d. ed. 2015), https://www.justiceinaging.org/wp-content/uploads/2015/06/Stories-from-the-Field.pdf.] A majority also thought that other residents would discriminate (81%) and, more specifically, that other residents would isolate an LGBTQ resident (77%). [Footnote 44: Id.] More than half also predicted that staff would abuse or neglect the person (53%). [Footnote 45: Id.]

These facts demonstrate the need for robust LGBTQ protections under Section 1557 and the harm caused by the 2020 Rule's departure from proper statutory interpretation. "[T]he unmistakable basis for HHS's action was a rejection of the position taken in the 2016 Rules that sex discrimination includes discrimination based on gender identity and sex stereotyping." [Italics: Walker], 480 F. Supp. 3d at 430. "[W]hether by design or bureaucratic inertia, the fact remains that HHS finalized the 2020 Rules without addressing the impact of the Supreme Court's decision in [Italics: Bostock]." Id. Instead, the 2020 Rule drew "from the Government's losing litigating position in [Italics: Bostock]" to justify stripping away needed protections. [Italics: Whitman-Walker Clinic], 485 F. Supp. 3d at 41 (citing 85 Fed. Reg. at 37,178-79). Abundant evidence of harm, discrimination, and health disparities experienced by LGBTQ people demands reversal. It is critical for HHS to finalize rules restoring the correct interpretation of "sex discrimination" under Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0018
All Sections: 15.2, 2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:

[Bold: 3. The Proposed Rule's expansive definition of discrimination "on the basis 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 ground 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-EPPC President Ryan Anderson and now-EPPC 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 the time of its passage, there was no such medical concept as gender identity. The DSM-IV, in use in 2010, referred to the term as "gender identity disorder." Indeed, the Proposed Rule does not (and cannot) cite to any legislative history in support of its expanded definition of sex discrimination, making its claim that the proposal is consistent with Congressional intent arbitrary and capricious.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0018
All Sections: 4.3.1.2.2, 2

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
In promulgating the 2016 Rule, HHS recognized that national origin discrimination includes

discrimination based on the "linguistic characteristics of a national origin group." 81 Fed Reg. at 31,467, 470-71. HHS emphasized that Congress intended, through Section 1557, to find 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 2 (May 1, 2012), https://aspe.hhs.gov/sites/default/files/private/pdf/37346/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 31,410, HHS provided specific protections to guarantee meaningful access to healthcare for LEP individuals, id. at 31,470-71. [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 medication regimes, 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 31,459.] 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 eviscerated the "meaningful access" requirement. In doing so, HHS cited the financial and administrative burden associated with compliance, but ignored substantial evidence that this change would deny LEP individuals critical language assistance services and access to healthcare.

Comment Number: HHS-OS-2022-0012-DRAFT-35384-0002
All Sections: 2

(b)(5)

Organization: American College of Emergency Physicians

Excerpt Text:
We also expressed concerns in our official response to the 2020 regulation, when it was proposed in 2019, that the modifications the U.S. Department of Health and Human Services (HHS) were planning to make represented a direct conflict to the federally mandated provision of emergency services. The Emergency Medical Treatment and Labor Act (EMTALA) requires clinicians to screen and stabilize every patient who comes to the emergency department (ED). Such patients have every right to expect the best possible care and to receive the most appropriate treatment and information about their condition. Patients with life-threatening injuries or illnesses may not have time to wait to be referred to another physician or other health care professional to treat them if the present provider has a moral or religious objection. Likewise, EDs operate on tight budgets and do not have the staffing capacity to be able to have additional personnel on hand 24 hours a day, seven days a week to respond to different types of emergencies that might arise involving patients with different backgrounds including sexual orientations and gender identities.

The previous rule implied that to meet EMTALA requirements, an ED must have anticipated treating transgender patients, surveyed its employees to ascertain who might object treating such a patient, and staffed accordingly. This would be an impossible task that jeopardizes the ability to provide care, both for standard emergency department readiness and for emergency preparedness. EDs serve as the safety net in many communities, providing a place where those who are most vulnerable and those in need of the most immediate attention can receive care. By not addressing the rights and needs of all patients undergoing an emergency, the legal obligations of emergency physicians, and the budget and staffing constraints that EDs face, the 2020 rule undermined the critical role that EDs play across the country.

In all, we strongly believe that discrimination in any form should be prohibited in health care, and therefore we encourage HHS to finalize the rule as proposed. The 2020 policy did not reflect nor allow for our moral and legal duty as emergency physicians to treat everyone who comes through the doors of the ED.

Comment Number: HHS-OS-2022-0012-DRAFT-52236-0002
All Sections: 2
(b)(5)

Organization: Arkansas Department of Human Services

Excerpt Text:
Bostock does not support the proposed regulations

In direct contravention of the specific language of the Bostock decision, the Biden administration is determined to expand the scope of that case and adopt radical policy changes beyond its authority. The Bostock decision directly addressed the application of its decision to other federal statutes and did not apply that ruling to any other statutes beyond Title VII of the Civil Rights Act [Footnote 2: Bostock, 140 S. Ct. 1731, 1753 ("[W]e do not purport to address bathrooms, locker rooms, or anything else of the kind")]. The Court specifically limited its decision to the question before it: whether an employer that fired a homosexual or transgender person on the basis of their sexual orientation or gender identity was in violation of Title VII [Footnote 3: Id].

The Biden administration has ignored the limitations of the Bostock ruling and sought to push through policies that directly conflict with state laws intended to protect vulnerable children [Footnote 4: Immediately after entering office, President Biden issued Executive Order 13988, Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, which set federal policy that Bostock applied to laws beyond Title VII] [Footnote 5: The Biden administration has recently proposed similar amendments to rules regarding education and nutrition programs receiving federal financial assistance]. Guidance from the Department "unequivocally [states] that gender affirming care for minors, when medically appropriate and necessary, improves their physical and mental health" [Footnote 6: HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy (March 2, 2022)]. However, the policy of the State of Arkansas, as articulated by findings of the Arkansas General Assembly, is that

gender transition procedures for children under the age of eighteen are neither "unequivocally" appropriate nor "unequivocally" medically necessary as their "risks … far outweigh any benefit at this stage of clinical study on these procedures" [Footnote 7: Arkansas Saves Adolescents from Experimentation (SAFE) Act, No. 626, § 1, 2021 Ark. Acts].

In the Affordable Care Act, Congress did not grant the Department the authority to expand the definition of discrimination on the basis of sex in such an expansive manner [Footnote 8: 42 U.S.C. § 18116]. The Affordable Care Act specifically references existing equal protection statutes rather than providing its own list of protected classes. Congress did not intend to expand the protected classes beyond those recognized by settled law at the time Section 1557 was enacted. Specifically, in other statutes passed contemporaneously with the Act, Congress included the terms "gender identity" and "sexual orientation" but did not do so in the Affordable Care Act [Footnote 9: See Franciscan Alliance, Inc. v. Burwell, 227 F.Supp. 3d 660, 668-669, for a discussion of other statutes passed around the time of the Affordable Care Act that specifically incorporated the terms "gender identity" and "sexual orientation." This indicates that Congress understood the term "sex" would not include those terms and "gender identity" and "sexual orientation" must be specifically used in the statute]. This shows that Congress had the understanding that "sexual orientation" and "gender identity" were not included within the term "sex." As Congress had the ability to include "gender identity" and "sexual orientation" in Section 1557 and chose not to do so, it is clear that Congress did not intend for Section 1557 to include discrimination based on sexual orientation or gender identity.

Comment Number: HHS-OS-2022-0012-DRAFT-39385-0002
All Sections: 2
(b)(5)
Organization: American Hospital Association

Excerpt Text:
Those principles apply to this proposed rule. A cornerstone of hospitals' and health systems' missions is a commitment to diversity, inclusion and health equity so that they can provide care, within their capabilities, to those in need. Federal and state laws, as well as specific codes of ethics for health professionals, reinforce this mission of ensuring that all patients have appropriate access to necessary care. Those include the Emergency Medical Treatment and Labor Act, Medicare Conditions of Participation and state licensure requirements.

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0002
All Sections: 2
(b)(5)
Organization: Covered California

Excerpt Text:

Sadly, much of this progress was reversed when revisions were later made to the rule in 2020 [Footnote 3: 85 Fed.Reg. 37160 (June 19, 2020)]. The 2020 rule significantly narrowed the prior interpretation by eliminating the general prohibition on discrimination based on gender identity and sex-stereotyping and specific health insurance coverage protections for transgender individuals. Additionally, the 2020 rule adopted blanket abortion and religious freedom exemptions for health care providers, eliminated the provision preventing health insurers from varying benefits in ways that discriminate against certain groups, such as people with HIV or LGBTQ+ individuals, reduced protections that provide access to interpretation and translation services for individuals with limited English proficiency, and eliminated prohibitions against discrimination based on gender identity and sexual orientation.

Just days before the 2020 rule was published, the U.S. Supreme Court determined in Bostock v. Clayton County that an individual's sexual orientation and gender identity are "inextricably bound up with sex," such that they must be protected under Title VII's protection against sex discrimination [Footnote 4: Bostock v. Clayton County 140 S.Ct. 1731, 1742 (2020)]. Despite the preamble's open acknowledgment that the interpretation of nondiscrimination provisions in Title VII has often informed the interpretation of protections in Title IX, the 2020 rule did not consider the Court's reasoning and instead suggested that the term "sex" would be interpreted solely as "biological sex" [Footnote 5: 85 Fed.Reg. 37160, 37168 (June 19, 2020)]. Covered California supports the renewed efforts to bring these requirements into alignment with other federal laws by clearly stating that discrimination based on an individual's sexual orientation and gender identity is discrimination on the basis of sex under Section 1557, consistent with the Bostock decision.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0002
All Sections: 6.2.2, 2

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Italics: The Bostock Supreme Court Case Ruling]

The Department's proposal to 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 in regulation 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: Morrison, "HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate in Health Care." https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-in-health-care-1]

The Supreme Court explicitly stated that Bostock v. Clayton County cannot be used to apply to matters beyond employment nondiscrimination under Title VII. As Justice Gorsuch wrote:

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; we have not had the benefit of adversarial testing about the meaning of their terms, and we do not prejudge any such question today.

Under Title VII, too, we do not purport to address bathrooms, locker rooms, or anything else of the kind. The only question before us is whether 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.'

This is not simply lip-service. The court's logic applies to matters of employment under Title VII in ways that it does not apply to matters covered by Title IX. Jobs may be performed equally well by qualified individuals regardless of sex. However, unlike matters of employment sexual differences are extremely relevant when it comes to things like health care, housing and bathroom facilities, and athletics.

The Department's attempt to apply [Italics: Bostock] to Section 1557 relies on poor legal reasoning and should not be finalized.

Comment Number: HHS-OS-2022-0012-DRAFT-69547-0002
All Sections: 7.6.1, 2

(b)(5)

Organization: Congressman Mike Quigley

Excerpt Text:
In 2013, the American Society for Reproductive Medicine defined infertility as "a 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, 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's or 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, 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 [Italicized: 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 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 identity. Consistent with the Supreme Court's decision in Bostock, HHS rightly clarifies that nondiscrimination protections on the basis of sex include sexual orientation and gender identity.

One of the primary reasons for HHS' undertaking this rulemaking is to ensure consistency with the Bostock decision. We applaud HHS for its efforts, but we believe additional clarity is

necessary to ensure covered entities properly comply with the law. We believe that HHS should be more specific about the policies and practices that are mandated or prohibited as a result of Section 1557 and the Bostock decision, such as cases of AR coverage where LGBTQI+ Americans have historically met pervasive discrimination. HHS could do so by including a discussion of fertility care at 42 CFR 92.206(b) in the final rule. The ACA's protections as passed by Congress extend to LGBTQI+ individuals and couples who wish to have children, including via AR. LGBTQI+ Americans deserve the same opportunity as heterosexual and cisgender Americans to start a family, and burdensome and unnecessary requirements that do not contemplate fertility as it relates to LGBTQI+ individuals and couples should not stand in their way.

Comment Number: HHS-OS-2022-0012-DRAFT-69031-0002
All Sections: 2

(b)(5)

Organization: Howard Brown Health

Excerpt Text:
The passing of the Affordable Care Act (ACA) and Section 1557 went a long way toward addressing pervasive discrimination in healthcare against the LGBTQI+ 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.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0021
All Sections: 9.1.1, 2

(b)(5)

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:

[Bold: IV. The proposed rule takes critical steps to align with international human 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 in the principles of universality and non-discrimination, as set forth in the Universal Declaration of Human Rights (UDHR): "[A]ll 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, 26, G.A. Res. 2200A (XXI), 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 Economic, Social and Cultural Rights (ICESCR). [Footnote 83: International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, art. 2, para 2, 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) [hereinafter ICESCR]. While the U.S. has not ratified ICESCR, it is a signatory and therefore has an obligation to refrain from acting against the intent of the treaty. Vienna Convention on the Law of Treaties, adopted May 23, 1969, art. 18, 1155 U.N.T.S. 331, 8 I.L.M. 679 (entered into force Jan. 27, 1980). See also Michael H. Posner, Assistant Secretary, Bureau of Democracy, Human Rights, and Labor, Address to the American Society of International Law (Mar. 24, 2011), https://2009-2017.state.gov/j/drl/rls/rm/2011/159195.htm (noting that while the United States is not a party to the ICESCR, "as a signatory, we are committed to not defeating the object and purpose of the treaty").]

The 2016 Rule's interpretation of sex-based discrimination advanced international human rights principles by incorporating a broad definition of "on the basis of sex" to include prohibitions on

discrimination based on pregnancy, false pregnancy, termination of pregnancy, gender identity, and sex stereotyping. [Footnote 84: 81 FR 31387.] As described above, the current proposed rule has not explicitly included termination of pregnancy in its description of prohibited discrimination. [Footnote 85: Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824 (proposed August 4, 2022).] We urge the Department to clarify that abortion is covered by the rule and provide examples of prohibited conduct, to ensure that the rule aligns with international human rights standards.

Human rights protect against discrimination based on pregnancy-related status. [Footnote 86: 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. 5, U.N. Doc. E/C.12/GC/22 (2016); Committee on Economic, Social and Cultural Rights, General Comment No. 20 Non- discrimination in economic, social and cultural rights (art. 2, para. 2, of the International Covenant on Economic, Social and Cultural Rights), para. 10(a), U.N. Doc. E/C.12/GC/20 (2009).] In fact, human rights experts have expressed particular concern over discrimination on the basis of termination of pregnancy. [Footnote 87: Brief for United Nations Mandate Holders as Amici Curiae Supporting Respondents, Dobbs v. Jackson Women's Health Organization, 142 S.Ct. 2228 (2022) (No. 19-1392).] The Special Rapporteur on the Right to Health has found that the marginalization and vulnerability of individuals resulting from abortion-related discrimination perpetuates and intensifies violations of the right to health. [Footnote 88: Anand Grover, Special Rapporteur of the Human Rights Council, Right of everyone to the enjoyment of the highest attainable standard of physical and mental health, para. 34, U.N. Doc. A/66/254 (2011).] In addition, multiple treaty monitoring bodies and human rights experts have also noted that particular communities, "such as, but not limited to, poor women, persons with disabilities, migrants, indigenous or other ethnic minorities, adolescents, lesbian, gay, bisexual, transgender and intersex persons, [and] people living with HIV/AIDS" may be "disproportionately affected by intersectional discrimination in the context of sexual and reproductive health." [Footnote 89: Committee on Economic, Social and Cultural Rights, General Comment No. 22, para. 30; See also, e.g., Committee on the Rights of the Child, General Comment No. 15 (2013) on the rights of the child to the enjoyment of the highest attainable standard of health (art. 24), paras. 8-11, U.N. Doc. CRC/C/GC/15 (Apr. 17, 2013); Committee on the Rights of People with Disabilities, General Comment No. 3 (2016) on women and girls with disabilities, para. 2, U.N. Doc. CRPD/C/GC/3 (Nov. 25, 2016); Human Rights Council, General Comment No. 28: Article 3 (The equality of rights between men and women), para. 30, U.N. Doc. CCPR/C/21/Rev.1/Add.10 (Mar. 29, 2000); CEDAW Committee, General Recommendation No. 34 (2016) on the rights of rural women, para. 38, U.N. Doc, CEDAW/C/GC/34 (Mar. 7, 2016); Human Rights Council, Report of the Special Rapporteur on Extreme Poverty and Human Rights on his mission to the United States of America, para. 56, U.N. Doc. A/HRC/38/33/Add.1 (May 4, 2018) (noting that "low-income women['s] lack of access to abortion services traps [them] in cycles of poverty.").]

The CEDAW Committee has also expressed concern over discrimination against individuals seeking abortion services. [Footnote 90: CEDAW Committee, Concluding observations on the eighth periodic report of Australia, para. 49(a), U.N. Doc. CEDAW/C/AUS/CO/8 (2018); CEDAW Committee, Inquiry concerning the United Kingdom of Great Britain and Northern Ireland under article 8 of the Optional Protocol to the Convention on the Elimination of All

Forms of Discrimination against Women, Report of the Committee, para. 65, U.N. Doc. CEDAW/C/OP.8/GBR/1 (March 6, 2018) (finding that abortion restrictions in Northern Ireland constituted discrimination because they affected only women, "preventing them from exercising reproductive choice.").] And the UN Working Group on the issue of discrimination against women in law and practice has called on states to ensure the right of pregnant women to access abortion services by "provid[ing] nondiscriminatory health insurance coverage for women" and "exercis[ing] due diligence to ensure that the diverse actors and corporate and individual health providers who provide health services or produce medications do so in a non-discriminatory way." [Footnote 91: WORKING GROUP ON THE ISSUE OF DISCRIMINATION AGAINST WOMEN IN LAW AND IN PRACTICE, WOMEN'S AUTONOMY, EQUALITY, AND REPRODUCTIVE HEALTH IN INTERNATIONAL HUMAN RIGHTS: BETWEEN RECOGNITION, BACKLASH AND REGRESSIVE TRENDS, OHCR 7 (2017), https://www.ohchr.org/Documents/Issues/Women/WG/WomensAutonomyEqualityReproductiveHealth.pdf.]

In its 2022 Abortion Care Guideline, the World Health Organization ("WHO") also integrates international human rights law recognizing that countries must remove all legal, practical and social barriers impeding individuals' equal and non-discriminatory access to sexual and reproductive health, including abortion. [Footnote 92: WORLD HEALTH ORGANIZATION, ABORTION CARE GUIDELINE 8, (Mar. 8, 2022), https://www.who.int/publications/i/item/9789240039483.] The Guideline also recognizes that states have obligations to address laws, institutional arrangements, and social practices that are discriminatory and that prevent people from effective enjoyment of their right to sexual and reproductive health. Since states look to HHS for guidance interpreting Section 1557, its guidance plays a potentially pivotal role in reinforcing international human rights law.

Human rights also protect against discrimination based on sex stereotypes, and treaty bodies likewise emphasize the prohibition on such discrimination. [Footnote 93: Convention on the Elimination 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 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. 9, 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. 20; 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 (1980) (entered into force May 3, 2008).] Indeed, human rights require states to ensure that reproductive health services, in particular, are provided in a manner that does not promote or exacerbate harmful gender stereotypes and assumptions. [Footnote 94: Convention on the Elimination of All Forms of Discrimination Against Women, adopted Dec. 18, 1979, art. 2(f), 5(a), 12, 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); L.C. v. Peru, CEDAW Committee, Commc'n No. 22/2009, para. 8.15, 9, U.N. Doc. CEDAW/C/50/D/22/2009 (2011). See also Simone Cusack, Gender Stereotyping as a Human Rights Violation, OHCHR Women's Rts & Gender 51-53 (2013), .]

Finally, human rights protect against discrimination on the basis of gender identity. As the UN High Commissioner for Human Rights has affirmed, "[a]ll people, including lesbian, gay, bisexual and transgender (LGBT) persons are entitled to enjoy the protections provided for by international human rights law, including . . . the right to be free from discrimination." [Footnote 95: 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 (Nov. 17, 2011).] Human rights treaty bodies have affirmed the right to non-discrimination based on gender identity, [Footnote 96: Human Rights Committee, General comment No. 36 (2018) on article 6 of the International Covenant on Civil and Political Rights, on the right to life, para. 61, U.N. Doc. CCPR/C/GC/36 (2018); Committee on Economic, Social and Cultural Rights, General Comment No. 20 Non-discrimination in economic, social and cultural rights (art. 2, para. 2 of the International Covenant on Economic, Social and Cultural Rights), para. 32, U.N. Doc. E/C.12/GC/20 (2009); Committee on the Rights of the Child, General Comment No. 13 The right of the child to freedom from all forms of violence, para. 60, 72(g), U.N. Doc. CRC/C/GC/13 (2011); Committee against Torture, General Comment No. 2 Implementation of article 2 by States parties, para. 21, U.N. Doc. CAT/C/GC/2 (2008); CEDAW Committee, Gen. 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. 18, U.N. Doc. CEDAW/C/GC/28 (Dec. 16, 2010); see also 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. 16, U.N. Doc. A/HRC/19/41 (Nov. 17, 2011) (noting that "[i]n their general comments, concluding observations and views on communications, human rights treaty bodies have confirmed that States have an obligation to protect everyone from discrimination on grounds of sexual orientation or gender identity.").] including with respect to sexual and reproductive health. [Footnote 97: 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. 2, U.N. Doc. E/C.12/GC/22 (2016).] The UN High Commissioner for Human Rights has identified discrimination in health care as an area in which individuals are particularly susceptible to discriminatory treatment, marginalization, and restriction in their enjoyment of rights because of sexual orientation or gender identity. [Footnote 98: 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. 50, 54-57, U.N. Doc. A/HRC/19/41 (Nov. 17, 2011).]

Countries have an obligation to both ensure that their own laws and policies do not discriminate against people based on sexual orientation and gender identity and also ensure that legal frameworks provide protection against discrimination by third parties. [Footnote 99: 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. 41, U.N. Doc. E/C.12/GC/22 (2016) (stating that the "obligation to respect also requires States to repeal, and refrain from enacting, laws and policies that create barriers to access to sexual and reproductive health services. This includes third-party authorization requirements, such as parental, spousal and judicial authorization requirements for access to sexual and reproductive health services and information, including for abortion and contraception.").] The High Commissioner recommends that governments enact comprehensive

anti-discrimination legislation that includes prohibitions on discrimination based on sexual orientation and gender identity. [Footnote 100: Id. para. 84(e), U.N. Doc. E/C.12/GC/22 (2016); see also Committee on Economic, Social and Cultural Rights, Concluding Observations: Germany, para. 26, U.N. Doc. E/C.12/DEU/CO/5 (2011).] We appreciate the proposed rule's recommendation of a private right of action to enforce Section 1557, as well as a robust interpretation of prohibited sex discrimination, in keeping with human rights norms and obligations.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0022
All Sections: 2, 8.1

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: B. International human rights law requires the government to ensure that 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. 93, 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 103: 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, protects 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 of an impermissible infringement on women's rights, [Footnote 105: Special Rapporteur on Freedom of Religion or Belief, Interim Rep. of The Special Rapporteur on Freedom of Religion or Belief, para. 24, U.N. Doc. A/72/365 (Aug. 28, 2017).] and has

expressed concern over the use of "religious liberty" to justify the refusal of providing goods and services to women and LGBTQI individuals. [Footnote 106: Id. para. 37, U.N. Doc. A/72/365 (Aug. 28, 2017).]

Accordingly, human rights standards require that where a refusal of care based on religious or conscience belief is permitted, it does not infringe on others' access to health care. [Footnote 107: 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), paras. 14, U.N. Doc. E/C.12/GC/22 (2016).] They require the government to ensure that health care providers' refusal to provide reproductive health care, including abortion care, on grounds of conscience does not jeopardize access to reproductive health care. [Footnote 108: Id. 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) (2008); 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).]

UN human rights experts have noted the United States' particular obligations in this regard. At the conclusion of its 2015 fact-finding visit to the United States, the UN Working Group on Discrimination Against Women reiterated that:

[Italics: Refusal to provide sexual and reproductive health services on the grounds of religious freedom should not be permitted where such refusal would effectively deny women immediate access to the highest attainable standard of reproductive health care and affect the implementation of rights to which they are entitled under both international human rights standards and domestic law.] [Footnote 109: 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. 71, 95(i), U.N. Doc. A/HRC/19/41 (Nov. 17, 2011)]

We therefore urge the Department to explicitly delineate the limitations of religious refusal laws. Specifically, the Department should clarify that health care entities are responsible for ensuring that patients do not experience discrimination even if individual providers object to providing that care. The final rule should address the harm caused by discrimination that occurs under the guise of a religiously motivated denial of care, which does not relieve a health care provider of their obligation to provide nondiscriminatory care.

To more closely align with international human rights standards, the final rule should ensure that health care providers' religious refusals to provide sexual and reproductive health care services do not result in discrimination against their patients and do not prevent a patient's access to care.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0023
All Sections: 6.2.1, 2
(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: C. The proposed regulation should be considered an important tool to 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 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. 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, 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, including on issues such as immigration and discrimination protections, which Section 1557 is also designed to protect.

The implications of the recent [Italics: Dobbs] decision have drawn concern from the international human rights community. Victor Madrigal-Borloz, the UN Independent Expert on Sexual Orientation and Gender Identity who visited the United States in August 2022, called the decision "a devastating action for the human rights of lesbian and bisexual women, as well as trans men and other gender diverse persons with gestational faculties." [Footnote 113: Victor Madrigal-Borloz, Mandate of the United Nations Independent Expert on Protection from Violence and Discrimination based on Sexual Orientation and Gender Identity 2 (2016).] Madrigal-Borloz further noted that such bans have or will lead "to the closure of clinics that are critical sources of sexual and reproductive health care for LGBT persons: contraception and

abortion services, wellness services, examinations, STI testing and treatment, hormone replacement therapy and insemination services." [Footnote 114: Id. at 3.] At the conclusion of its 2022 review of the United States, the Committee on the Elimination of Racial Discrimination (CERD Committee) noted deep concerns with the decision in Dobbs and recommended that the United States address the disparate impact that it will have on racial and ethnic minorities, Indigenous women, and those with low incomes. [Footnote 115: U.N. CERD, International Convention on the Elimination of All Forms of Racial Discrimination: Concluding observations on the combined tenth to twelfth reports of the United States of America, CERD/C/USA/CO/10-12, para 35 (Sept. 21, 2022).]

The proposed rule's renewed emphasis on protections against discrimination on the basis of sex are an important tool in holding strong against a retrogression of rights. This is critical to reenforcing core international human rights principles.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0025
All Sections: 4.3.1.2.3, 2

(b)(5)

Organization: Center for American Progress

Excerpt Text:
Federal law, including Title IX, recognizes that protections against sex discrimination include termination of pregnancy [Footnote 39: The Department of Education's Title IX regulations prohibit discrimination related to "termination of pregnancy or recovery therefrom." 34 C.F.R. § 106.40(b)(1)]. Discrimination in health care based on termination of pregnancy can show up in many ways. For example, patients needing emergency abortion care have been denied care at hospitals. Patients have reported being denied medical care unrelated to abortion because their medical history includes a prior abortion. Pharmacies have refused to fill prescriptions needed to manage a miscarriage or complications from pregnancy loss because these medications can also be used to terminate a pregnancy.

Often, discrimination based on termination of pregnancy is rooted in abortion stigma [Footnote 40: Alison Norris et al., Abortion Stigma: A Reconceptualization of Constituents, Causes, and Consequences, 21 WOMEN'S HEALTH ISSUES 1, 6 (2011), https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/Abortion-Stigma.pdf; Anuradha Kumar et al., Conceptualising Abortion Stigma, 11 CULTURE, HEALTH & SEXUALITY 625, 628–29 (2009)]. This stigma is experienced by a majority of people seeking abortion and is rooted in sex-based conventions that women are: inherently nurturing and maternal; expected by society to be chaste (which an unwanted pregnancy is seen as diametrically opposed to); and expected to biologically desire to birth children and fulfill traditional roles of homemaker and child caretaker within the nuclear family structure [Footnote 41: See Paula Abrams, The Scarlet Letter: The Supreme Court and the Language of Abortion Stigma, 19 MICH. J. GENDER & L. 293, 328–29 (2013); M. ANTONIA BIGG ET AL., PERCEIVED ABORTION STIGMA AND PSYCHOLOGICAL WELL-BEING OVER FIVE

YEARS AFTER RECEIVING OR BEING DENIED AN ABORTION 2 (Whitney S. Rice ed., 2020) (finding that most people considering abortion perceive some stigma related to their decision)] [Footnote 42: Norris, supra note 5, at 6;; Kumar, supra note 5, at 628-29]. The stigmatization of abortion also stems from a misperception that abortion is an immoral act as opposed to a personal medical decision [Footnote 43: COCKRILL K ET AL., ADDRESSING ABORTION STIGMA THROUGH SERVICE DELIVERY: A WHITE PAPER 17(2013); https://www.ibisreproductivehealth.org/publications/addressing-abortion-stigma-through-service-delivery-white-paper].

Abortion stigma often shapes the experiences of patients seeking all forms of medical care, simply because they present as capable of pregnancy [Footnote 44: Transgender, nonbinary, and gender-expansive people who were assigned female or intersex at birth experience pregnancy, have abortions, and are underrepresented and underserved in abortion policy discourse. See e.g. Heidi Moseson et al., Abortion Experiences and Preferences of Transgender, Nonbinary, and Gender-expansive People in the United States, AM. J. OBSTET GYNECOL, Sep. 2020, at 1, 1-2]. Sex-based discrimination in health care—including abortion care—has a disproportionate impact on women, trans, and non-binary individuals in comparison to cis men [Footnote 45: See Emily Paulsen, Recognizing, Addressing Unintended Gender Bias in Patient Care, DUKE HEALTH (Jan. 14, 2020), https://physicians.dukehealth.org/articles/recognizing-addressing-unintended-gender-bias-patient-care]. When reproductive health care is marred by abortion stigma, the stigma "diminishes the trust that is essential to the patient-provider relationship and undermines women's ability to make informed medical decisions" [Footnote 46: NAT'L P'SHIP FOR WOMEN & FAMS., BAD MEDICINE: HOW POLITICAL AGENDA IS UNDERMINING ABORTION CARE AND ACCESS 2 (2019), https://www.nationalpartnership.org/our-work/repro/reports/bad-medicine-oklahoma.html]. These experiences are precisely the discriminatory conduct that Section 1557 protects against.

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0003
All Sections: 2

(b)(5)

Organization: Concerned Women for America

Excerpt Text:
[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 VI, or the ACA. The Department has no legitimate authority to rewrite 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 in 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 to 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 political and policy desires, not adherence to settled law or statute. This is legislative rulemaking 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.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0030
All Sections: 6.2.1, 6.1, 2

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0031
All Sections: 6.2.8, 2

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[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 provision undermines Title IX's potence 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 could 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).

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0037
All Sections: 4.3.1.2.4, 4.3.1.2.1, 4.3.1.2.3, 2
(b)(5)

Organization: Center for American Progress

Excerpt Text:
b. Sex Discrimination in Coverage

U.S. health insurance and other health-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 certain types of care that are traditionally used by women, such as in vitro fertilization (IVF) [Footnote 83: Gabriela Weigel and others, "Coverage and Use of Fertility Services in the U.S." (San Francisco: Kaiser Family Foundation, 2020), available at https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/]. 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 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 that providers do not take their fertility concerns seriously, instead "emphasiz[ing] birth control over procreation" [Footnote 84: Ethics Committee of the American Society for Reproductive Medicine. "Disparities in access to effective treatment for infertility in the United States: an Ethics Committee opinion." Fertility and Sterility 104.5 (2015): 1104-1110, available at 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].

As the 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 from their state family planning programs and contraceptive coverage mandates [Footnote 85: Guttmacher Institute, "Emergency Contraception," available at https://www.guttmacher.org/state-policy/explore/emergency-contraception (last accessed September 2022)]. This results in discrimination against people of color and people with low-incomes who face higher rates of unintended pregnancy and adverse reproductive health outcomes due to these barriers [Footnote 86: American College of Obstetricians and Gynecologists, "Access to Contraception" available at https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception (last accessed September 2022)]. Robust enforcement of Section 1557 is necessary to ensure health entities and providers do not perpetuate discriminatory policies against contraceptive care.

Comment Number: HHS-OS-2022-0012-DRAFT-71242-0004
All Sections: 2

(b)(5)

Organization: National Alliance on Mental Illness

Excerpt Text:
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, including the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0004
All Sections: 2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[Bold: 1. 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 replacing 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: without] causing equal or greater harms and burdens. [Footnote 6: Michigan v. EPA, 135 S. Ct. 2699 (2015) (regulation is irrational if it disregards the relationship between its costs and benefits); Alltelcorp v. FCC, 838 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0048
All Sections: 15.2, 2
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[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 ED'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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0005
All Sections: 15.2, 2
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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. 47829.] It also claims its proposed regulations are "consistent with the statutory text of Section 1557 and Congressional intent." [Footnote 8: 87 Fed. Reg. 47828.] 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 cite 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).

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0005
All Sections: 2

(b)(5)

Organization: Concerned Women for America

Excerpt Text:
The only conclusion is that this Rule embodies the same illegitimacy in policy and practice that the Biden Administration is currently pursuing under all titles of civil rights law, but only for the personal preference of self-identified sexual attraction and identity, not for any other category of discrimination.

Resting "authority" for this Rule on a unilateral interpretation of Bostock, specifically rejected by the court, is untenable. Nowhere did the U.S. Supreme Court say its decision could or should be extended to require destructive medical surgeries and treatments for any "gender transition" claim, especially if requested by youth or caretakers who have been persuaded by reckless "gender specialists" and "professional" organizations peddling harmful "standards of care" protocols that are experimental and contrary to improving physical health. Bostock gives no legitimate claim to justify such a Rule.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0006
All Sections: 6.2.6, 6.2.5, 2

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
[Bold/Underline: II. The New Rule Correctly Adopts Widely Held Interpretations of Sex Discrimination, But It Could More Explicitly Define It To Prevent Confusion]

The reinclusion of sexual orientation and gender identity into the protected characteristics under Section 1557 is consistent with applicable case law and the law's stated purpose. Moreover, it affirms what has already been recognized across the federal government and by many federal courts, including the Supreme Court of the United States: that discrimination based on sexual

orientation, gender identity, gender transition, transgender status, or sex-based stereotypes are forms of sex discrimination. The proposed rule will also foster consistency between Federal agencies, regulations, and case law. [Footnote 2: See, e.g., Department of Labor, Job Corps Program Instruction Notice No. 14-31, Ensuring Equal Access for Transgender Applicants and Students to the Job Corps Program (May 1, 2015); Bostock v. Clayton County, No. 17–1618, 723 Fed. Appx. 964; No. 17–1623, 883 F. 3d 100, No. 18–107, 884 F. 3d 560.] All taken together, the proposed rule's creation of more inclusive definitions of sex discrimination acknowledges the necessity of recognizing non-binary identities in the provision of health care and health-related programs, as it has been widely accepted among medical organizations. [Footnote 3: Am. Psychological Ass'n, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People 6 (2015); World Prof. Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender and Gender-Nonconforming People 171, 175 (2012) (requiring physicians to provide affirming care for both binary and non-binary transgender and gender non-conforming patients); Am. College of Obstetricians and Gynecologists, Committee Opinion No. 512: healthcare for Transgender Individuals, Obstetrics & Gynecology 118(6): 1454 (2011) (same); see also Am. Psychiatric Ass'n, Diagnostic and Statistical Manual of Mental Disorders, Version 5 451-53 (2013) (defining gender identity to include identities other than male or female, and specifying diagnostic criteria for gender dysphoria to include such identities); Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding, 25-26 (2011) (same).]

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0008
All Sections: 5.4.5.1, 7.7.1, 5.4.4.1, 2

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
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 nondiscrimination requirements in health insurance coverage and other health-related coverage, as discussed further below.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0008
All Sections: 8.2, 2

(b)(5)

Organization: Center for American Progress

Excerpt Text:

c. The Danforth Amendment

We strongly support the Proposed Rule's repeal 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 to Section 1557 via 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, 463 n.9 (1988) (Stevens, J., dissenting) (Court presumes that "Congress is aware of this longstanding presumption [disfavoring 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 Health Programs and Activities, 81 Fed. Reg. 31376, 31377 (May 18, 2016)] [Footnote 16: Id. at 31380]. Abortion is a critical form of health care, and patients seek or need abortion care for a wide variety of reasons, including personal reproductive health decisions, miscarriage management, or emergency procedures related to adverse pregnancy outcomes. Patients not only deserve but require nondiscriminatory access to abortion care, in accordance with the congressional intent of Section 1557. The Danforth Amendment should not be included because it is the Department's responsibility to ensure regulations accurately implement the protections provided in Section 1557, not limit the protections, contrary to Congress's intent.

Abortion patients already face additional barriers to care that often lead to an inability to access abortion care altogether, especially following the Dobbs v. Jackson Women's Health Org. decision declaring that there is no federal constitutional right to abortion [Footnote 17: Dobbs v. Jackson Women's Health Org., 142 S.Ct. 2228 (2022)]. Within 30 days of the Dobbs decision, eleven states had banned abortion, with some imposing criminal penalties [Footnote 18: Marielle Kirstein, Rachel K. Jones & Jesse Philbin, One Month Post-Roe: At Least 43 Abortion Clinics

Across 11 States Have Stopped Offering Abortion Care, Guttmacher (July 28, 2022), https://www.guttmacher.org/article/2022/07/one-month-post-roe-least-43-abortion-clinics-across-11-states-have-stopped-offering]. This number continues to grow: 26 states are likely to ban or have already banned abortion, leaving people without access to care in their state. Many people are not able to travel to another state to access abortion, or are significantly delayed by the cost and logistical arrangements required to do so. Delays in accessing abortion, or being unable to access abortion at all, pose risks to people's health.

While abortion is very safe at any point in pregnancy, risks increase with gestational age. And because pregnancy and childbirth are far more medically risky than abortion, forcing people to carry a pregnancy to term exposes them to an increased risk of physical harm [Footnote 19: Elizabeth Raymond & David Grimes, The Comparative Safety of Legal Induced Abortion and Childbirth in the United States, 119 J. Obstet. Gynecol. 215 (Feb. 2012)]. U.S. maternal health outcomes are worsening at an alarming rate, with Black women and birthing people bearing the brunt of this crisis–a persisting legacy of discrimination, unequal distribution of resources, and inequitable access to care. Indeed, as of 2020, the national maternal mortality rate for Black women was approximately three times the rate for white women [Footnote 20: Donna L. Hoyert, Maternal Mortality Rates in the United States, 2020, CDC (Feb. 2022), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/E-stat-Maternal-Mortality-Rates-2022.pdf]. Because of the heightened mortality and morbidity risks faced by Black women and birthing people, it is particularly unconscionable to force the continuation of an unwanted pregnancy. Restrictions on abortion care have far reaching consequences, both deepening existing inequities and worsening health outcomes for pregnant people and people giving birth. Adding the Danforth Amendment to Section 1557 would compound the harms of barriers that patients already face when seeking care. Evidence shows that when a person is denied a wanted abortion their household falls deeper into poverty, and that impact lasts for years [Footnote 21: Advancing New Standards in Reproductive Health, The Harms of Denying a Woman a Wanted Abortion Findings from the Turnaway Study, https://www.ansirh.org/sites/default/files/publications/files/the_harms_of_denying_a_woman_a_wanted_abortion_4-16-2020.pdf]. Every person should be able to choose whether or not to continue a pregnancy.

Abortion care is a normal and important part of the spectrum of reproductive health care and those seeking this care must be able to get evidence-based information, referrals, and services to the greatest extent possible. Applying the Danforth Amendment in the health care context would cause life-threatening situations and hinder a person's equal access to a health program or provider based upon their pregnancy related condition.

We strongly support the Department's position that "as a textual matter, the more natural understanding of 'grounds prohibited' is that it refers simply to the basis on which discrimination is prohibited."

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0009
All Sections: 2

(b)(5)

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:

The conclusion that discrimination based on sex characteristics, including intersex traits, is necessarily discrimination on the basis of sex flows directly from [Italics: Bostock v. Clayton County], [Footnote 13: 140 S. Ct. 1731 (2020).] and is supported by other precedents including [Italics: Price Waterhouse v. Hopkins]. [Footnote 14: 490 U.S. 228 (1989).] Prior to [Italics: Bostock], one federal court recognized that discrimination based on variations in sex characteristics is inherently sex-based, while another 35-year-old case rejected such a claim on the same grounds rejected in [Italics: Bostock]. [Footnote 15: Compare Wood v. C.G. Studios, Inc., 660 F. Supp. 176, 177-78 (E.D. Pa. 1987) (rejecting what the court termed a claim of discrimination based on "gender-corrective surgery"), with Kastl v. Maricopa County Community College District, No. 02–1531, 2004 WL 2008954 (D. Ariz. June 3, 2004) ("neither a woman with male genitalia nor a man with stereotypically female anatomy, such as breasts, may be deprived of a benefit or privilege of employment by reason of that nonconforming trait"). The court later held Kastl had "provided no evidence that she was a biological female and member of a protected class" and ruled for the employer, 2006 WL 2460636 (D. Ariz. Aug. 22, 2006). A Ninth Circuit per curiam opinion (joined by then-Judge Gorsuch) framed the case as one of anti-transgender discrimination recognized under circuit precedent, but ruled restroom "safety" concerns were a nondiscriminatory motive. 325 Fed. Appx. 492 (9th Cir. 2009).] In other cases, defendants did not dispute that anti-intersex bias was unlawful, [Footnote 16: See, e.g., Hughes v. Home Depot, Inc., 804 F.Supp.2d 223 (D.N.J. 2011).] or cases were resolved on other grounds. [Footnote 17: See, e.g., Zzyym v. Pompeo, 341 F.Supp.3d 1248 (D. Colo. 2018) (ruling for intersex passport applicant on APA claim and declining to reach equal protection claim), vacated and remanded on other grounds, 958 F.3d 1014 (10th Cir. 2020). See also Estate of DiMarco v. Wyoming Dep't of. Corr., 300 F. Supp. 2d 1183 (D. Wyo. 2004) (ruling for intersex prisoner on due process grounds but rejecting equal protection claim based on intersex status, without considering sex discrimination), rev'd on other grounds, 473 F.3d 1334 (10th Cir. 2007).] At least one state agency issued pre-[Italics: Bostock] guidance that sex discrimination laws encompass anti-intersex bias. [Footnote 18: N.Y.S. Div. Of Hum. Rts., Guidance on Protections from Gender Identity Discrimination under the New York State Human Rights Law, 9 (2020), https://dhr.ny.gov/sites/default/files/pdf/nysdhr-GENDA-guidance-2020.pdf.] No reported case law since [Italics: Bostock] has expressly addressed discrimination claims by intersex people, though courts have increasingly recognized that intersex people exist and that bias against them raises questions of the applicability of sex discrimination laws. [Footnote 19: See Grimm v. Gloucester County School Board, 972 F.3d 586, 596, 615 (4th Cir. 2020) (noting "there are ... youth born intersex who do or do not identify with their sex-assigned-at-birth," and this is one reason why some youth "do not have genitalia that match the binary sex listed on their birth certificate—let alone that matches their gender identity"; id. at 623 (Wynn, concurring) ("if the Board's concern were truly that individuals might be exposed to those with differing physiology, it would presumably have policies in place to address … intersex individuals who possess some mix of male and female physical sex characteristics and who comprise a greater fraction of the population than transgender individuals"); Frappied v. Affinity Gaming Black Hawk, 966 F.3d 1038, 1057 n. 3 (10th Cir. 2020) (noting the "framework requiring a comparison

between male and female employees assumes that sex is binary," but that "[t]his case does not raise, and we do not address, sex discrimination involving intersex or gender non-binary individuals").]

Prior to [Italics: Bostock], the Department of Health and Human Services (HHS) explained in the preamble to its 2016 ACA nondiscrimination final rule that sex discrimination includes discrimination based on sex characteristics, including intersex traits. [Footnote 20: US Department of Health and Human Services, Nondiscrimination in Health Programs and Activities, 81 FR 31375, 31389 (May 18, 2016).] Following [Italics: Bostock], the Department of Justice (DOJ) updated its [Italics: Title IX Legal Manual] to clarify that the [Italics: Bostock] Court's reasoning "applies with equal force to discrimination against intersex people," concluding:

Discrimination against intersex individuals is similarly motivated by perceived differences between an individual's specific sex characteristics and their sex category (either as identified at birth or some subsequent time). Additionally, discrimination based on anatomical or physiological sex characteristics (such as genitals, gonads, chromosomes, and hormone function) is inherently sex-based. Intersex traits, like gender identity and sexual orientation, are "inextricably bound up with" sex. In other words, it is impossible to discuss intersex status without also referring to sex. Lastly, discrimination based on intersex traits may also involve sex stereotypes, as intersex people by definition have traits that do not conform to stereotypes about male or female bodies. [Footnote 21: US Department of Justice, Title IX Legal Manual (updated Aug. 12, 2021) (internal citations omitted), https://www.justice.gov/crt/title-ix#Bostock.]

DOJ applied this interpretation to several other federal funding statutes in a March 2022 memorandum. [Footnote 22: DOJ Civil Rights Division, Interpretation of Bostock v. Clayton County regarding the nondiscrimination provisions of the Safe Streets Act, the Juvenile Justice and Delinquency Prevention Act, the Victims of Crime Act, and the Violence Against Women Act (Mar. 10, 2022), https://www.justice.gov/crt/page/file/1481776/download.]

While recognizing that discrimination based on sexual orientation, gender identity, and sex characteristics are all inherently sex-linked, HHS rightly chose to expressly enumerate these grounds in the nondiscrimination provision of the recent Title X rule. [Footnote 23: US Department of Health and Human Services, Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services, 86 FR 56144, 56159, 56178 (Oct. 7, 2021), to be codified at 42 CFR § 59.5.] The Department of Education followed the same approach in its recent proposed rule on Title IX. [Footnote 24: Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance, 87 FR 41390 (Jul. 12, 2022).] We welcome HHS's embrace of the same approach in this NPRM, as express enumeration is particularly important for communities that have not traditionally had their rights recognized and affirmed.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0009
All Sections: 5.2.3, 2

(b)(5)

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[Bold: 2. 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 47,838. [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 47,838.] 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. § 92.3(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 47,829. [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 broadening 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66316-0009
All Sections: 2

(b)(5)

Organization: American Association of Christian Schools

Excerpt Text:
[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. This 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.

Section 3 - Types of Health Inequities at Issue

Comments associated with this issue are included in the subsections below

Section 3.1 - Bases of Discrimination

Comment Number: HHS-OS-2022-0012-DRAFT-72212-0008
All Sections: 3.1
(b)(5)

Organization: Senate Democrats

Excerpt Text:
The Proposed Rule Continues to Recognize Protections for Intersectional Discrimination

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 47870]. 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.

Section 3.1.1 - Race Discrimination; Title VI

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0014
All Sections: 3.1.1, 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
[Bold: 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 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 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 within comprehensive sex education, factoring for intersection 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-poc-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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72795-0002
All Sections: 3.1.1

(b)(5)

Organization: Tribal Technical Advisory Group to CMS (TTAG)

Excerpt Text:
[Bold: American Indians and Alaska Natives are a Political Group]

TTAG is 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 include Indian-specific provisions in 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 Education 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 [italics: 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) system is the primary vehicle by which the United States fulfills its trust obligation to provide the services and resources needed to "to maintain and improve the health of the Indians." In addition, many AI/AN people receive care through systems operated or supported in whole or in part by the Department, including Medicaid and Medicare. At times, the Department has also partnered with other agencies, like the Department of Veterans Affairs, to better fulfill the trust responsibility for healthcare. In fulfillment of the trust responsibility, the United States has provided or supported services at I/T/U providers, or through other programs, which are at times limited to AI/ANs.

The IHS itself states on its website that "[i]t's important to clarify that the IHS […] can provide healthcare to only eligible Alaska Native and American Indians at its federal hospitals and clinics." [Footnote 4: Indian Health Service, IHS.gov. For Patients, https://www.ihs.gov/forpatients/.] The TTAG requests that the proposed rule be amended to explicitly refer in the Preamble to the unique political status of Indian Tribes, the federal trust responsibility for Indian health, and the Indian health program exemption to non- discrimination claims under Title VI and otherwise.

Comment Number: HHS-OS-2022-0012-DRAFT-43142-0002
All Sections: 3.1.1
(b)(5)
Organization: American Psychological Association

Excerpt Text:

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 healthcare 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. (2009). 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0033
All Sections: 3.1.1, 3.1.2

(b)(5)

Organization: Center for American Progress

Excerpt Text:

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. The 2022 Proposed Rule proscribes many forms of discrimination that amplify the impacts of racism and subject people to dual discrimination. For example, the 2022 Proposed Rule seeks to eliminate discrimination against LEP individuals and people living with disabilities—groups that are predominately comprised of people of color. 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.

It has been long recognized that the denial of adequate language services to LEP individuals constitutes discrimination on the basis of national origin. However, there are clear intersections between LEP status and race and/or ethnicity. According to the most recent data, 63 percent of LEP individuals are Latino and 21 percent are Asian/Pacific Islander [Footnote 67: Jie Zong and Jeanne Batalova, "The Limited English Proficient Population in the United States in 2013" (Washington: Migration Policy Institute, 2015), available at

https://www.migrationpolicy.org/article/limited-english-proficient-population-united-states-2013]. Moreover, according to one study, a "substantial number of Asian Americans reported encountering racial discrimination and possessing limited English proficiency" [Footnote 68: Gilbert C. Gee and Ninez Ponce, "Associations Between Racial Discrimination, Limited English

Proficiency, and Health-Related Quality of Life Among 6 Asian Ethnic Groups in California," American Journal of Public Health 100 (5) (2010): 888-895, available at https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2009.178012]. Another study revealed that "more than half (65 percent) of [patients in the study] indicated that they have felt discriminated against by [health care] staff because of their Hispanic ethnicity or LEP" [Footnote 69: William Calo and others, "Experiences of Latinos with limited English proficiency with patient registration systems and their interactions with clinic front office staff: an exploratory study to inform community-based translational research in North Carolina," BMC Health Services Research 15 (570) (2015) available at https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-015-1235-z]. Improving language access services is therefore a critical tool to addressing discrimination against people of color by health care providers.

Improving health care access for people living with disabilities is also 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 National Disability Institute, 14 percent of Black people live with disabilities compared to 11 percent of Non-Hispanic Whites and 8 percent of Latinos [Footnote 70: National Disability Institute, "Financial Inequality: Disability, Race, and Poverty In America," available at https://www.nationaldisabilityinstitute.org/wp-content/uploads/2019/02/disability-race-poverty-in-america.pdf (last accessed September 2022)].

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0005
All Sections: 3.1.1, 3.1.4
(b)(5)
Organization: Alliance of Multicultural Physicians

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0064
All Sections: 3.1.1, 16, 3.1.3
(b)(5)

(b)(5)

Organization: Justice in Aging

Excerpt Text:
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 47,870.] 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.

Section 3.1.2 - National Origin Discrimination (including Language); Title VI

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0033
All Sections: 3.1.1, 3.1.2

(b)(5)

Organization: Center for American Progress

Excerpt Text:
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. The 2022 Proposed Rule proscribes many forms of discrimination that amplify the impacts of racism and subject people to dual discrimination. For example, the 2022 Proposed Rule seeks to eliminate discrimination against LEP individuals and people living with disabilities—groups that are predominately comprised of people of color. 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.

It has been long recognized that the denial of adequate language services to LEP individuals constitutes discrimination on the basis of national origin. However, there are clear intersections between LEP status and race and/or ethnicity. According to the most recent data, 63 percent of LEP individuals are Latino and 21 percent are Asian/Pacific Islander [Footnote 67: Jie Zong and Jeanne Batalova, "The Limited English Proficient Population in the United States in 2013" (Washington: Migration Policy Institute, 2015), available at

https://www.migrationpolicy.org/article/limited-english-proficient-population-united-states-2013]. Moreover, according to one study, a "substantial number of Asian Americans reported encountering racial discrimination and possessing limited English proficiency" [Footnote 68: Gilbert C. Gee and Ninez Ponce, "Associations Between Racial Discrimination, Limited English Proficiency, and Health-Related Quality of Life Among 6 Asian Ethnic Groups in California,"

American Journal of Public Health 100 (5) (2010): 888-895, available at https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2009.178012]. Another study revealed that "more than half (65 percent) of [patients in the study] indicated that they have felt discriminated against by [health care] staff because of their Hispanic ethnicity or LEP" [Footnote 69: William Calo and others, "Experiences of Latinos with limited English proficiency with patient registration systems and their interactions with clinic front office staff: an exploratory study to inform community-based translational research in North Carolina," BMC Health Services Research 15 (570) (2015) available at https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-015-1235-z]. Improving language access services is therefore a critical tool to addressing discrimination against people of color by health care providers.

Improving health care access for people living with disabilities is also 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 National Disability Institute, 14 percent of Black people live with disabilities compared to 11 percent of Non-Hispanic Whites and 8 percent of Latinos [Footnote 70: National Disability Institute, "Financial Inequality: Disability, Race, and Poverty In America," available at https://www.nationaldisabilityinstitute.org/wp-content/uploads/2019/02/disability-race-poverty-in-america.pdf (last accessed September 2022)].

Section 3.1.3 - Age Discrimination; Age Act

Comment Number: HHS-OS-2022-0012-11936-0001
All Sections: 6.2.6, 3.1.3, 6.2.5

(b)(5)

Organization: John Clarke Senior Living

Excerpt Text:
We strongly support Proposed Rule Section 1557 of the Affordable Care Act.

John Clarke increasingly cares for residents of the LGBTQI 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0064
All Sections: 3.1.1, 16, 3.1.3

(b)(5)

Organization: Justice in Aging

Excerpt Text:
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 47,870.] 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0066
All Sections: 9.1, 3.1.3

(b)(5)

Organization: Justice in Aging

Excerpt Text:
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 complained of, or lose their right to relief; [Footnote 60: 45 C.F.R. § 91.42(a).] to be legally sufficient, they must report facts in their 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 their ageism claim or proceed through onerous administrative exhaustion to seek a remedy in court for the intersectional discrimination they experienced.

Comment Number: HHS-OS-2022-0012-DRAFT-68554-0007
All Sections: 4.3.1.1, 6.1, 3.1.3

(b)(5)

Organization: Compassion & Choices

Excerpt Text:
Intersectional Claims that Include 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 ?ling, investigating, and remediating discrimination complaints, including intersectional claims. As Sec. 1557 is its own statute enforceable by private right of action in the courts, an older adult who is discriminated against based on age 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 include regulatory language in the ?nal rule that clari?es that administrative exhaustion is not required to bring an intersectional claim including age under Sec. 1557. We urge HHS to identify other ways to address intersectional discrimination in the regulatory provisions of the rule itself, including making an explicit reference to intersectional discrimination in the regulatory text of Sec. 92.101.

Section 3.1.4 - Disability Discrimination; Section 504; ADA

Comment Number: HHS-OS-2022-0012-DRAFT-66245-0001
All Sections: 3.1.4

(b)(5)

Organization: Institute for Exceptional Care

Excerpt Text:
Individuals with IDD are the subject of current and prevalent discriminatory practices. There is [Hyperlink: physician bias; https://www.downtothestruts.com/episodes/season-2-physicians-healthcare-access-lisa-iezzoni], with 82 percent of clinicians believing that patients with disabilities have a lower quality of life than patients without disabilities eve though many individuals 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 de-prioritized 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/2022/09/13/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,disabilities%20(IDD)%20in%202020.] was more lethal for people with intellectual disability.

Although the [Hyperlink: Americans with Disabilities Act; https://www.statnews.com/2022/01/13/doctors-confused-accommodations-people-disability/] (ADA) mandates that people with disabilities receive equal care and accommodations so they can get proper care, problems with accommodations and equitable care persist. According to a 2019-2020 survey, nearly 36 percent of physicians know little or nothing about their ADA legal duties. There is a lack of accommodations in the physical environment, for alternative methods of communication, and other aspects of care such as quiet spaces for those with sensory challenges. A large barrier for people with IDD is an [Hyperlink: insufficient appointment time; https://www.cdc.gov/ncbddd/disabilityandhealth/disability-barriers.html] with clinicians. It is not uncommon for clinicians to speak to the caregiver or support person, rather than the patient with IDD. [Hyperlink: Patients with developmental disabilities; https://www.apa.org/monitor/2020/11/feature-ada] were less likely to say that they have a clinician who provided good explanations of clinical issues. [Hyperlink: Qualified people with IDD; https://www.cdc.gov/ncbddd/disabilityandhealth/disability-barriers.html] can also be denied access to public? programs and other benefits. [Hyperlink: Many people with IDD are denied organ; https://khn.org/news/article/organ-transplant-discrimination-disabilities-state-legislation/] transplants despite the Americans with Disabilities Act prohibiting this practice. According to a 2008 study, 44 percent of organ transplant centers said they would not add a child with a neurodevelopment disability to the organ transplant list.

Comment Number: HHS-OS-2022-0012-DRAFT-69700-0001
All Sections: 4.3.1.2.7, 3.1.4

(b)(5)

Organization: Senator Kirsten Gillibrand

Excerpt Text:
We write to you today in response to the Department of Health and Human Services (HHS) proposed rule to Strengthen Nondiscrimination in Health Care and to express our support for continued action from HHS to clarify specific guidelines on 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 their 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=3d44507be9-Daily_Recap&utm_medium=email&utm_term=0_8cab1d7961-3d44507be9-148644513> [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. Post-Roe, many autoimmune patients lose access to 'gold standard' drug. [online] Los Angeles Times. Available at: <https://www.latimes.com/california/story/2022- 07-11/post-roe-many-autoimmune-patients-lose-access-to-gold-standard-drug> [Accessed 19 July 2022]]. There are confirmed reports of methotrexate being denied to women of childbearing age, which is the main medication that provides relief to many people with severe arthritis pain [Footnote 5: Rath, L., 2022. New Barrier to Methotrexate for Arthritis Patients. [online] Arthritis.org. Available at: <https://www.arthritis.org/about-us/news-and-updates/new-barrier-to-methotrexate- for-arthritis-patients> [Accessed 14 July 2022]]. Physicians and disability advocates have been clear that continued access to this and similar medications is needed to treat these conditions [Footnote 6: Arthritis.org. 2022. Arthritis Foundation Statement on Methotrexate Access. [online] Available at: <https://www.arthritis.org/about-us/news-and-updates/statement-on-methotrexate- access> [Accessed 19 July 2022]. Cantrell, J. and Saag, MD, MSc, K., 2022. The ACR Responds to Impact of the Dobbs v. Jackson Decision on Rheumatology Patients and Providers - The Rheumatologist. [online] The Rheumatologist. Available at: <https://www.the-rheumatologist.org/article/the-acr-responds-to- impact-of-the-dobbs-v-jackson-decision/> [Accessed 19 July 2022]].

While people with disabilities already face barriers to abortion access, the Dobbs decision has exposed numerous chilling incidents of systemic discrimination against people with disabilities with respect to medical decision-making, medical privacy, and access to treatment [Footnote 7: Ducharme, J., 2022. Abortion Restrictions May Be Making Methotrexate Harder to Access. [online] Time. Available at: <https://time.com/6194179/abortion-restrictions- methotrexate-cancer-arthritis/> [Accessed 14 July 2022]]. It has been reported that people with disabilities are less likely to receive access to critical medications, are more likely to experience high-risk and life- threatening pregnancies, are highly likely to visit doctors or other health care providers who refuse or feel ill-equipped to serve their needs, and are more likely to face barriers to obtaining

care even when they have insurance [Footnote 8: Krahn, G. L., Walker, D. K., & Correa-De-Araujo, R. (2015). Persons With Disabilities as an Unrecognized Health Disparity Population. American Journal of Public Health, 105(S2), S198– S206. https://doi.org/10.2105/AJPH.2014.302182] [Footnote 9: National Institute of Health. 2021. NIH study suggests women with disabilities have higher risk of birth complications and death. [online] Available at: https://www.nih.gov/news- events/news-releases/nih-study-suggests-women-disabilities-have-higher-risk-birth- complications-death [Accessed 19 July 2022] Sarkar, D. (2012). Recurrent pregnancy loss in patients with thyroid dysfunction. Indian Journal of Endocrinology and Metabolism, 16(Suppl 2), S350–S351. https://doi.org/10.4103/2230-8210.104088] [Footnote 10: Iezzoni, L. I., Rao, S. R., Ressalam, J., Bolcic-Jankovic, D., Agaronnik, N. D., Donelan, K., Lagu, T., & Campbell, E. G. (2021). Physicians' Perceptions Of People With Disability And Their Health Care. Health Affairs, 40(2), 297–306. https://doi.org/10.1377/hlthaff.2020.01452] [Footnote 11: Kennedy, J., Wood, E. G., & Frieden, L. (2017). Disparities in Insurance Coverage, Health Services Use, and Access Following Implementation of the Affordable Care Act: A Comparison of Disabled and Nondisabled Working-Age Adults. Inquiry : a journal of medical care organization, provision and financing, 54, 46958017734031. https://doi.org/10.1177/0046958017734031 Lezzoni, L. I., Frakt, A. B., & Pizer, S. D. (2011). Uninsured persons with disability confront substantial barriers to health care services. Disability and Health Journal, 4(4), 238–244. https://doi.org/10.1016/j.dhjo.2011.06.001]. Additionally, a June 2022 memorandum was developed to document the broader legal implications of disability discrimination that could occur in anticipation of the Dobbs decision [Footnote 12: Autisticadvocacy.org. 2022. Memorandum: Dobbs v. Jackson Women's Health Organization and Its Implications for Reproductive, Civil, and Disability Rights. [online] Available at: <https://autisticadvocacy.org/wp-content/uploads/2022/06/Dobbs-memo.pdf> [Accessed 14 July 2022]].

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0011
All Sections: 3.1.4

(b)(5)

Organization: Concerned Women for America

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-69700-0002
All Sections: 7.8.3, 3.1.4, 7.8.4

(b)(5)

Organization: Senator Kirsten Gillibrand

Excerpt Text:
While the Biden administration has recently signed an executive order protecting 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 13: DOBBS, STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH, ET AL. v. JACKSON WOMEN'S HEALTH ORGANIZATION ET AL. [2022] §41–41–191 19-1392 (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 a 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 14: Rosman, K. (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- accessibility-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 issuing guidance to the nation's retail pharmacies, and we know further explicit regulatory action to restore the patient-physician relationship can help our nation take great strides forward to help people with disabilities make health care decisions in a non-coercive environment, in which their lives will be rightfully valued on an equal basis [Footnote 16: U.S. Department of Health And Human Services, 2022. Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services. Office for Civil Rights, pp.1-4]. We urge you to clearly outline: specific guidance surrounding medical professionals 'ability to prescribe life-saving medications to people with disabilities without delay and to include protections for providers who terminate pregnancies with dangerous complications. We urge you to include:

specific guidance surrounding medical professionals 'ability to prescribe life-saving medications to people with disabilities without delay in the final rule to implement Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-65692-0003
All Sections: 4.3.1.2.7, 3.1.4

(b)(5)

Organization: Disability Rights Maine

Excerpt Text:
The "no visitation" policies adopted almost universally among in-patient facilities during 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 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 wellbeing. 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 law 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 award 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 refuse to accommodate Deaf individuals by modifying policies or practices such as having an in-person interpreter when discussing important and vial healthcare information. DRM has had Deaf clients go to hospitals where the video remote interpreting system did not work or it froze, in violation of federal regulations. DRM has had Deaf clients who are in hospitals or nursing homes and do understand the treatment instructions because they are Deaf and the facilities do not accommodate the clients. Deaf clients were administered medications in a nursing home using only notes. The client did not understand what the medications, were, or what the risks were.

Violations of disability civil rights laws occur not only due to intentional ill will. They can happen because of ignorance, neglect, and administrative indifference, as noted in the findings of the ADA. In the arena of health care, covered entities tend to prioritize the establishment of policies, procedures, and a "chain of command" for meeting medical regulations, viewing civil rights regulations as an inconvenient add-on obligation; sometimes even a nuisance. Fortunately, there is a growing awareness across all segments of the healthcare system, from providers to insurers to public health, that technical adherence to medical regulations does not automatically achieve equitable health care and more needs to be done to eliminate embedded systemic and implicit bias.

Comment Number: HHS-OS-2022-0012-DRAFT-66790-0005
All Sections: 3.1.4

(b)(5)

Organization: The Arc of Pennsylvania

Excerpt Text:
6. Highlight unique experiences of intersectionality. Many individuals identify on an intersectional plane, one 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0005
All Sections: 3.1.1, 3.1.4

(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0006
All Sections: 3.1.4

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
The Americans with Disabilities Act and the Rehabilitation Act both prohibit discrimination against people with disabilities, though Section 1557 strengthens these antidiscrimination protections.

Section 4 - Reasons for Proposed Rule

Comments associated with this issue are included in the subsections below

Section 4.1 - Miscellaneous

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0006
All Sections: 15.2, 4.1

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
The Section 1557 proposed rule seeks to replace the 2020 Rule on Section 1557. 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 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: Priyanka Chopra 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/o95OaVB79Hk.] But the mission of HHS is to "enhance the health and well-being of [Italics: 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#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. 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 violations of Section 1557 and Title VI of the Civil Rights Act of 1964, HHS inexplicably dismissed the complaint without any conclusions of law. Nevertheless, HHS states in the Proposed Rule that "ensuring nondiscriminatory access to health care, vaccines, and protective equipment during a public health emergency will more effectively and expeditiously end the emergency for everyone." 87 Fed. Reg. 47831.] rather, the law imposes equal protection and nondiscrimination obligations. Thus, it is arbitrary and capricious for HHS to pursue health equity when it contradicts equality, especially when it would result in illegal discrimination. An elementary principle of civil rights law is that disparities in and of themselves do not prove illegal discrimination. It is therefore incumbent on the Agency to prove any disparities are the result of illegal discrimination in every particular instance. Broad, conclusory, and unsubstantiated allegations of "structural racism on health and health care in the United States" made by the Proposed Rule are insufficient to support the equity mandates contained within it, including the idea that "implicit bias must be addressed." [Footnote 13: 87 Fed. Reg. 47832.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0008
All Sections: 4.1

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
There is no evidence that the 2020 Rule has or will cause any harms or burdens 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 15: 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").]

Section 4.2 - Remove unnecessary confusion in compliance (preamble II.C)

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0007
All Sections: 15.2, 4.2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 substantial concrete evidence is arbitrary and capricious.

Section 4.3 - Consistent with statute/further statutory purpose (preamble II.D)

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0001
All Sections: 4.3, 2
(b)(5)

Organization: Covered California

Excerpt Text:
Section 1557 of the ACA explicitly prohibits discrimination on the basis of race, sex, 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 utilize 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 their 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 buildings and services.

Comment Number: HHS-OS-2022-0012-DRAFT-40175-0006
All Sections: 4.3
(b)(5)

Organization: California Department of Health Care Services

Excerpt Text:

CalHHS believes this NPRM largely alleviates our prior concerns over equity and impeding 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 faced 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 equal and effective access to health care, free from discrimination, for all.

Comment Number: HHS-OS-2022-0012-DRAFT-39933-0007
All Sections: 4.3
(b)(5)
Organization: Minnesota Association of Community Health Centers

Excerpt Text:
MNACHC 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: Thus, MNACHC strongly supports HHS' restoration of and improvements to § 92.207, including its inclusion of specific forms of prohibited discrimination.

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0007
All Sections: 4.3
(b)(5)
Organization: Blue Cross Blue Shield Association

Excerpt Text:
• Consistent Regulatory Requirements. BCBSA 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 tagline could be used for both MA/Part D and the commercial businesses.

Section 4.3.1 - Health equity/health disparities (preamble II.D.1-5)

No comments are associated with this issue

Section 4.3.1.1 - Generally

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0001
All Sections: 4.3.1.1
(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
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 i: 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.

Comment Number: HHS-OS-2022-0012-DRAFT-44581-0001
All Sections: 4.3.1.1
(b)(5)

Organization: Academy of Managed Care Pharmacy (AMCP)

Excerpt Text:
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 directly to adverse health outcomes for a variety of populations, including women, LGBTQ+ 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/lgbt-health-ib.pdf; https://www.medicalnewstoday.com/articles/gender-bias-in-healthcare#examples] [Footnote 3: https://journalofethics.ama-assn.org/article/language-based-inequity-health-care-who-poor-historian/2017-03]. 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 yet decisive 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].

Comment Number: HHS-OS-2022-0012-DRAFT-66814-0001
All Sections: 4.3.1.1

(b)(5)

Organization: American Academy of Child and Adolescent Psychiatry

Excerpt Text:
AACAP strongly supports the proposed rule. It clarifies and strengthens nondiscrimination protections and will reduce barriers to care for patients who have historically been marginalized and underrepresented in the health care delivery system and who carry a greater disease burden, including mental health conditions. A recently published report from the Farley Policy Center illuminates the scope of the problem and demonstrates the economic impact of mental health inequities. [Footnote 1: The-Economic-Burden-of-Mental-Health-Inequities-in-the-US-Report-Final-single-pages.V6.pdf (satcherinstitute.orgl] Mental health is critical to overall wellbeing, but not all Americans have equal access to behavioral health services, such as therapy, medication, and residential treatment. This is true for both children and adults. The report examines the impact of mental health inequities on American society by quantifying the potential economic and health savings that an equitable system would provide.

Researchers conducted a comprehensive literature review, analysis of public data sets, and analysis of state and national policies to demonstrate the relationship between economic status, mental health status, and racial and ethnic status. During the five-year study period between 2016 and 2020, they found:

- At least 116,722 premature deaths due to mental and behavioral health-related racial inequities.
- Racial inequities generated at least $278 billion dollars in excess cost burden

The report makes several policy recommendations that are echoed in many of the proposals in this NPRM, such as ensuring that behavioral healthcare is accessible to those who need it through insurance coverage, adoption of culturally centered mental and behavioral health care, and policy options to address intersectional and specific populations' needs, from pregnant people to LGBTQ+ groups.

We believe that reinstating the Section 1557 regulatory framework to align with the legislative intent in the Affordable Care Act is a critical step in addressing these inequities and we appreciate the agency's focus on ensuring that these important nondiscrimination protections are restored. AACAP member experts would be happy to engage on these topics.

Comment Number: HHS-OS-2022-0012-DRAFT-68065-0001
All Sections: 4.3.1.1

(b)(5)

Organization: National PACE Association

Excerpt Text:
NPA commends the Biden Administration's efforts to advance health equity and notes that the spirit of these anti-discrimination protections is consistent with NPA's broader mission and that of the PACE program.

Therefore, NPA supports HHS' proposed rule, "Nondiscrimination in Health Programs and Activities," without modifications.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0010
All Sections: 7, 4.3.1.1

(b)(5)

Organization: Health Care For All

Excerpt Text:
Protections on the Basis of Race and Ethnicity

While the proposed rule does not 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 Medine 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 a higher rate from COVID-19 [Footnote 14: Jilliam McKoy, 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 in health systems and health policy, § 1557 of the ACA is a significant step towards rectifying centuries of policies and practices that have created worse health outcomes for underserved groups.

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0011
All Sections: 4.3.1.1
(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
These health disparities hurt society as a whole, increasing health care spending and removing people from the workforce. An analysis by the W.K. Kellogg Foundation and Altarum estimated that health disparities cost the United States approximately $93 billion in excess medical care and $42 billion in lost productivity per year, as well as additional losses due to unnecessary and premature deaths. [Footnote 36 ANI TURNER, ALTARUM & W.W. KELLOGG FOUNDATION, THE BUSINESS CASE FOR RACIAL EQUITY 9 (2018), https://altarum.org/sites/default/files/uploaded-publication-files/WKKellogg_Business-Case-Racial- Equity_National-Report_2018.pdf.] Improving health equity is essential to creating a more just and vital society.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0011
All Sections: 4.3.1.1
(b)(5)

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
We also recommend that the Department include examples of forms of discrimination on the basis of pregnancy or related care in the preamble. With the increasing attacks on abortion access, contraception, and fertility care, opponents of reproductive health care have been emboldened to deny care, and it is essential that the Department clearly state the types of conduct that are prohibited under Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0013
All Sections: 4.3.1.1, 2

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
[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 antidiscrimination 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 recommend 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0017
All Sections: 4.3.1.1

(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
The Proposed Rule identifies the proper scope of Section 1557 necessary for antidiscrimination enforcement across health care programs and activities

The former 2020 NPRM was an often inaccurate and restrictive interpretation of the law The Department therefore had limited enforcement power in preventing discrimination. We now offer strong support for the Department's clarification 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 those administered by the Department itself, as well as health insurance plans.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0018
All Sections: 4.3.1.1, 1.6.1.1

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
[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 11: Feibel, Carrie. "Because of Texas Abortion Law, Her Wanted Pregnancy Became a Medical Nightmare." NPR, 26 July 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 heavy on those who experience intersectional discrimination.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0002
All Sections: 4.3.1.1
(b)(5)
Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
At SIECUS, we advocate for the right of young people to have access to accurate and holistic 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 41% of LGBTQAI+ youth [embedded hyperlink text (https://patientengagementhit.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-u-s-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 LGBTQAI+ community can be alleviated.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0021
All Sections: 7.10.1, 7.7.1, 4.3.1.1
(b)(5)
Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-71242-0003
All Sections: 4.3.1.1

(b)(5)

Organization: National Alliance on Mental Illness

Excerpt Text:
[Bold: The proposed rule will strengthen mental health and access to mental health care]

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 i: Graham Thornicroft, Diana Rose and Aliya 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 ii: 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/35/4/888/686369.] and are more likely to underutilize mental health care. [Footnote iii: 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 iv: 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 helps mitigate these negative effects by prohibiting discrimination in health programs and activities receiving federal financial assistance, and extending protection on the basis of race, color, national origin (including language access), sex, age, and disability. It also recognizes that individuals may be part of multiple protected classes and may face discrimination because they belong to one or more of these classes.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0003
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 4.3.1.1, 4.3.1.2.3

(b)(5)

(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
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-lgbtqi-communities/)] by Center for American Progress. 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0032
All Sections: 4.3.1.1

(b)(5)

Organization: Justice in Aging

Excerpt Text:
[Italics: Intersectional Discrimination]

Often the discrimination that older adults experience in health care and LTSS 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 LGBTQI+ person, and/or as a woman. For example, during focus groups Black and Latino 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, 2022), www.commonwealthfund.org/publications/2022/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, overlooked, and/or ignored by the drafters of most civil rights laws, including Title VI, Section 504, Title IX, and the Age Act. So often, 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 provisions 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: 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/.]

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0032
All Sections: 9.1, 4.3.1.1, 6.1

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
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 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) [Italics: General]. (1) Except as prohibited 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 singular standard, regardless of a plaintiff's protected class or classes.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0033
All Sections: 4.3.1.1
(b)(5)

Organization: Justice in Aging

Excerpt Text:
In the preamble of this 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. [Bold: Specifically, we recommend making an explicit reference to intersectional discrimination in the regulatory text of § 92.101.] We propose amending 92.101(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, [Underline: or any combination thereof,]"

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0004
All Sections: 4.3.1.1
(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
To better understand these disparities and challenges faced by the LGBTQAI+ youth, 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 LGBTQAI+ 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 text (https://storage.courtlistener.com/recap/gov.uscourts.txnd.330381/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-lawsuit/)] 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 invariably 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 refute LGBTQIA-affirming healthcare.

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0007
All Sections: 4.3.1.1

(b)(5)

Organization: Covered California

Excerpt Text:
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 QHP issuer accountability 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 align our work on quality and equity. Covered California has also had longstanding contractual requirements for QHP issuers on demographic data collection. Our experiences may prove helpful for both federal and state efforts in this area.

Comment Number: HHS-OS-2022-0012-DRAFT-68554-0007
All Sections: 4.3.1.1, 6.1, 3.1.3

(b)(5)

Organization: Compassion & Choices

Excerpt Text:
Intersectional Claims that Include 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 ?ling, investigating, and remediating discrimination complaints, including intersectional claims. As Sec. 1557 is its own statute enforceable by private right of action in the courts, an older adult who is discriminated against based on age 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 include regulatory language in the ?nal rule that clari?es that administrative exhaustion is not required to bring an intersectional claim including age under Sec. 1557. We urge HHS to identify other ways to address intersectional discrimination in the regulatory provisions of the rule itself, including making an explicit reference to intersectional discrimination in the regulatory text of Sec. 92.101.

Section 4.3.1.2 - Access Barriers to Care and Service

No comments are associated with this issue

Section 4.3.1.2.1 - Race

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0001
All Sections: 4.3.1.2.2, 4.3.1.2.7, 4.3.1.2.1, 4.3.1.2.3
(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-71940-0001
All Sections: 4.3.1.2.2, 4.3.1.2.1
(b)(5)

Organization: Jefferson County Public Health

Excerpt Text:
We applaud the voluntary steps other healthcare systems, federal agencies, and other healthcare partners are taking to ensure that their services are equitable and accessible to all and recognize that some are farther on this path than others. It is encouraging to see a growing focus in healthcare on addressing health inequities and there is much work yet to do. Racism and other

unchecked biases within the healthcare system can lead to patients being neglected, discounted or actively discriminated against, furthering health disparities. Everyone is deserving of respect and dignity, no matter who they are, where they are from, what religious practices they do or do not observe, or what language they speak. No one should be denied healthcare or face additional barriers to quality care because of who they are.

Comment Number: HHS-OS-2022-0012-DRAFT-68873-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: Fenway Community Health Center

Excerpt Text:
Discrimination based on sexual orientation and gender identity (SOGI) negatively affects the health of LGBTQIA+ people and functions as a barrier to care [Footnote 1: Gruberg S, Mahowald L, Halpin J. The state of the LGBTQ community in 2020. A national public opinion study. Washington, DC: Center for American Progress. 2020, October 6. https://www.americanprogress.org/issues/lgbtq- rights/reports/2020/10/06/491052/state-lgbtq-community-2020/]. Discrimination in health care may cause sexual and gender minority patients to have higher rates of medical mistrust, which may constitute a barrier to accessing care [Footnote 2: Ahmed Mirza, Shabab and Rooney, Caitlin (2018). Discrimination Prevents LGBTQ People from Accessing Health Care. Washington, DC: Center for American Progress]. LGBTQIA+ people of color experience intersectional stigma. Racism is a major barrier to care for Black lesbian and bisexual women [Footnote 3: Brenick A, Romano K, Kegler C, Eaton LA. Understanding the Influence of Stigma and Medical Mistrust on Engagement in Routine Healthcare Among Black Women Who Have Sex with Women. LGBT Health. 2017 Feb;4(1):4-10]. Anti-Black stigma is common in predominantly White LGBT settings [Footnote 4: McConnell EA, Janulis P, Phillips G 2nd, Truong R, Birkett M. Multiple Minority Stress and LGBT Community Resilience among Sexual Minority Men. Psychol Sex Orientat Gend Divers. 2018 Mar;5(1):1-12]. The long history of structural stigma and discrimination against Black people in healthcare settings contributes to medical mistrust that acts as a major barrier to accessing care for Black LGBT people [Footnote 5: Quinn KG, Christenson E, Spector A, Amirkhanian Y, Kelly JA. The Influence of Peers on PrEP Perceptions and Use Among Young Black Gay, Bisexual, and Other Men Who Have Sex with Men: A Qualitative Examination. Arch Sex Behav. 2020 Aug;49(6):2129-2143] [Footnote 6: Cahill S, Taylor SW, Elsesser SA, Mena L, Hickson D, Mayer KH. Stigma, medical mistrust, and perceived racism may affect PrEP awareness and uptake in black compared to white gay and bisexual men in Jackson, Mississippi and Boston, Massachusetts. AIDS Care. 2017 Nov;29(11):1351-1358].

Partly as a result of widespread societal discrimination, LGBT people are more likely than cisgender, straight people to live in poverty (22% vs. 16%), with transgender people (29%), bisexual women (29%), and bisexual men (19%) experiencing the highest rates of poverty [Footnote 7: Badget L, Choi S, Wilson B. (October 2019). LGBT Poverty in the United States: A study of differences between sexual orientation and gender identity groups. UCLA School of Law: The Williams Institute. Available at:

https://williamsinstitute.law.ucla.edu/publications/lgbt-poverty-us/]. Furthermore, LGBT people of color had significantly higher rates of poverty compared to their White counterparts [Footnote 8: Ibid].

Lack of access to health insurance is also a key correlate of health disparities. Sexual minority women are less likely to have health insurance and a primary care provider than heterosexual women. An analysis of 2013-2015 National Health Interview Survey data found that lesbian and gay women were significantly less likely to have health insurance (80.7% of sexual minority women versus 85.2% of heterosexual women) and a usual primary care provider (79.6% of sexual minority women versus 84% of heterosexual women) compared to heterosexual women [Footnote 9: Lunn MR, Cui W, Zack MM, Thompson WW, Blank MB, Yehia BR. Sociodemographic Characteristics and Health Outcomes Among Lesbian, Gay, and Bisexual U.S. Adults Using Healthy People 2020 Leading Health Indicators. LGBT Health. 2017 Aug;4(4):283-294. doi: 10.1089/lgbt.2016.0087. Epub 2017 Jul 20. PMID: 28727950; PMCID: PMC5564038]. Striking racial/ethnic disparities in insurance coverage—with American Indians and Alaska Natives, Hispanics, and Black people less likely to be insured than White non-Hispanic and Asian Pacific Islander people—also affect LGBTQI+ people of color [Footnote 10: Artiga S, Hill L, Orgera K, Damico A. Health coverage by race and ethnicity, 2010-2019. Kaiser Family Foundation. July 16, 2021. https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/].

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0010
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1
(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
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 Mahowal, 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 Caroline Medina, 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0012
All Sections: 4.3.1.2.1, 4.3.1.2.3
(b)(5)

(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
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. 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 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-Womens- Procreative-Liberty-Amicus-Brief.pdf.] Birth control gave Black people control over their health and their lives. [Footnote 39 Id. at 13 ("The ability to control whether to give birth is a fundamental component of freedom for all women. But for Black women, whose procreation had been forced, monetized, and monitored since they arrived on American shores, access to birth control represented a unique form of liberty.").]

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0013
All Sections: 4.3.1.2.1, 4.3.1.2.3
(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
Unfortunately, Black Americans continue to face unique obstacles to controlling if, 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 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 Desert? 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/PMC6660992/pdf/nihms-1017159.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-ma-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 clinics to close, 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 costs of the procedure and related travel, these barriers often meant that they could not access abortion even where it was technically legal. [Footnote 44 Artiga, et al., supra note 30.]

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0014
All Sections: 4.3.1.2.1, 4.3.1.2.3

(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
The Dobbs decision has had immediate and significant impacts on Black communities. As of August 16, 2022, most abortions are now banned in 17 states, and five more states are expected to or likely to 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/2022/06/24/abortion-state-laws-criminalization-roe/ (last visited 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/2022-08-23/black- women-are-hardest-hit-by-abortion-restrictions-sweeping-the-deep-south?leadSource=uverify%20wall.]

Delays and denials of abortion care will 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, 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 (July, 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 that Black people would see a 33% increase in deaths under a total abortion ban—the highest of any racial group. [Footnote 49 Amanda Jean Stevenson, The Pregnancy-Related Mortality Impact of a Total Abortion Ban in the United States: A Research Note on Increased Deaths Due to Remaining Pregnant, 58 DEMOGRAPHY 2019 (2021), https://read.dukeupress.edu/demography/article/58/6/2019/265968/The-Pregnancy-Related-Mortality-Impact-of-a- Total.]

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0016
All Sections: 4.3.1.2.7, 4.3.1.2.1, 4.3.1.2.3

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[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 47,832. 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0002
All Sections: 4.3.1.2.1

(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
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'd encourage 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1
(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:
As health care providers we have witnessed first-hand the harm discrimination 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.apa.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-death-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 all Black people reporting this happens often or very often [embedded hyperlink text (https://patientengagementhit.com/news/one-quarter-of-adults-report-racial-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 [embedded hyperlink text (https://www.nationalpartnership.org/our-work/health/reports/black-womens-maternal-health.html)]to die from a pregnancy related cause than white women. For LGBTQ+ people, pervasive discrimination also discourages a significant number of patients from seeking health care. According to data from the Center for American Progress [embedded hyperlink text (https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/)], 8 percent of all LGBTQ+ people and 14 percent of those who had experienced discrimination on the basis of their sexual orientation or gender identity in the past year – avoided or postponed needed medical care. Among transgender people 22 percent reported such

avoidance. The pervasive discrimination in our health care systems must be addressed through robust implementation and enforcement of Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: Colors+

Excerpt Text:
These problems persist in 2022. Data in a 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" [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 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 risk for anxiety, depression, suicidality, obesity, isolation, and bullying/assault because of how society, individuals, and organizations respond to them. This rule would be vital in not only allowing our LGBTQ+ youth to survive, but thrive as young people and adults. We want to support our youth in becoming healthy individuals and community members with this rule, we can make a big step toward doing that.

Comment Number: HHS-OS-2022-0012-DRAFT-65871-0002
All Sections: 4.3.1.2.1

(b)(5)

Organization: AARP

Excerpt Text:
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, deal 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 2030 due to these inequities in health care access.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0002
All Sections: 4.3.1.2.1, 7.8.3

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
Diminished trust in health care providers is likely to increase in the wake of [Italics: Dobbs]. We expect a stark increase in prosecution for self-managed abortion; likely, 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 Criminalization 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 (Jul. 3, 2022), https://www.npr.org/2022/07/03/1109015302/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/ (citing 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 Dirks, Criminalization of Pregnancy has Already Been Happening to the Poor and Women of Color, NPR (Aug. 3, 2022), https://www.npr.org/2022/08/03/1114181472/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: This has already occurred while the protections of Roe were intact. Pregnant people have been investigated, penalized, and even incarcerated where there is suspicion that a person was responsible for the termination of their pregnancy. See Brief for If/When/How: Lawyering for Reproductive Justice et al. as Amici Curiae Supporting Petitioners, June Medical Services L.L.C v. Russo, 140 S. Ct. 2103 (2020) (No. 18-1323), at 3, https://www.if whenhow.org/resources/amicus-brief-june-v-gee/.] This growing health crisis has exacerbated unjustifiable dangers to pregnant people, as the criminalization of pregnancy outcomes harms the health and wellbeing of patients and violates their civil and human rights. [Footnote 27: Brief for Experts, Researchers, and Advocates Opposing the Criminalization of People Who Have Abortions, as Amici Curiae Supporting Respondents, Dobbs v. Jackson Women's Health Organization, et al., 142 S.Ct. 2228 (2022) (No. 19-1392 at ii).]

The burden of abortion bans falls disproportionately on people of color and others at the intersection of marginalized identities, who already face disproportionate discrimination within the health care system as well as higher rates of poverty and policing. [Footnote 28: Brief for If/When/How: Lawyering for Reproductive Justice et al. as Amici Curiae Supporting Petitioners, June Medical Services L.L.C v. Russo, 140 S. Ct. 2103 (2020) (No. 18-1323), at 3, https://www.ifwhenhow.org/resources/ amicus-brief-june-v-gee/; A Post Roe America: The Legal Consequences of the Dobbs Decision Before the Sen. Comm. on the Judiciary, 117th Cong. 11-12 (2022) (statement of Kharia M. Bridges, Professor of Law, UC Berkeley School of Law) https://www.judiciary.senate.gov/meetings/a-post-roe-america-the-legal-consequences-of-the- dobbs-decision.] Even prior to the overturn of Roe, people of color, especially Black pregnant people, were prosecuted for the outcomes of their pregnancies at disproportionate rates, including by using fetal assault laws, or policies that punish or penalize pregnant people for substance use during pregnancy. [Footnote 29: In one instance, a South Carolina hospital serving a predominantly Black and low-income community engaged in targeted searches of pregnant women for narcotics and assisted the arrests, prosecution, and incarceration of pregnant Black women and those who recently gave birth; women were removed from their hospital beds in handcuffs and shackles. Ferguson v. Charleston, 532 U.S. 67 (2001).] Often this prosecution occurred with the assistance of the pregnant person's health care provider. A study of 413 cases in which pregnant women were arrested or otherwise deprived of their liberty on the basis of harm or perceived harm to a fetus found that 58 percent were reported by hospital personnel. [Footnote 30: See Lynn M. Paltrow & Jeanne 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 Pol., Pol'y & L. 299, 311 tbl. 1 (2013).] In particular, Black pregnant people who suffered from stillbirths, miscarriages, or simply alerted their doctors to substance use, irrespective of pregnancy outcomes, have been and continue to be incarcerated with the

assistance of the health care system. [Footnote 31: Sandhya Dirks, Criminalization of Pregnancy Has Already Been Happening to the Poor and Women of Color, NPR (Aug. 3, 2022) https://www.npr.org/2022/08/03/1114181472/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); Cortney Loller, Criminalizing Pregnancy, 92 Indiana Law Journal 947 (2017).] With the rapid increase of states criminalizing abortion post-[Italics: Roe], patients will question whether they can trust their providers with their full medical history, or trust them with their pregnancy-related care at all. [Footnote 32: Making Abortion a Crime (Again), IF/WHEN/HOW (2022), https://www.ifwhenhow.org/resources/making- abortion-a-crime-again/.]

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0021
All Sections: 4.3.1.2.7, 4.3.1.2.5, 4.3.1.2.1, 4.3.1.2.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:
Discrimination in health care remains a widespread problem for LGBTQI+ people, especially for LGBTQI+ people of color, transgender people, and people with intersex traits [Footnote 31: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/ ; Shabab Ahmed Mirza and Caitlin Rooney, "Discrimination Prevents LGBTQ People from Accessing Health Care," (Washington: Center for American Progres, 2018), available at https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/]. LGBTQI+ individuals may experience discrimination when a health care provider refuses to provide them with care due to their sexual orientation, gender identity, or variations in sex characteristics. New data from CAP's nationally representative survey emphasize that discrimination in the form of denial of care by a health care provider is a significant concern among LGBTQI+ people. For example, in the past year [Footnote 32: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/]:

? 17 percent of LGBQ respondents reported having concerns that if they disclosed their sexual orientation to a health care provider, they could be denied good medical care.

? 49 percent of transgender or nonbinary respondents reported having concerns that if they disclosed their gender identity to a health care provider, they could be denied good medical care.

? 61 percent of intersex respondents reported having concerns that if they disclosed their intersex status to a health care provider, they could be denied good medical care.

CAP's 2022 survey also examined instances when doctors or other health care providers refused to provide care to LGBTQI+ respondents in the year prior. According to the data, overall [Footnote 33: Ibid]:

? 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 past year.

? 32 percent of transgender or nonbinary respondents, including 46 percent of transgender or nonbinary respondents of color, reported that, in the past year, they experienced at least one kind of care refusal by a health care provider.

? 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.

Not only does health care discrimination directly negatively affect the mental and physical health of LGBTQI+ people, but it also engenders avoidance behavior, delays, or denials of care that exacerbate health disparities among LGBTQI+ populations [Footnote 34: See National Academies of Sciences, Engineering, and Medicine, "Understanding the Well-Being of LGBTQI+ Populations" (Washington: 2020), available at https://www.nap.edu/read/25877/chapter/1]. For example, according to CAP's nationally representative survey data from 2022 [Footnote 35: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/]:

? 23 percent of LGBTQI+ people - including 27 percent of LGBTQI+ respondents of color, 32 percent of LGBTQI+ respondents with disabilities, 37 percent of transgender or nonbinary respondents, and 50 percent of intersex respondents - 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. By comparison, 7 percent of non-LGBTQI+ people reported the same.

? 21 percent of LGBTQI+ people - including 26 percent of LGBTQI+ respondents of color, 28 percent of LGBTQI+ respondents with disabilities, 41 percent of transgender or nonbinary respondents, and 42 percent of intersex respondents - reported that in the past year they postponed or avoided getting preventive screenings due to disrespect or discrimination from doctors or other health care providers. By comparison, 7 percent of non-LGBTQI+ people reported the same.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0028
All Sections: 4.3.1.2.2, 4.3.1.2.7, 4.3.1.2.1, 5.11, 4.3.1.2.3

(b)(5)

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:

[Bold: B. The final rule must require disaggregated data collection]

The availability 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: 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 & Mark V. Johnston, Relationships between level of disability and receipt of preventive health services, Archives of Physical Medicine and Rehabilitation, 749 (2004).] Racial and ethnic minorities with disabilities experience greater disparities in diagnoses and utilization of assistive technology. [Footnote 22: D.S. Mandell et al., Racial/ethnic disparities in the identification of children with autism spectrum disorders, Am. J. Public Health 493 (2009); H.S. Kaye, P. Yeager & M. Reed, Disparities in usage of assistive technology among people with disabilities, 20 Assist. Technol. 194 (2008).]

While investigations of alleged discrimination sometimes focus on variations based on a single demographic variable, in our increasingly multicultural society, it is imperative that HHS's civil

rights enforcement should support these types of analyses. This requires standardized categories and definitions for all these demographic variables and relevant combinations. The department must act decisively and require covered entities to collect demographic data, as existing data collection efforts are insufficient.

Additionally, the department must ensure that data collected is maintained safely and securely by the appropriate entities. Strict standards must be adopted to make clear that data cannot be used for negative actions such as immigration or law enforcement, redlining, or targeting of specific groups. While requests for data should be required, individuals' responses must be voluntary and should be self-reported to ensure accuracy. It is critical to train relevant staff on the collection of demographic data, including how to explain why data is being collected. These policies will help to ensure that data collected can be best utilized to prevent discrimination and disparities in health care access and outcomes.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0029
All Sections: 4.3.1.2.1, 7.7.1, 7.6.1, 4.3.1.2.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:

iv. The Final Rule must enumerate specific forms of discrimination related to pregnancy or other related conditions, including termination of pregnancy.

Throughout the Final Rule, we urge the Department to specifically name and include – both in the text and preamble, including the language specified in § 92.206 and § 92.207 – examples of discrimination related to the full range of reproductive health care and type of services. The Final Rule must name the full range of reproductive health care protected from discrimination. Section 1557's protection against sex discrimination includes protections against discrimination relating to all reproductive health decisions. Specifically, the Final Rule must explicitly name that Section 1557 reaches discrimination related to fertility care, contraception, mistreatment in maternity care, and sex discrimination in access to medications and treatments for disabilities and emergency medical conditions.

With respect to discrimination against people seeking or accessing fertility treatment, it is essential that the Final Rule explicitly name that Section 1557's protects against discrimination on this basis because discrimination persists in the context of accessing infertility diagnosis, treatment, and services including assisted reproductive technology. Sex discrimination in the context of fertility care can take many forms. Some insurance companies refuse to cover certain types of care that are traditionally used by women (e.g., in vitro fertilization (IVF)) [Footnote 48: Gabriela Weigel et al., Kaiser Family Foundation, Coverage and Use of Fertility Services in the U.S. (2020), https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-

fertility-services-in-the-u-s/. These benefit exclusions disproportionately affect women of color due to racial disparities in the rate of certain diseases that may cause infertility. See Jennifer O'Hara, Mayo Clinic Q&A Podcast: The Link Between Racial Disparities and Cervical Cancer, Mayo Clinic News Network (Jan. 10, 2022), https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-qa-podcast-the-link-between-racial-disparities-and-cervical-cancer/#:~:text=Hispanic%20women%20have%20the%20highest,Race%20is%20a%20social%20construct(describing that Hispanic women have the highest incidence rate of cervical cancer, followed by non-Hispanic Black women)]. Even in those states that do require insurance providers to provide IVF, some insurance providers require that patients use their "spouse's sperm" to fertilize their eggs to be eligible for IVF insurance coverage, discriminating against patients based on their marital status, sexual orientation, and gender identity [Footnote 49: E.g., Haw. Rev. Stat. § 431:10A-116.5 (1987); Ark. Code R. 054.00.1–5(B) (1991). Furthermore, Texas, which only requires insurance providers to offer IVF insurance, also includes this same eligibility requirement. See Tex. Ins. Code Ann. § 1366.005]. In a recent example of discrimination on the basis of sexual orientation and marital status, OSF HealthCare, a self-insured Catholic hospital system with facilities in Illinois and Michigan, recently adopted an insurance policy for its employees that limits IVF coverage to "married couple[s] of opposite sex spouses" [Footnote 50: Shira Stein, Hospital Chain Blocks Fertility Coverage for Its LGBTQ Employees, Bloomberg L. (July 18, 2022), https://news.bloomberglaw.com/health-law-and-business/hospital-chain-blocks-fertility-coverage-for-its-lgbt-employees https://www.bgov.com/core/news_articles/RF7N4HT0G1LX].

Additionally, public and private insurers often discriminate against patients based on sex by requiring that they meet outdated and heteronormative definitions of infertility before providing IVF coverage. For example, relying on a 2013 definition of infertility that has since been rescinded by the American Society of Reproductive Medicine, many insurer require simply that patients in different-sex relationships attest that they have unsuccessfully tried to become pregnant by having unprotected sex for six months or a year, depending on their age, but require same-sex couples and single individuals to undergo six to twelve unsuccessful cycles of intrauterine insemination (IUI) at their own expense before deeming them eligible for IVF coverage [Footnote 51: Compare Practice Committee of the American Society for Reproductive Medicine, Definitions of Infertility and Recurrent Pregnancy Loss: A Committee Opinion, 99 Fertility & Sterility 63, 63 (2013) (defining infertility as "a disease defined by failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination," with Practice Committee of the American Society for Reproductive Medicine, Definitions of Infertility and Recurrent Pregnancy Loss: A Committee Opinion, 113 Fertility & Sterility 533, 533 (2020) (defining infertility as "a disease historically defined by the failure to achieve a successful pregnancy after 12 months or more of regular, unprotected sexual intercourse or due to an impairment of a person's capacity to reproduce either as an individual or with her/his partner")]. These patients are thereby forced to absorb exorbitant costs out of pocket and are delayed or denied access to IVF coverage benefits solely due to their sexual orientation [Footnote 52: See Goidel complaint, supra note TK, at ¶ 8 (describing that a patient was forced to pay out of pocket $45,000 to achieve a successful pregnancy after she was denied coverage for the benefits in her plan because, as a queer woman, she could not attest to engaging in heterosexual sex)].

Studies have found that physicians may consciously or unconsciously block patients from accessing fertility treatment by making assumptions or possessing biases about who can or deserves to be a parent and who wants or deserves fertility treatment. For example, women of color "have reported 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 53: The Ethics Committee of the American Society for Reproductive Medicine, Disparities in Access to Effective Treatment for Infertility in the United States: An Ethics Committee Opinion, 116 FERTILITY & STERILITY 54, 57 (2021) (discussing the various inequitable barriers to fertility care), 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]. We urge the Department to clarify in the regulatory text that such discrimination in health care, including in the context of seeking or accessing fertility care, is impermissible discrimination on the basis of sex under Section 1557, and to include examples of a broad range of impermissible sex discrimination in the context of seeking or accessing fertility care in the Final Rule.

With respect to contraception, the Final Rule must make clear that Section 1557 prohibits discrimination against those seeking contraception or specific types of contraception. The Final Rule also should include the examples included in the guidance that the Department issued on July 13, 2022, to retail pharmacies, responding to incidents occurring after Dobbs, and explicit clarification of other types of discrimination against those seeking contraception [Footnote 54: U.S. DEPT. OF HEALTH & HUM. SERVS., GUIDANCE TO NATION'S RETAIL PHARMACIES: OBLIGATIONS UNDER FED. C.R. L. TO ENSURE ACCESS TO COMPREHENSIVE REPRODUCTIVE HEALTH CARE SERVS. (Jul. 13, 2022), https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html#:~:text=Pharmacies%2C%20therefore%2C%20may%20not%20discriminate,medications%20and%20how%20to%20take]. Additional examples could include: a state program that otherwise provides coverage of contraceptives but excludes a specific contraceptive because of an assertion that the contraception causes an abortion or a provider network that would only include facilities that refuse to perform female sterilization procedures [Footnote 55: In addition to violating section 1557, a state program in this instance may also be violating the ACA contraceptive coverage requirement. The Department has already made clear that the ACA contraceptive coverage requirement is a floor for coverage. Should a state restriction on contraceptives make compliance with the ACA's contraceptive coverage requirement impossible, the federal government will step in to enforce the ACA. Dep'ts of Lab., Health & Hum. Serv., & Treasury, FAQs About Affordable Care Act Implementation Part 54 (July 28, 2022) at 7, https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf]. The Department must also specify that items or services related to contraception are also protected [Footnote 56: In the context of insurance coverage requirements, the Department already recognizes that any item or service necessary to access contraception is part of contraception. Dep'ts of Lab., Health & Hum. Serv., & Treasury, supra note 22, at 10]. Additional medications or services are often needed to facilitate use of contraception, such as anesthetics for insertion of long-acting reversible contraceptives. For example, a pharmacy

refusal to provide misoprostol to a patient who was prescribed it in order to make IUD insertion easier could be a Section 1557 violation.

Additionally, the Final Rule must make clear that Section 1557 prohibits discrimination where a patient is denied medications or treatments for care unrelated to abortion because the medicine is also used for abortion care. Dobbs emboldened covered entities to start denying medications and treatments for chronic health conditions and other disabilities that could prevent, complicate, or end pregnancies or fertility. As the Department has already recognized in its July 13, 2022 guidance, Section 1557 prohibits discrimination in the form of refusing to fill prescriptions for medications that are considered "abortifacients" but may be prescribed to treat other health conditions, such as cancer, arthritis, and ulcers [Footnote 57: U.S. DEPT. OF HEALTH & HUM. SERVS., supra note 21]. This form of discrimination has occurred in states where abortion is now banned [Footnote 58: Katie Shepherd & Frances Stead Sellers, Abortion Bans Complicate Access to Drugs for Cancer, Arthritis, Even Ulcers, WASH POST (Aug. 8, 2022), https://www.washingtonpost.com/health/2022/08/08/abortion-bans-methotrexate-mifepristone-rheumatoid-arthritis/]. Similarly, the drug mifepristone is currently being tested for treating breast cancer, brain cancer, prostate cancer, alcoholism, post-traumatic stress disorder, and depression, among other conditions [Footnote 59: Caroline Hopkins, The 'Abortion Pill' May Treat Dozens of Diseases, but Roe Reversal Might Upend Research, ABC NEWS (June 25, 2022), https://www.nbcnews.com/health/health-news/abortion-pill-may-treat-dozens-diseases-roe-reversal-might-upend-resea-rcna34812]. It also is approved for termination of pregnancies. Following the Dobbs decision, patients who could be pregnant are at risk when seeking mifepristone for purposes besides abortion. Patients being refused any form of health care—because of stereotyping that the patient could be pregnant and having an abortion—falls under Section 1557's protections. To this end, the Final Rule must include language in § 92.206 and § 92.207 addressing the denial of medications or treatments that could prevent, complicate, or end pregnancies yet are prescribed for purposes beyond sexual and reproductive health care, including treatment for severe chronic conditions [Footnote 60: See U.S. DEPT. OF HEALTH & HUM. SERVS., supra note 21; see also Shepherd & Sellers, supra note 25].

The Final Rule should make clear that Section 1557 protects against discriminatory refusals to provide information or referrals about abortion and other reproductive health care. Section 1557 prohibits refusing to provide information, resources, or referrals about abortion care and other reproductive health care. Such discriminatory refusal of care constitutes discrimination based on pregnancy or related conditions. For example, many Indigenous individuals rely on Indian Health Service for health care, but IHS facilities often fail to provide information to patients about abortion care or counseling about pregnancy options [Footnote 61: Ex. F Decl. of Rachael Lorenzo 15, Nov. 18, 2020, 1:20-cv-11297-PBS]. These are forms of sex-based discrimination that Section 1557 protects against. Providers who operate in states that ban abortion may also be emboldened to deny information about abortion that a patient can receive outside of their state, even if such information is not unlawful to provide. It is critical for the Final Rule to make clear to providers, hospitals, and other entities subject to Section 1557 requirements their responsibility to continue providing information and referrals relating to a pregnancy, including termination of pregnancy.

The Final Rule should also make clear that Section 1557 protects against discrimination based on a person's actual or perceived decision relating to abortion care. In the preamble discussion of § 92.206, the Department should include examples making clear that it is discriminatory to refuse to provide health care because of a patient's actual or perceived abortion care history, because doing so is discrimination based on sex. Patient health suffers when a provider's own biases against abortion are substituted for necessary medical care. Not only is the patient denied the immediate care they need, but also the patient's trust in the health care system erodes when they do not feel safe with their providers and may even fear consequences for disclosing their medical history. This is precisely the discrimination that Section 1557 was meant to address.

Additionally, the Final Rule should make clear that Section 1557 prohibits discrimination related to discrimination in maternity care. Pregnant Black, Indigenous, Latina/x, 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 mistreatment during labor and delivery [Footnote 62: Saraswathi Vedam, et al. The Giving Voice to Mothers study: inequity and mistreatment during pregnancy and childbirth in the United States. Reprod Health 16, 77 (2019). https://doi.org/10.1186/s12978-019-0729-2]. For example, in a 2018 California survey, Black, Asian, and Pacific Islander women who gave birth in hospitals reported higher rates of unfair treatment, harsh language, and rough handling than white women [Footnote 63: Carol Sakala et al., National Partnership for Women & Families, Listening to Mothers in California: A Population-Based Survey of Women's Childbearing Experiences, Full Survey Report, 64-65 (Sept. 2018) https://www.chcf.org/wp-content/uploads/2018/09/ListeningMothersCAFullSurveyReport2018.pdf]. Among subspecialty provider offices, 44 percent of gynecology offices were inaccessible due to factors such as inaccessible equipment and lack of transfer assistance, leaving wheelchair users unable to access abortion or maternal care [Footnote 64: Tara Lagu, MD, MPH, et al. Access to Subspecialty Care for Patients With Mobility Impairment, Annals of Internal Medicine, (2013). https://www.acpjournals.org/doi/10.7326/0003-4819-158-6-201303190-00003]. Section 1557 implementing regulations must address this discrimination.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0003
All Sections: 4.3.1.2.1
(b)(5)
Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
Additionally, people 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 12% and 10% 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0003
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 4.3.1.1, 4.3.1.2.3

(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
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-lgbtqi-communities/)] by Center for American Progress. 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0030
All Sections: 6.2.1, 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:
The 2022 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. Proscribing discrimination on these bases will improve health care access for LGBTQI+ people of color, in particular. Further, transgender people of color face significant barriers to health care access. As noted in a 2021 CAP report, transgender people of color more frequently experience denial of care and medical abuse than white transgender people [Footnote 71: Caroline Medina and others, "Protecting and Advancing Health Care for Transgender Adult Communities" (Washington: Center for American Progress, 2021), available at https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/]. That report further notes that transphobia is often inseparable from racism and sexism in the medical system.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0031
All Sections: 4.3.1.2.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:
OCR properly notes that racial health disparities in the United States are directly attributable to "persistent bias and racism" in the health care 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0032
All Sections: 6.2.1, 4.3.1.2.1, 6.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:
X. The Proposed Rule Addresses Discriminatory Conduct that Disproportionately Impacts Communities of Color

While the Proposed Rule does not have specific provisions related 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. Given the deep legacy of racism and other forms of discrimination in health systems and health policy, Section 1557 of

the ACA is a significant step towards rectifying centuries of policies and practices that have created worse health outcomes for underserved groups.

This 2022 Proposed Rule not only clarifies the broad civil rights protections extended in Section 1557, but provides concrete tools to combat racism and other forms of discrimination in health care. First, the 2022 Proposed Rule addresses various forms of discrimination that disproportionately affect communities of color, including on the basis of disability status, age, national origin, and sex. Second, the 2022 Proposed Rule addresses systemic discrimination, including policies and practices that harm people of color. Ultimately, we support this Proposed Rule as an important regulatory effort to address discrimination and racism in health care.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0035
All Sections: 4.3.1.2.1, 7.7.1, 7.6.1, 4.3.1.2.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:

b. Addressing Critical Gaps in the Forms of Prohibited Sex Discrimination Enumerated

We appreciate HHS' enumeration of specific forms of sex discrimination prohibited in § 92.206(b) and § 92.207(b). 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 not refuse gender-affirming care to a patient based on a personal 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(b) and § 92.207(b) to prevent covered entities from using state or local laws that ban 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 Dobbs, we also urge you to add enumerated specific forms of discrimination related to pregnancy and related conditions. In this section of our comments, we offer analysis on how discrimination related to pregnancy and related conditions undermines program access and recommend amendments to the proposed regulatory text. Under § 92.207, we build on this analysis and recommend amendments to address discrimination related to pregnancy and related conditions in health insurance and other health-related coverage.

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, 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, 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 mistreatment during labor and delivery [Footnote 75: Vedam, S., Stoll, K., Taiwo, T.K. et al. The Giving Voice to Mothers study: inequity and mistreatment during pregnancy and childbirth in the United States. Reprod Health 16, 77 (2019). https://doi.org/10.1186/s12978-019-0729-2]. People with disabilities often experience multiple barriers to sexual and reproductive health care [Footnote 76: Agaronnik N, Pendo E, Lagu T, DeJong C, Perez-Caraballo A, Iezzoni LI. Ensuring the Reproductive Rights of Women with Intellectual Disability. J Intellect Dev Disabil. 2020;45(4):365-376. doi: 10.3109/13668250.2020.1762383. Epub 2020 Jun 10. PMID: 35046755; PMCID: PMC8765596. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8765596/]. For example, among subspecialty provider offices, 44 percent of gynecology offices were inaccessible due to factors such as inaccessible equipment and lack of transfer assistance, leaving wheelchair users unable to access abortion or maternal care [Footnote 77: Lagu, Tara, et al. "Access to subspecialty care for patients with mobility impairment: a survey." Annals of Internal Medicine 158.6 (2013): 441-446, available at https://www.acpjournals.org/doi/10.7326/0003-4819-158-6-201303190-00003]. Discrimination persists for many people when accessing infertility diagnosis, treatment, and services, including assisted reproductive technology. It is essential that the Final Rule explicitly name this as prohibited sex discrimination.

When the Supreme Court overturned the constitutional right to abortion in Dobbs, it provoked covered entities to begin discriminatorily denying or erecting barriers to medications and treatments that can prevent, complicate, or end pregnancies. Covered entities are struggling to understand their compliance with rapidly changing state laws. The impacts of Dobbs are compounding preexisting barriers to abortions, contraception, miscarriage management, fertility care, and other sexual and reproductive health care, particularly for communities of color, people with disabilities, the LGBTQI+ community (especially transgender people), and more [Footnote 78: Bella Isaacs-Thomas, "For many pregnant trans people, competent medical care is hard to find," PBS News Hour, May 26, 2021, available at https://www.pbs.org/newshour/health/for-many-pregnant-trans-people-competent-medical-care-is-hard-to-find]. For example, people with disabilities are increasingly denied or subjected to unconscionable barriers to methotrexate, which is regularly used to treat cancer and autoimmune conditions [Footnote 79: Laura Weiss, "Pharmacists and Patients Are Freaking Out Over New Medication Restrictions Post-Roe" The New Republic, July 27, 2022, available at https://newrepublic.com/article/167165/dobbs-pharmacists-walgreens-methotrexate]. We expect that under Dobbs, people with disabilities will face increasing discriminatory denials of and barriers to the vast array of medications and treatments prescribed for their conditions that happen to prevent, complicate, or end pregnancies or fertility. Accordingly, we urge you to amend proposed § 92.206(b) as follows:

(3) 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, italic: 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, [bold, italic: fertility care, or any health services], [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, [bold, underline: transgender status] or gender otherwise recorded.

(5) [Bold, italic: 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, that could 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].

In addition, HHS must strengthen the language pertaining to providers complying with a state or local law as a justification for denying gender-affirming care, abortions, or other reproductive or sexual health care to state unequivocally that Section 1557, as federal law, preempts any such state or local law restricting access to this care.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0037
All Sections: 4.3.1.2.4, 4.3.1.2.1, 4.3.1.2.3, 2

(b)(5)

Organization: Center for American Progress

Excerpt Text:

b. Sex Discrimination in Coverage

U.S. health insurance and other health-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 certain types of care that are traditionally used by women, such as in vitro fertilization (IVF) [Footnote 83: Gabriela Weigel and others, "Coverage and Use of Fertility Services in the U.S." (San Francisco: Kaiser Family Foundation, 2020), available at https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/]. 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 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 that providers do not take their fertility concerns seriously, instead "emphasiz[ing] birth control over procreation" [Footnote 84: Ethics Committee of the American Society for Reproductive Medicine. "Disparities in access to effective treatment for infertility in the United States: an Ethics Committee opinion." Fertility and Sterility 104.5 (2015): 1104-1110, available at 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].

As the 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 from their state family planning programs and contraceptive coverage mandates [Footnote 85: Guttmacher Institute, "Emergency Contraception," available at https://www.guttmacher.org/state-policy/explore/emergency-contraception (last accessed September 2022)]. This results in discrimination against people of color and people with low-incomes who face higher rates of unintended pregnancy and adverse reproductive health outcomes due to these barriers [Footnote 86: American College of Obstetricians and Gynecologists, "Access to Contraception" available at https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception (last accessed September 2022)]. Robust enforcement of Section 1557 is necessary to ensure health entities and providers do not perpetuate discriminatory policies against contraceptive care.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0004
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 4.3.1.2.3
(b)(5)
Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0040
All Sections: 4.3.1.2.1

(b)(5)

Organization: Justice in Aging

Excerpt Text:
[Italics: Discrimination Based on Race and Color]

Race-based discrimination in 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 enrollees 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 counseling 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.119.014706.] 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. 29, 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/]

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0041
All Sections: 4.3.1.2.1, 4.3.1.2.6

(b)(5)

Organization: Justice in Aging

Excerpt Text:
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: Ana Sandoiu, '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.]

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0042
All Sections: 4.3.1.2.1, 4.3.1.2.6

(b)(5)

(b)(5)

Organization: Justice in Aging

Excerpt Text:

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 Holgash & 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/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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0049

All Sections: 4.3.1.2.2, 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 5.11, 4.3.1.2.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:

b. Data Collection

We appreciate that the Department recognizes the importance of demographic data collection to understand program populations and advance health equity and that the Proposed Rule acknowledges that demographic data collection and civil rights enforcement are inextricably linked [Footnote 104: HHS has incorporated demographic data collection into its 2022 Equity Action Plan, U.S. Dep't of Health & Hum. Svcs., Equity Action Plan (Apr. 2022), available at https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf, and demographic data collection has long been a stated priority for its subagencies; see, e.g., Ctrs. for Medicare & Medicaid Svcs., The CMS Equity Plan for Improving Quality in Medicare (Sept. 2015), available at https://www.cms.gov/about-cms/agency-information/omh/omh_dwnld-cms_equityplanformedicare_090615.pdf; Ctrs. for Medicare & Medicaid Svcs., CMS Framework for Health Equity 2022-2032 (Apr. 2022); available at https://www.cms.gov/files/document/cms-framework-health-equity.pdf; Ctrs. for Medicare & Medicaid Svcs., CMS Strategic Plan, Pillar: Health Equity (Aug. 2022), available at

https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf].

While the Department considered a demographic data collection requirement outside of Section 1557 regulations, we encourage the Department to adopt a basic demographic data requirement in the Final Rule. Establishing a clear requirement will improve demographic data collection across the agency, enhance civil rights enforcement, and further the Department's goal of advancing health equity.

Investing in demographic data collection across programs and activities used by the public will better equip the Department to equitably serve all people, especially members of historically underserved populations. Establishing demographic data as a function of civil rights monitoring across the agency will also help to ensure and demonstrate compliance with the civil rights requirements of Section 1557.

Currently, health data stratified by key demographic variables such as race, ethnicity, disability, sexual orientation, gender identity, and variations in sex characteristics remains incomplete or inadequate [Footnote 105: For example, see Nat'l Acad. of Sciences, Engineering & Medicine, Understanding the Well-Being of LGBTQI+ Populations 75-81 (White, J., Sepulveda M.J., & Patterson C.J., eds., 2020), available at https://www.ncbi.nlm.nih.gov/books/NBK563325/pdf/Bookshelf_NBK563325.pdf and Bonnelin Swenor, A Need for Disability Data Justice, Health Affairs (Aug. 22, 2022), available at https://www.healthaffairs.org/content/forefront/need-disability-data-justice]. Studies have overwhelmingly shown high acceptability among patients and enrollees in self-reporting race and ethnicity, sexual orientation and gender identity, and other demographic information, given that appropriate steps are taken to support data collection activities [Footnote 106: David Baker et al., Patients' attitudes toward health care providers collecting information about their race and ethnicity, 20 J. Gen. Intern. Med. 895-900 (2005), available at https://pubmed.ncbi.nlm.nih.gov/16191134/; David W. Baker, Romana Hasnain-Wynia, Namratha R. Kandula, Jason A. Thompson, and E. Richard Brown, Attitudes Toward Health Care Providers, Collecting Information About Patients' Race, Ethnicity, and Language, 45 Med. Care 1034 (Nov. 2007)] [Footnote 107: Sean Cahill et al., Do Ask Do Tell: High Levels of Acceptability by Patients of Routine Collection of Sexual Orientation and Gender Identity Data in Four Diverse American Community Health Centers, PLoS One (2014), available at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0107104] [Footnote 108: See, e.g., Chris Grasso et al., Planning and implementing sexual orientation and gender identity data collection in electronic health records, 26 J. Am. Med. Inform. Assoc. 66-70 (2019), available at https://pubmed.ncbi.nlm.nih.gov/30445621/; Pittman et al., Who, When, and How: The Current State of Race, Ethnicity, and Primary Language Data Collection in Hospitals, The Commonwealth Fund (2004), available at https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2004_may_who__when__and_how__the_current_state_of_race__ethnicity__and_primary_language_data_collection_in_ho_hasnain_wynia_whowhenhow_726_pdf.pdf]. Information gathered through these data collections have shaped policy interventions to address disparities and improve access to health care for underserved communities [Footnote 109: See, e.g., U.S. Dep't of Health & Hum. Svcs., HHS Initiatives to Address the Disparate Impact of

COVID-19 on African Americans and Other Racial and Ethnic Minorities (2020), available at https://www.hhs.gov/sites/default/files/hhs-fact-sheet-addressing-disparities-in-covid-19-impact-on-minorities.pdf].

We recognize the Department's concern about dynamic and responsive data collection methods and standards given the fluctuating nature of populations and that understandings of identity continue to evolve. However, the Department's proposal to adopt an approach modeled after the U.S. Department of Education (ED), may not be the most effective means of collecting these data. While we agree that HHS has the authority to require data collection and reporting for compliance reporting under Section 1557 as well as other civil rights statutes, a sub-regulatory approach has thus far not yielded sufficient progress toward standardized demographic data collection within HHS [Footnote 110: See Charly Gilfoil, Nat'l Health L. Prog., Demographic Data Collection in Medicaid & CHIP: CMS Authority to Collect Race & Ethnicity Data (Sept. 7, 2022), available at https://healthlaw.org/resource/demographic-data-collection-in-medicaid-chip-cms-authority-to-collect-race-ethnicity-data/]. Additionally, ED's civil rights data collection program is not an ideal proxy for how the Department could collect demographic data since the Department's scope of demographic data to collect will be larger, it will need to collect these data from more entities, and each entity engages with patients, enrollees, and grantees using different methods and at different frequencies. These differences may pose significant challenges for the Department to standardize and coordinate demographic data collection and report across the agency's many programs and activities.

For these reasons, we believe that a better approach would be for the Department to set a baseline demographic data collection requirement within the 2022 Final Rule and direct each sub-agency or program to set its own requirements and methods for data collection with a specific timeline for implementation. Notably, 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. HHS has already established or acknowledged recommended practices for engaging in demographic data collection in each of these demographic categories. HHS should adopt those existing data collection practices and engage in additional research where necessary.

Whether the Department includes a demographic data collection requirement in the 2022 Final Rule, engages in further rulemaking, or issues sub-regulatory guidance, we offer the following recommendations for principles to guide demographic data collection. Specifically, the Department should develop resources and toolkits for collecting demographic data; provide appropriate training and technical assistance to programs and grantees; adopt clear privacy and nondiscrimination protections; ensure that data collected is maintained safely and securely by the appropriate entities; ensure requests for data are required but that providing demographic data is voluntary and self-reported; set, review, and update minimum standard variables for each demographic category; support analyses based on multiple demographic variables; conduct regular review and meaningfully engage in community feedback; ensure public reporting of data and analysis. It is also essential that strict standards are adopted to make clear that data cannot be used for negative actions such as immigration or law enforcement, redlining or targeting of specific groups.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0005
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1
(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
[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 [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.

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0005
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 4.3.1.2.3
(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
As a result of discriminatory government policies and bias in the health care 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 THURGOOD MARSHALL INST. & INST. ON ASSETS AND SOC. POL'Y AT BRANDEIS UNIV. THE BLACK-WHITE RACIAL WEALTH GAP (2019), https://tminstituteldf.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. 10, 2022), https://www.npr.org/2022/03/10/1085882933/redlining-pollution-racism; Daniel Cusick, 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, MILBANK Q., Jun. 2005, at 247, 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 C. Arcaya & Alina Schnake-Mahl, Health in the Segregated City, NYU FURMAN CTR. (Oct. 2017), https://furmancenter.org/research/iri/essay/health-in-the-segregated-city] Black households also struggle to access healthy food: One out of every five Black households is situated in a food desert, [Footnote 15 Michael Chui, et al., A $300 billion opportunity: Serving the emerging Black consumer, MCKINSEY Q. (Aug. 6, 2021), https://www.mckinsey.com/featured-insights/diversity-and-inclusion/a-300-billion-dollar-opportunity- serving-the-emerging-black-american-consumer.] and communities of color have fewer large supermarkets than predominantly white neighborhoods, even when controlling for income. [Footnote 16 Kelly Brooky, Research Shows Food Deserts More Abundant in Minority Neighborhoods, JOHNS HOPKINS UNIV. MAG. (Spring 2014), https://hub.jhu.edu/magazine/2014/spring/racial-food-deserts/.]

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0006
All Sections: 4.3.1.2.1

(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
Research has also shown that Black Americans often receive inadequate health care 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/NBK220337/.] The literature review further concluded 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 HHS' 2021 National Health Care Quality and Disparities Report, which found that Black

people received worse care than white people across 43 percent of 195 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, D–3–D–51, https://www.ahrq.gov/sites/default/files/wysiwyg/research/ findings/nhqrdr/2021qdr.pdf.]

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0007
All Sections: 4.3.1.2.1, 7.10.1

(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
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 remain identical. [Footnote 21 Rae Ellen Bitchell & 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%20Daily%20Health%20Policy%20Report&utm_medium=email&_hsmi=13 2394588&_hsenc=p2ANqtz--4ODxarsKPHQSQeAfuOeyLJlAbaGTNgUoPyX4KJJqtvaQOUyan-ZRycCujUe8kMR623a6e7lV0KBUtZgGVacR1ynlazQ_Tte4IvXmfHP2n4J1zvI0&utm_content=132394588&utm_s ource=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 discrimination 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 Stare Vartan, Racial 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/.].

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0008
All Sections: 4.3.1.2.1

(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
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 Risa 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-equity-gap-between- whites-and-minorities.]Black infants die at a rate 2.3 times higher than white infants, [Footnote 25U.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%20blacks%2FAfrican %20Americans,to%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.]

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0008
All Sections: 4.3.1.2.7, 4.3.1.2.1, 4.3.1.2.6

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
Improving health care access for 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0009
All Sections: 4.3.1.2.1, 4.3.1.2.3

(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
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/10425271002/.]

Section 4.3.1.2.2 - National Origin (including Language)

Comment Number: HHS-OS-2022-0012-DRAFT-46426-0001
All Sections: 4.3.1.2.2

(b)(5)

Organization: Genesee County Legal Aid Society dba Center for Civil Justice

Excerpt Text:
Language Access

Language access is essential to ensure effective communication 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 healthcare. 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 2019, 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 on 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 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 (not the ADHS-1605) and 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 about the implementation of the translation of documents from MDHHS. (CCJ recently assisted Spanish-speaking individuals and noted that they received these notices in Spanish).

In anticipation of the public health emergency unwinding, MDHHS produced a flyer "Get Ready to Renew Now" in English as part of its Stakeholder Toolkit. CCJ requested that the flyer be translated into Spanish and Arabic. CCJ received a response that the department is primarily focusing on getting updated contact information from beneficiaries and has not translated the flyer. LEP individuals should receive notice in their preferred language to update their contact information to ensure they are not dis-enrolled at the end of the public health emergency even though they remain eligible.

Comment Number: HHS-OS-2022-0012-DRAFT-66598-0001
All Sections: 4.3.1.2.2

(b)(5)

Organization: Farmworker Justice

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0001
All Sections: 4.3.1.2.2, 4.3.1.2.7, 4.3.1.2.5

(b)(5)

Organization: Health Care For All

Excerpt Text:
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 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0001
All Sections: 4.3.1.2.2, 4.3.1.2.7, 4.3.1.2.1, 4.3.1.2.3

(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68054-0001
All Sections: 4.3.1.2.2, 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)

Organization: Washington Health Benefit Exchange

Excerpt Text:
The proposed rule strengthens our state's ability to make progress toward these goals and preserves the gains our state has made to reduce the uninsured rate and improve access to care, particularly for underserved communities, women, LGBTQ Washingtonians, pregnant women, and individuals with limited English proficiency (LEP). The proposed rule aligns with the Supreme Court's 2020 Bostock v. Clayton County opinion which established clear federal protections against employment discrimination based on sexual orientation and gender identity discrimination.

WAHBE supports the overall approach of the proposed rule. It comprehensively addresses discrimination that can contribute to health disparities. The proposed rule reinstates essential protections announced in 2016 and eliminates the confusion and uncertainty created by the later 2020 rulemaking. The 2020 changes excluded many insurers, third-party administrators, and lines of business from being bound by 1557 protections; reduced language access requirements; narrowed the definition of sex as a basis for discrimination; and reduced the scope and applicability of Section 1557 to exclude a variety of HHS programs.

Comment Number: HHS-OS-2022-0012-DRAFT-71940-0001
All Sections: 4.3.1.2.2, 4.3.1.2.1
(b)(5)

Organization: Jefferson County Public Health

Excerpt Text:
We applaud the voluntary steps other healthcare systems, federal agencies, and other healthcare partners are taking to ensure that their services are equitable and accessible to all and recognize that some are farther on this path than others. It is encouraging to see a growing focus in healthcare on addressing health inequities and there is much work yet to do. Racism and other unchecked biases within the healthcare system can lead to patients being neglected, discounted or actively discriminated against, furthering health disparities. Everyone is deserving of respect and dignity, no matter who they are, where they are from, what religious practices they do or do not observe, or what language they speak. No one should be denied healthcare or face additional barriers to quality care because of who they are.

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0011
All Sections: 4.3.1.2.2
(b)(5)

(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
[Bold and Underline: Language Access Requirements]

Immigrant children or 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#detailed/1/any/false/1729,37,871,870,573,869,36,868,867,133/any/445,446] Children in immigrant families are less likely to be insured compared to children of nonimmigrant families. Further, the chilling effect from the Trump Administration's public charge rule has contributed to increased fears 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 Immigrant Families. Pediatrics September 2019; 144 (3): e20192077. 10.1542/peds.2019-2077] Without access to qualified medical interpreters in health care settings, language barriers can place English-speaking children in the unacceptable position of interpreting between health care providers and their family members. [Footnote xxix: 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]
The Academy has previously recommended that all health facilities have access to trained interpreter services. [Footnote xxx: https://downloads.aap.org/DOFA/1557 RFI Comment Letter Final.pdf] Trained medical interpreters, via phone or tablet or in-person, facilitate mutual understanding and a high quality of communication. Use of trained interpreters maintains confidentiality, reduces errors and cost, and increases the quality of health care delivery. Similarly, we strongly support the proposed rule's specific requirements to ensure meaningful

access for individuals with limited English proficiency because they help to prevent discrimination and improve the quality of care for children and families. When in-person interpreter services are not possible, remote interpretation serves as a crucial tool for providers to improve communication with patients and families. [Footnote xxxi: Lion KC, Brown JC, Ebel BE et al. Effect of Telephone vs Video Interpretation on Parent Comprehension, Communication, and Utilization in the Pediatric Emergency Department: A Randomized Clinical Trial. JAMA Pediatr. 2015;169(12):1117-1125. doi:10.1001/jamapediatrics.2015.2630]

Patients and families with LEP need adequate language resources and access to language professionals— including posted signs in multiple languages, written materials, live interpreters (preferably in-person, but also remote video and telephonic interpreters), and dedicated translators of written instructions. Such services are not only crucial for equitable care but have been demonstrated to improve patient care outcomes and satisfaction. [Footnote xxxii: Karliner LS, Jacobs EA, Chen AH, Mutha S. Do professional interpreters improve clinical care for patients with limited English proficiency? A systematic review of the literature. Health Serv Res. 2007;42(2):727-754. doi:10.1111/j.1475- 6773.2006.00629.x] For example, a pediatrician from South Carolina shares the successful experience of a hospital with full-time, in-person interpreters, where parents and pregnant women often drive more than an hour to seek medical care for themselves and their children because they know they will have an in-person interpreter, which they know will improve their capacity to support their own health and well-being. In one instance, a child with severe visual impairment and limited English proficiency was able to connect to primary pediatric care only because the interpreter recognized that he did not have a medical home and called a case manager to facilitate connection to care.

When language services are lacking, patient care suffers. For example, one New England Journal of Medicine article discusses cases of medication being placed in the ear instead of taken by mouth, resulting in paralysis and a $71 million lawsuit. [Footnote xxxiii: Flores G. Language Barriers to Health Care in the United States. N Engl J Med. 2006;355(3):229-231. doi:10.1056/NEJMp058316] A pediatrician from South Carolina shares a patient example from her local community hospital, where a pregnant mother presented in labor without the availability of an interpreter. The mother was subsequently not able to understand the questions or instructions provided due to a language barrier and lack of an interpreter. The infant was admitted to the neonatal intensive care unit, leading to increased medical expenses and serious stress for the family, an admission that may have been preventable and was attributed to communication barrier.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0017
All Sections: 4.3.1.2.2

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[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 53: See Karen Ziegler & Steven A. Camarota, Center for Immigration Studies, 67.3 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 1,088 percent), North Carolina (up 802 percent), Washington (up 432 percent), and Oregon (up 380 percent). Id at 6.] Indeed, it well-known that language-related barriers can severely limit an individual's opportunity to access healthcare services, assess options, express choices, follow medication 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_settingsexamples_from_th e_field_lep_actionkit_reprint_0204_pdf.pdf.]

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0018
All Sections: 4.3.1.2.2, 2

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
In promulgating the 2016 Rule, HHS recognized that national origin discrimination includes discrimination based on the "linguistic characteristics of a national origin group." 81 Fed Reg. at 31,467, 470-71. HHS emphasized that Congress intended, through Section 1557, to find 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 2 (May 1, 2012), https://aspe.hhs.gov/sites/default/files/private/pdf/37346/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 31,410, HHS provided specific

protections to guarantee meaningful access to healthcare for LEP individuals, id. at 31,470-71. [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 medication regimes, 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 31,459.] 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 eviscerated the "meaningful access" requirement. In doing so, HHS cited the financial and administrative burden associated with compliance, but ignored substantial evidence that this change would deny LEP individuals critical language assistance services and access to healthcare.

Comment Number: HHS-OS-2022-0012-DRAFT-69166-0002
All Sections: 4.3.1.2.2
(b)(5)

Organization: UnidosUS

Excerpt Text:
[Bold: Robust civil rights protections are essential for people with limited English 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] 80%.

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 i: UnidosUS 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.mdedge.com/files/s3fs-public/pdfs/journals/658_ftp.pdf] to be readmitted than English-speaking patients. In fact, one study found that patients with LEP who do not receive professional interpretation services at admission spent as many as 1.5 days longer in the hospital, on average, than patients with LEP who do receive [Hyperlink: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3445680/pdf/11606_2012_Article_2041.pdf] these services. Individuals with LEP who have an emergency department (ED) visit are significantly more likely [Hyperlink: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4958500/] to need a return visit within 72 hours—a costly failure for a common measure of ED quality of care.

Language barriers can often contribute to and exacerbate health conditions that Latinos disproportionately suffer from. Latinos have higher rates of hypertension than non-Hispanic Whites, but LEP is also a demonstrated driver of poorer health outcomes for patients with hypertension. LEP Latinos with diabetes also experience better health outcomes when they are treated by bilingual or Spanish-speaking primary care providers, and LEP patients with diabetes more frequently [Hyperlink: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2907435/pdf/nihms188899.pdf] report dissatisfaction with their provider-patient interactions.

Individuals with LEP often face numerous intersecting barriers to health care, including uninsured status, limited health literacy, and racial discrimination and bias within the health system. Even after controlling for various demographic factors such as lack of insurance, income, and education level, individuals with LEP are more likely [Hyperlink: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1490205/] to struggle with medical comprehension. As a result, patients with LEP face challenges adhering to a prescribed course of treatment, partly driven by lack of language-concordant providers and discharge instructions.

LEP is associated with health care underuse among Latinos, whether measured by spending, episodes of care, or prescriptions. This is likely the result of a combination of factors that disproportionately impact Latinos, including lower health literacy, familiarity with what one's health plan covers, and obstacles presented by the digital language divide. [Hyperlink: https://nces.ed.gov/pubs2018/2018161.pdf] Gaps in spending and use raise concerns that language barriers are obstructing [Hyperlink: https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.02510] access to care, resulting in underuse of medical services by LEP Latinos. Strong civil rights protections are one essential tool to help guarantee individuals with LEP can access quality care.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0028
All Sections: 4.3.1.2.2, 4.3.1.2.7, 4.3.1.2.1, 5.11, 4.3.1.2.3
(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
[Bold: B. The final rule must require disaggregated data collection]

The availability 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: 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 & Mark V. Johnston, Relationships between level of disability and receipt of preventive health services, Archives of Physical Medicine and Rehabilitation, 749 (2004).] Racial and ethnic minorities with disabilities experience greater disparities in diagnoses and utilization of assistive technology. [Footnote 22: D.S. Mandell et al., Racial/ethnic disparities in the identification of children with autism spectrum disorders, Am. J. Public Health 493 (2009); H.S. Kaye, P. Yeager & M. Reed, Disparities in usage of assistive technology among people with disabilities, 20 Assist. Technol. 194 (2008).]

While investigations of alleged discrimination sometimes focus on variations based on a single demographic variable, in our increasingly multicultural society, it is imperative that HHS's civil rights enforcement should support these types of analyses. This requires standardized categories and definitions for all these demographic variables and relevant combinations. The department must act decisively and require covered entities to collect demographic data, as existing data collection efforts are insufficient.

Additionally, the department must ensure that data collected is maintained safely and securely by the appropriate entities. Strict standards must be adopted to make clear that data cannot be used for negative actions such as immigration or law enforcement, redlining, or targeting of specific groups. While requests for data should be required, individuals' responses must be voluntary and should be self-reported to ensure accuracy. It is critical to train relevant staff on the collection of demographic data, including how to explain why data is being collected. These policies will help to ensure that data collected can be best utilized to prevent discrimination and disparities in health care access and outcomes.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0003
All Sections: 4.3.1.2.2
(b)(5)
Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
[Bold: A. The proposed rule requires adequate language access services that will improve health care access and outcomes]

Improving language access services is a critical tool to addressing intersectional discrimination. LEP patients often experience inadequate or inaccurate interpretation by the provider, patient's family, or untrained staff, leading to greater patient risk and disparities in health outcomes. It has been long recognized that the denial of adequate language services to LEP individuals constitutes discrimination on the basis of national origin, and there are clear intersections between LEP status and other forms of discrimination. According to the most recent data, 63 percent of LEP individuals are Latino and 21 percent are Asian/Pacific Islander. [Footnote 2: Batalova, Jeanne, et al. "The Limited English Proficient Population in the United States in 2013." Migrationpolicy.org, 8 July 2015, https://www.migrationpolicy.org/article/limited-english-proficient-population-united-states-2013.] Another study noted that a "substantial number of Asian Americans reported encountering racial discrimination and possessing limited English proficiency." [Footnote 3: Gee, Gilbert C., et al.. "Associations Between Racial Discrimination, Limited English Proficiency, and Health-Related Quality of Life Among 6 Asian Ethnic Groups in California." American Journal of Public Health, vol. 100, no. 5, May 2010, pp. 891-892., https://ajph.alphapublications.org/doi/pdf/10.2105/AJPH.2009.178012] Robust language access resources and protections from discrimination are also key to ensuring that older adults, including the more than 6.5 million seniors over age 60 and 4 million people with Medicare who are LEP, can access care and services, receive important health care information in a language they understand, and are informed of their rights and how to enforce them.

Comment Number: HHS-OS-2022-0012-DRAFT-73220-0043
All Sections: 4.3.1.2.2
(b)(5)

Organization: National Immigration Law Center

Excerpt Text:
This comment focuses on support for and recommended improvements to the portions of the rule that relate to ensuring meaningful access to health care services and programs for individuals with limited English proficiency (LEP). Given that nearly half of people born outside the U.S. have LEP, inadequate provision of language services is a major barrier to immigrants' health. [Footnote 1: "State Immigration Data Profiles," Migration Policy Institute, https://www.migrationpolicy.org/data/state- profiles/state/language/US] We also support the rule's proposed provisions around discrimination based on sex and disability, and echo the comments of our partners, including the National Health Law Program and Leadership Conference of Civil and Human Rights. We support the rule's recognition that discrimination is often multifaceted. Like other people, immigrants experience discrimination based on multiple facets of their intersectional identities.

Despite decades of theoretical protections under civil rights laws that ban discrimination against people on the basis of national origin, which courts have interpreted as including on the basis of English proficiency, people with LEP face a variety of health disparities stemming from poor access to language services in medical and health care settings. [Footnote 2 Goenka, Pratichi K. "Lost in translation: impact of language barriers on children's healthcare." Current Opinion in

pediatrics, 2016, https://pubmed.ncbi.nlm.nih.gov/27496057/] This rule creates an important set of standards to strengthen those rights by ensuring that covered entities take step to provide meaningful access to their services. Given that people with LEP experience worse cancer treatment outcomes, barriers to health coverage, and challenges to chronic disease management, this action is needed. [Footnote 3 Qureshi, Muhammad, et al, "The influence of limited English proficiency on outcome in patients treated with radiotherapy for head and neck cancer," Patient Education and Counseling, November 2014, https://pubmed.ncbi.nlm.nih.gov/25190640/ Cook, W.K., John, I., Chung, C. et al, "Medicaid Expansion and Healthcare Access: Lessons from Asian American and Pacific Islander Experiences in California," Journal of Immigrant and Minority Health, 2017, https://link.springer.com/article/10.1007/s10903-016-0496-x#citeas Pandey, M., Maina, R.G., Amoyaw, J. et al, "Impacts of English Language Proficiency on Healthcare Access, Use, and Outcomes Among Immigrants: a Qualitative Study," BMC Health Serv , 2021, https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-021-06750-4] The COVID-19 pandemic has shed light on these trends, with people with LEP testing positively more often and having worse outcomes in hospital settings for COVID treatment. [Footnote 4 Cohen-Cline, Hannah et al, "Major disparities in COVID-19 test positivity for patients with non-English preferred language even after accounting for race and social factors in the United States in 2020," BMC Public Health, November 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8600352/ Wang, P.G., Brisbon, N.M., Hubbell, H. et al. Is the Gap Closing? Comparison of Sociodemographic Disparities in COVID-19 Hospitalizations and Outcomes Between Two Temporal Waves of Admissions. J. Racial and Ethnic Health Disparities (2022). https://doi.org/10.1007/s40615-022-01249-y] Yet when quality language access services are provided, quality of care improves, with reduced readmission rates and lower costs and higher patient satisfaction and use of services. [Footnote 5 Karliner, Leah S. et al, "Convenient Access to Professional Interpreters in the Hospital Decreases Readmission Rates and Estimated Hospital Expenditures for Patients With Limited English Proficiency", Medical Care: March 2017, https://journals.lww.com/lww-medicalcare/Fulltext/2017/03000/Convenient_Access_to_Professional_Interpreters_in.1.aspx Lopez-Bushnell, Frances K.; Guerra-Sandoval, Geraldine; Schutzman, E. Zoe; Langsjoen, Jens; Villalob. "Increasing Communication with Healthcare Providers for Patients with Limited English Proficiency Through Interpreter Language Services Education," July 12 2022, MEDSURG Nursing, https://www.thefreelibrary.com/Increasing+Communication+with+Healthcare+Providers+for+Patients+with...-a0641362810]

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0049
All Sections: 4.3.1.2.2, 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 5.11, 4.3.1.2.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:
b. Data Collection

We appreciate that the Department recognizes the importance of demographic data collection to understand program populations and advance health equity and that the Proposed Rule acknowledges that demographic data collection and civil rights enforcement are inextricably linked [Footnote 104: HHS has incorporated demographic data collection into its 2022 Equity Action Plan, U.S. Dep't of Health & Hum. Svcs., Equity Action Plan (Apr. 2022), available at https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf, and demographic data collection has long been a stated priority for its subagencies; see, e.g., Ctrs. for Medicare & Medicaid Svcs., The CMS Equity Plan for Improving Quality in Medicare (Sept. 2015), available at https://www.cms.gov/about-cms/agency-information/omh/omh_dwnld-cms_equityplanformedicare_090615.pdf; Ctrs. for Medicare & Medicaid Svcs., CMS Framework for Health Equity 2022-2032 (Apr. 2022); available at https://www.cms.gov/files/document/cms-framework-health-equity.pdf; Ctrs. for Medicare & Medicaid Svcs., CMS Strategic Plan, Pillar: Health Equity (Aug. 2022), available at https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf].

While the Department considered a demographic data collection requirement outside of Section 1557 regulations, we encourage the Department to adopt a basic demographic data requirement in the Final Rule. Establishing a clear requirement will improve demographic data collection across the agency, enhance civil rights enforcement, and further the Department's goal of advancing health equity.

Investing in demographic data collection across programs and activities used by the public will better equip the Department to equitably serve all people, especially members of historically underserved populations. Establishing demographic data as a function of civil rights monitoring across the agency will also help to ensure and demonstrate compliance with the civil rights requirements of Section 1557.

Currently, health data stratified by key demographic variables such as race, ethnicity, disability, sexual orientation, gender identity, and variations in sex characteristics remains incomplete or inadequate [Footnote 105: For example, see Nat'l Acad. of Sciences, Engineering & Medicine, Understanding the Well-Being of LGBTQI+ Populations 75-81 (White, J., Sepulveda M.J., & Patterson C.J., eds., 2020), available at https://www.ncbi.nlm.nih.gov/books/NBK563325/pdf/Bookshelf_NBK563325.pdf and Bonnelin Swenor, A Need for Disability Data Justice, Health Affairs (Aug. 22, 2022), available at https://www.healthaffairs.org/content/forefront/need-disability-data-justice]. Studies have overwhelmingly shown high acceptability among patients and enrollees in self-reporting race and ethnicity, sexual orientation and gender identity, and other demographic information, given that appropriate steps are taken to support data collection activities [Footnote 106: David Baker et al., Patients' attitudes toward health care providers collecting information about their race and ethnicity, 20 J. Gen. Intern. Med. 895-900 (2005), available at https://pubmed.ncbi.nlm.nih.gov/16191134/; David W. Baker, Romana Hasnain-Wynia, Namratha R. Kandula, Jason A. Thompson, and E. Richard Brown, Attitudes Toward Health Care Providers, Collecting Information About Patients' Race, Ethnicity, and Language, 45 Med. Care 1034 (Nov. 2007)] [Footnote 107: Sean Cahill et al., Do Ask Do Tell: High Levels of Acceptability by Patients of Routine Collection of Sexual Orientation and Gender Identity Data

in Four Diverse American Community Health Centers, PLoS One (2014), available at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0107104] [Footnote 108: See, e.g., Chris Grasso et al., Planning and implementing sexual orientation and gender identity data collection in electronic health records, 26 J. Am. Med. Inform. Assoc. 66-70 (2019), available at https://pubmed.ncbi.nlm.nih.gov/30445621/; Pittman et al., Who, When, and How: The Current State of Race, Ethnicity, and Primary Language Data Collection in Hospitals, The Commonwealth Fund (2004), available at https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2004_may_who__when__and_how__the_current_state_of_race__ethnicity__and_primary_language_data_collection_in_ho_hasnain_wynia_whowhenhow_726_pdf.pdf]. Information gathered through these data collections have shaped policy interventions to address disparities and improve access to health care for underserved communities [Footnote 109: See, e.g., U.S. Dep't of Health & Hum. Svcs., HHS Initiatives to Address the Disparate Impact of COVID-19 on African Americans and Other Racial and Ethnic Minorities (2020), available at https://www.hhs.gov/sites/default/files/hhs-fact-sheet-addressing-disparities-in-covid-19-impact-on-minorities.pdf].

We recognize the Department's concern about dynamic and responsive data collection methods and standards given the fluctuating nature of populations and that understandings of identity continue to evolve. However, the Department's proposal to adopt an approach modeled after the U.S. Department of Education (ED), may not be the most effective means of collecting these data. While we agree that HHS has the authority to require data collection and reporting for compliance reporting under Section 1557 as well as other civil rights statutes, a sub-regulatory approach has thus far not yielded sufficient progress toward standardized demographic data collection within HHS [Footnote 110: See Charly Gilfoil, Nat'l Health L. Prog., Demographic Data Collection in Medicaid & CHIP: CMS Authority to Collect Race & Ethnicity Data (Sept. 7, 2022), available at https://healthlaw.org/resource/demographic-data-collection-in-medicaid-chip-cms-authority-to-collect-race-ethnicity-data/]. Additionally, ED's civil rights data collection program is not an ideal proxy for how the Department could collect demographic data since the Department's scope of demographic data to collect will be larger, it will need to collect these data from more entities, and each entity engages with patients, enrollees, and grantees using different methods and at different frequencies. These differences may pose significant challenges for the Department to standardize and coordinate demographic data collection and report across the agency's many programs and activities.

For these reasons, we believe that a better approach would be for the Department to set a baseline demographic data collection requirement within the 2022 Final Rule and direct each sub-agency or program to set its own requirements and methods for data collection with a specific timeline for implementation. Notably, 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. HHS has already established or acknowledged recommended practices for engaging in demographic data collection in each of these demographic categories. HHS should adopt those existing data collection practices and engage in additional research where necessary.

Whether the Department includes a demographic data collection requirement in the 2022 Final Rule, engages in further rulemaking, or issues sub-regulatory guidance, we offer the following recommendations for principles to guide demographic data collection. Specifically, the Department should develop resources and toolkits for collecting demographic data; provide appropriate training and technical assistance to programs and grantees; adopt clear privacy and nondiscrimination protections; ensure that data collected is maintained safely and securely by the appropriate entities; ensure requests for data are required but that providing demographic data is voluntary and self-reported; set, review, and update minimum standard variables for each demographic category; support analyses based on multiple demographic variables; conduct regular review and meaningfully engage in community feedback; ensure public reporting of data and analysis. It is also essential that strict standards are adopted to make clear that data cannot be used for negative actions such as immigration or law enforcement, redlining or targeting of specific groups.

Section 4.3.1.2.3 - Sex

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0001
All Sections: 4.3.1.2.3

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:
"Intersex" is an umbrella term encompassing dozens of naturally occurring variations in sex characteristics (such as chromosomes, genitals, internal reproductive organs, and hormone production and response) that may cause an individual's body to differ from typical notions of male or female. The prevalence of intersex traits has been estimated at 1.7%—meaning millions of Americans are born with variations in their sex characteristics—although since this figure does not reflect all known variations, the true prevalence is likely higher. [Footnote 3: Blackless M. et al., How Sexually DimorphicDimorphic Are We? Review and Synthesis, 12 AM. J. HUM. BIOL. 151 (2000).]

Despite the fact that most intersex traits pose no immediate health concerns at birth or in early childhood, children who are discovered to possess an intersex variation are often subjected to surgery to erase their physical differences and make their bodies conform more closely to stereotypes associated with male or female bodies. [Footnote 4: Human Rights Watch, "I Want to be Like Nature Made Me": Medically Unnecessary Surgeries on Intersex Children in the US (2017), https://www.hrw.org/report/2017/07/25/i-want-be-nature-made-me/medically-unnecessary-surgeries-intersex-children-us.]

Health researchers and human rights organizations have documented how "normalizing" surgeries continue to be performed to alter the genitals or remove the gonads of many children with intersex variations—most commonly before age two—absent any evidence of medical need, and insufficient information provided to families on risks and alternative.2 Unlike other cases in

which parents consent to interventions on behalf of their children, such early intersex surgeries violate inherent human rights and raise major ethical concerns due to lack of medical necessity and lifelong impacts on a person's health and reproductive choices, as well as insufficient information given to parents regarding alternatives to and risks of immediate surgery and about accessing psychosocial support in accepting their healthy children.

A 2020 National Academies of Sciences consensus study summarized the "scant evidence [of] psychosocial benefit" from such surgeries and "strong evidence of the risk of irreversible harm." Despite "the absence of data on alternative affirming pathways," it found that in view of human rights concerns and evidence of other SGM populations' ability to thrive with appropriate supports, this evidence was "insufficient evidence of benefit to justify early genital surgery," absent "scenarios with urgent medical need" [Footnote 5: Id. at 378-79.] Notably, the report compared these practices to efforts to change an individual's sexual orientation or gender identity, calling both "dangerous to the health and well-being of sexual and gender diverse people". [Footnote 6: Id. at 380.] Medical associations, [Footnote 7: See, e.g., American Academy of Family Physicians, Genital Surgeries in Intersex Children (Jul. 2018), https://www.aafp.org/about/policies/all/genital-surgeries-intersexchildren.html; Massachusetts Medical Society, Evidence-Based Care of Individuals Born with Differences in Sex Development (DSD)/Intersex (Dec. 7, 2019); http://www.massmed.org/News/Press-Releases/Massachusetts-Medical-Society-announces-policies-on-opioid-use-disorder,-intersex-children-and-e-cigarettes/#.Xz7jNS2z0nU; Michigan State Medical Society, Opposing Surgical Sex Assignment for Infants with Differences of Sex Development, Res. 12-18 (2018), https://www.msms.org/hodresolutions/2018/12.pdf.] major US hospitals, [Footnote 8: Human Rights Watch, NYC Hospitals Prohibit Unnecessary Intersex Surgeries (Jul. 16, 2021), https://www.hrw.org/news/2021/07/16/new-york-city-hospitals-prohibit-unnecessary-intersex-surgeries; Lurie Children's Hospital, Intersex Care at Lurie Children's and our Sex Development Clinic (Jul. 28, 2020), https://www.luriechildrens.org/en/blog/intersex-care-at-lurie-childrens-and-our-sex-development-clinic/; Kimberly Zieselman, Boston Children's Hospital's Change on Intersex Surgeries was Years in the Making (Oct. 23, 2020), https://interactadvocates.org/boston-childrens-hospital-intersex-surgery/.] and global human rights bodies increasingly agree. [Footnote 9: See, e.g., UN OHCHR, Background note on human rights violations against intersex people (2019); UN OHCHR, UN Women, UNAIDS, UNDP, UNFPA, UNICEF & WHO, Eliminating forced, coercive or otherwise involuntary sterilization: An interagency statement (2014); UN OHCHR, Report of the Special Rapporteur on Torture, Juan E. Mendez, UN Doc. A/HRC/22/53 (2013).] Several US legal questions exist, including under laws against discrimination, genital mutilation, forced sterilization. [Footnote 10: See, e.g., 18 U.S.C. § 116; Fraser S., Constructing the female body: using female genital mutilation law to address genital-normalizing surgery on intersex children in the US, 9 INT'L J. HUM. RTS. HEALTH. 62 (2016); Tamar-Mattis A., Sterilization and Minors with Intersex Conditions in California Law, 3 CAL. L. REV. CIRCUIT 126 (2012).] US courts have held parents' general right of medical consent does not extend to elective sterilization. [Footnote 11: See, e.g., Am. Acad. of Pediatrics v. Lungren, 940 P.2d 797, 814–16 (Cal. 1997); In re Moe, 432 N.E.2d 712, 715–18 (Mass. 1982); In re Terwilliger, 450 A.2d 1376, 1381–83 (Pa. Super. Ct. 1982).] Nonetheless, people with intersex variations continue to be harmed by unnecessary and non-consensual surgical interventions and by other discriminatory treatment in health care settings.

Clear interpretation and enforcement of the ACA's protections for intersex people are needed now more than ever, as more and more intersex adults and youth are coming out—or threaten to be outed by growing scrutiny on youth who don't conform to gender stereotypes. State legislation aimed at prohibiting gender-affirming care for transgender youth and adults, while appearing to expressly endorse sterilizing and genital surgeries on intersex children too young to have an opportunity to drive their own health care decisions, serves to reinforce stigma and mistreatment toward intersex people in health care.

Comment Number: HHS-OS-2022-0012-DRAFT-65871-0001
All Sections: 4.3.1.2.3

(b)(5)

Organization: AARP

Excerpt Text:
Discrimination against LGBTQI+ individuals is an issue that threatens the health and personal fulfillment of too many Americans aged 50 plus, and it is particularly problematic when these individuals face discrimination from the entities that they traditionally rely upon for support – especially health care services and institutions. Our 2018 landmark national LGBTQI+ research study, Maintaining Dignity [embedded hyperlink text (https://www.aarp.org/content/dam/aarp/research/surveys_statistics/life-leisure/2018/maintaining-dignity-lgbt.doi.10.26419%252Fres.00217.001.pdf)], found that while LGBTQI+ individuals are largely satisfied with their current health care relationships, they are also fearful of discrimination and prejudice and continue to face barriers to care. The report states that 52 percent of respondents have concerns about discrimination or prejudice affecting quality of care, while 57 percent have concerns about providers not being sensitive to patient needs. The high cost of health care also presents a hurdle to access. Dignity 2022 [embedded hyperlink text (https://www.aarp.org/research/topics/life/info-2022/lgbtq-community-dignity-2022.html)], our follow-up to the 2018 study, found that 21 percent of LGBTQI+ older adults did not see a specialist when care was needed because it was unaffordable.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0001
All Sections: 4.3.1.2.3

(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
It is imperative that access to health care is coupled with inclusive education in order to best mitigate the disparities the LGBTQAI+ community faces, especially in the scope of sexual and reproductive health. Currently, the LGBTQIA+ community faces discrimination within the system of health insurance coverage, according to National Academies of Sciences, Engineering, and Medicine. [Embedded hyperlink text

(https://nap.nationalacademies.org/catalog/25877/understanding-the-well-being-of-lgbtqi-populations)] By incorporating Section 1557 into the Affordable Care Act, this discrimination can be prohibited and prevented so that this disparity is mitigated.

Comment Number: HHS-OS-2022-0012-DRAFT-69031-0001
All Sections: 4.3.1.2.4, 4.3.1.2.3
(b)(5)

Organization: Howard Brown Health

Excerpt Text:
Far too many LGBTQ+ and intersex people across the country continue to 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-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 55% 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/PMC5508186/]. Discrimination also takes a toll on mental health, with LGBTQI+ patients having higher rates of mental health distress and suicidality [Footnote 6: Ibid].

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0001
All Sections: 4.3.1.2.2, 4.3.1.2.7, 4.3.1.2.1, 4.3.1.2.3
Classification: Substantive
Position:
Commenter Type: Professional Association
Organization: Alliance of Multicultural Physicians

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66750-0001
All Sections: 4.3.1.2.5, 4.3.1.2.3
(b)(5)
Organization: Jacobs Institute of Women's Health

Excerpt Text:
The [Italics: Dobbs v. Jackson Women's Health Organization] decision has been disastrous for public health, and several changes to the draft rule are necessary to limit the harm that state responses to [Italics: Dobbs] are causing to women, girls, and other people capable of becoming pregnant.

Several states have now banned abortion, leaving residents seeking abortion care a choice between spending thousands of dollars to travel elsewhere for services, risking arrest by self-managing their abortions at home, or bearing children against their will. Those with low incomes – who, because of structural racism, are disproportionately likely to be Black women or other people of color – or other barriers to travel are least likely to be able to leave their states to end their pregnancies legally. For those forced to continue their pregnancies and bear children against their will, maternal mortality risks are particularly high for Black and American Indian/Alaska Native women, [Footnote 1: Trost S, Beauregard J, Chandra Gy, Njie F, Berry J, Harvey A, Goodman DA. (2022). Pregnancy-Related Deaths: Data from Maternal Mortality Review Committees in 36 US States, 2017–2019. https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc.html] and risks of severe complications are higher among Black, Latina, and Asian women compared to White women. [Footnote 2: BlueCross BlueShield. (2022). Racial and Ethnic Disparities in Maternal Health. https://www.bcbs.com/sites/default/files/file-attachments/health-of-america-report/HOA-Maternal-Health_2022.pdf] Being pregnant in an abortion-banning state has now become even more risky, because providers in states that ban abortion, facing the threat of lawsuits, have curtailed the care they provide to people who are pregnant or could become pregnant. [Footnote 3: Arey W, Lerma K, Beasley An, Harper L, Moayedi G, White, K. (2022). A Preview of the

Dangerous Future of Abortion Bans, Texas Senate Bill 8. New England Journal of Medicine, 387:388-390.] [Footnote 4: Nambiar A, Patel S, Santiago-Munoz P, Spong CY, Nelson DB. (2022). American Journal of Obstetrics & Gynecology, 27(4): 648-650.] Women experiencing miscarriages have been denied care even as their conditions threaten their health and lives. [Footnote 5: Feibel C. (2022). Because of Texas abortion law, her wanted pregnancy became a medical nightmare. NPR, July 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] [Footnote 6: CNN. (2022). Woman says Texas abortion law prevented her from getting timely miscarriage care. WIBW, July 18, 2022. https://www.wibw.com/2022/07/18/woman-says-texas-abortion-law-prevented-her-getting-timely-miscarriage-care/]

Problems extend beyond care for those who are pregnant. Women who are not pregnant and require drugs or procedures that could interfere with pregnancies have been denied the treatments they need to manage their conditions. [Footnote 7: Shepherd K & Stead Sellers F. (2022). Abortion Bans Complicate Access to Drugs for Cancer, Arthritis, Even Ulcers. Washington Post (August 8, 2022). www.washingtonpost.com/health/2022/08/08/abortion-bans-methotrexate- mifepristone-rheumatoid-arthritis/] [Footnote 8: Ollstein AM & Payne D. (2022). Patients face barriers to routine care as doctors warn of ripple effects from broad abortion bans. POLITICO, September 28, 2022. https://www.politico.com/news/2022/09/28/abortion-bans-medication-pharmacy-prescriptions-00059228] Lawmakers in some states seek to ban some forms of contraception or prohibit Medicaid from covering them. [Footnote 9: Rovner J. (2022). A GOP Talking Point Suggests Birth Control Is Not at Risk. Evidence Suggests Otherwise. KHN, August 5, 2022. https://khn.org/news/article/republican-talking-point-birth-control-risk-abortion-false-claim/] Those who have a history of abortion – or face anti-abortion providers who suspect that patients have had or might in the future obtain an abortion – could face discrimination if abortion bans embolden providers who might have curbed discriminatory practices in the past.

The Dobbs decision has exacerbated existing inequities related to pregnancy. Those who live in areas served only by religiously affiliated institutions have long been at greatest risk of being unable to receive timely, appropriate care for miscarriages and other forms of reproductive healthcare. [Footnote 10: Barry-Jester AM & Thomson-DeVeaux A. (2018). How Catholic Bishops Are Shaping Health Care In Rural America. FiveThirtyEight, July 25, 2018. https://fivethirtyeight.com/features/how-catholic-bishops-are-shaping-health-care-in-rural-america/] In many cases, women have not been aware that they could not receive appropriate care at their local facilities because of religious directives until they were in the position of needing prompt care. [Footnote 11: Catholics for Choice. (2017). Is Your Health Care Compromised? How the Catholic Directives Make for Unhealthy Choices. https://www.catholicsforchoice.org/wp-content/uploads/2017/01/2017_Catholic-Healthcare-Report.pdf] [Footnote 12: Kaye J, Amiri B, Melling L, Dalven J. (2016). Health Care Denied. American Civil Liberties Union. https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied]

Comment Number: HHS-OS-2022-0012-DRAFT-39726-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3

(b)(5)

Organization: Family Equality

Excerpt Text:
We are pleased to submit this comment in support of the proposed changes to Section 1557 rules that HHS is now considering. Significantly, the proposed rules directly address the widespread discrimination against LGBTQI+ families in our healthcare system by restoring provisions which prevent healthcare entities and insurance companies from discriminating against anyone based on sex and reaffirms that discrimination based on sexual orientation and gender identity is considered unlawful discrimination. These rules are consistent with the Bostock decision and with current legal precedent, and they ensure that discrimination on the basis of association also is expressly prohibited. This means that children and other family members of LGBTQI+ people are explicitly protected from unlawful refusal of care. Addressing this discrimination, which often puts the health of children at risk, is vital to address ongoing health disparities and to improve the nation's overall health outcomes.

Comment Number: HHS-OS-2022-0012-DRAFT-68054-0001
All Sections: 4.3.1.2.2, 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3

(b)(5)

Organization: Washington Health Benefit Exchange

Excerpt Text:
The proposed rule strengthens our state's ability to make progress toward these goals and preserves the gains our state has made to reduce the uninsured rate and improve access to care, particularly for underserved communities, women, LGBTQ Washingtonians, pregnant women, and individuals with limited English proficiency (LEP). The proposed rule aligns with the Supreme Court's 2020 Bostock v. Clayton County opinion which established clear federal protections against employment discrimination based on sexual orientation and gender identity discrimination.

WAHBE supports the overall approach of the proposed rule. It comprehensively addresses discrimination that can contribute to health disparities. The proposed rule reinstates essential protections announced in 2016 and eliminates the confusion and uncertainty created by the later 2020 rulemaking. The 2020 changes excluded many insurers, third-party administrators, and lines of business from being bound by 1557 protections; reduced language access requirements; narrowed the definition of sex as a basis for discrimination; and reduced the scope and applicability of Section 1557 to exclude a variety of HHS programs.

Comment Number: HHS-OS-2022-0012-DRAFT-65682-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3

(b)(5)

Organization: Primary Care Development Corporation

Excerpt Text:

I. PCDC Supports the Reinstatement of Nondiscrimination Protections for LGBTQ Individuals

The proposed rule will reduce incidents of discrimination towards members of the LGBTQ community by reinstating nondiscrimination protections for LGBTQ individuals that were removed by the Trump administration's 2020 Final Rule and expanding on the original protections found in the Obama administration's 2016 Final Rule. Members of the LGBTQ community were disproportionally affected by Trump administration's revision of the 2016 Section 1557 Final Rule – especially as it relates to primary care access.

We appreciate and want to emphasize the Biden administration's acknowledgment that LGBTQ people "face pervasive health disparities and barriers in accessing needed health care." LGBTQ patients are more likely than their heterosexual counterparts to encounter stigma and discrimination and are at increased risk for physical and emotional health challenges. [Footnote 2: St. Catherine University, How Discrimination Impacts LGBTQ Healthcare, https://www.stkate.edu/academics/healthcare-degrees/lgbtq-health-discrimination, (last visited September 21, 2022)] For example, transgender individuals are less likely to have health insurance, [Footnote 3: Luisa Kcomt et al., Healthcare avoidance due to anticipated discrimination among transgender people: A call to create trans-affirmative environments, SSM Popul. Health, August 11, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7276492/. (last visited September 21, 2022).] and as a result, face significant barriers in accessing health care, including primary care. [Footnote 4: Hudaisa Hafeez et al., Health Care Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review, Cureus, April 17, 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478215/. (last visited September 21, 2022)] Similarly, lesbian women are less likely to access preventive cancer screening, a routine part of primary care, due in part to poor patient experiences seeking health care and in part due to both patient's and provider's lack of knowledge about cancer risk. [Footnote 5: Id]. This lack of access to general and preventative care correlates with the LGBTQ community's higher prevalence of mental health issues and sexually transmitted infections (STIs), including HIV. [Footnote 6: Id].

Although most primary care providers and other health care providers aspire to provide non-discriminatory person-centered, comprehensive care, as was clear from the groundswell of opposition from established medical organizations when the Trump Administration's rollback of protections was proposed, [Footnote 7: See, e.g., Todd Shryock, Physician groups oppose rollback of anti-discrimination protections, Medical Economics, May 30, 2019, https://www.medicaleconomics.com/view/physician-groups-oppose-rollback-anti-discrimination- protections (describing a joint letter in opposition to the rule change signed by American Medical Association, American College of Physicians, American Academy of

Nursing, American Academy of PAs, American Nurses Association, American Academy of Pediatrics, American Psychiatric Association, American Psychological Association, and others).] nonetheless many transgender patients specifically report experiencing discrimination when accessing health care. When polled about their experiences with primary care, for example, transgender and gender nonconforming respondents reported experiencing the highest rates of discrimination and barriers to care. To underscore this point, about 10% of respondents reported that health care professionals used harsh language towards them, 11% reported that health professionals refused to touch them or used excessive precautions, and more than 12% of respondents reported being blamed for their health status. [Footnote 8: Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV, Report, 2010, available at https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt- caring.pdf.] The anti-discrimination provisions in the proposed rule have the potential to reduce these incidents by clarifying the obligations of both providers and insurers.

Reducing discrimination on the basis of sex, including sexual orientation and gender identity, are necessary steps towards achieving health equity for all communities. We strongly support the rule change and believe that the provisions mentioned will help ensure that members of LGBTQ community are able to access a full range of necessary health care, including primary care.

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0012
All Sections: 4.3.1.2.1, 4.3.1.2.3
(b)(5)
Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
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. 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 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-Womens- Procreative-Liberty-Amicus-Brief.pdf.] Birth control gave Black people control over their health and their lives. [Footnote 39 Id. at 13 ("The ability to control whether to give birth is a fundamental component of freedom for all women. But for Black women, whose procreation had been forced, monetized,

and monitored since they arrived on American shores, access to birth control represented a unique form of liberty.").]

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0013
All Sections: 4.3.1.2.1, 4.3.1.2.3
(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
Unfortunately, Black Americans continue to face unique obstacles to controlling if, 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 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 Desert? 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/PMC6660992/pdf/nihms-1017159.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-ma-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 clinics to close, 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 costs of the procedure and related travel, these barriers often meant that they could not access abortion even where it was technically legal. [Footnote 44 Artiga, et al., supra note 30.]

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0014
All Sections: 4.3.1.2.1, 4.3.1.2.3
(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
The Dobbs decision has had immediate and significant impacts on Black communities. As of August 16, 2022, most abortions are now banned in 17 states, and five more states are expected to or likely to 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/2022/06/24/abortion-state-laws-criminalization-roe/ (last visited 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/2022-08-23/black- women-are-hardest-hit-by-abortion-restrictions-sweeping-the-deep-south?leadSource=uverify%20wall.]

Delays and denials of abortion care will 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, 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 (July, 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 that Black people would see a 33% increase in deaths under a total abortion ban—the highest of any racial group. [Footnote 49 Amanda Jean Stevenson, The Pregnancy-Related Mortality Impact of a Total Abortion Ban in the United States: A Research Note on Increased Deaths Due to Remaining Pregnant, 58 DEMOGRAPHY 2019 (2021), https://read.dukeupress.edu/demography/article/58/6/2019/265968/The-Pregnancy-Related-Mortality-Impact-of-a- Total.]

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0016
All Sections: 4.3.1.2.7, 4.3.1.2.1, 4.3.1.2.3
(b)(5)
Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[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 47,832. 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
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 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-lgbtqi-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.

Comment Number: HHS-OS-2022-0012-DRAFT-39726-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)

Organization: Family Equality

Excerpt Text:
LGBTQI+ Families and Children

LGBTQI+ people face discrimination and barriers to health care which can directly lead to disparities in health outcomes. A recently published report by the Center for American Progress highlighted 2022 data revealing the continued extent of discrimination and disparities faced by LGBTQI+ people when seeking health care.

- Fifteen 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.

- 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 refusal by a health care provider in the past year.

- 55 percent of intersex respondents reported that a health care provider refused to see them because of their sex characteristics or intersex variation, with over half of those cases being due to the religious beliefs or tenants of the hospital or health care facility.

Comment Number: HHS-OS-2022-0012-DRAFT-65682-0002
All Sections: 6.2.4, 4.3.1.2.3
(b)(5)
Organization: Primary Care Development Corporation

Excerpt Text:
II. Inclusion of Pregnancy, Including Pregnancy Termination, Under the Definition of Sex Discrimination

High-quality, comprehensive primary care includes the full suite of physical and behavioral health services people need to live healthy, productive lives. Sexual and reproductive (SRH) health care, including birth control, preconception care, counseling, and abortion services, is an essential component of primary care, and it is critical that primary care providers both directly provide and refer for the full range of SRH services. The proposed rule's reinstatement of anti-discrimination protections for SRH care, and specifically for pregnancy termination services, is a needed change at a time when many who need these services are being denied care and when our country continues to face unacceptably high levels of maternal mortality and morbidity.

For many years, the United States has had by far the highest rates of maternal mortality compared to other developed nations, with over 23 deaths per 100,000 live births in 2020. [Footnote 9: Centers for Disease Control and Prevention, Maternal Mortality Rates in the United States, 2020, Centers for Disease Control and Prevention,

https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality- rates-2020.htm (last visited September 21, 2022).] In addition, recent research has found that more than eighty percent of those deaths are preventable, if only the pregnant individuals had received appropriate health care. [Footnote 10: Susanna Trost, MPH et al., Pregnancy-Related Deaths: Data from Maternal Mortality Review Committees in 36 US States, 2017–2019, Report, Centers for Disease Control and Prevention, https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc.html (last visited September 21, 2022).] Moreover, this serious failure of our health care system is not felt equally among communities – as with many health care outcomes, Black women and other women of color are more likely to suffer, with Black women "three times more likely to die from a pregnancy- related cause than White women" [Footnote 11: Center for Disease Control and Prevention, Health Equity: Working Together to Reduce Black Maternal Mortality, https://www.cdc.gov/healthequity/features/maternal-mortality/index.html (last visited May 31, 2022).] and 93% of maternal deaths among American Indian and Alaska Native women were found to be preventable. [Footnote 12: Susanna Trost, MPH et. al, Pregnancy-Related Deaths Among American Indian or Alaska Native Persons: Data from Maternal Mortality Review Committees in 36 US States, 2017–2019, Report, Centers for Disease Control and Prevention, https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc-aian.html (last visited September 21, 2022) (finding that 93% of maternal deaths for American Indian and Alaska Natives were preventable).] It is clear that this disparity stems largely from lack of access to high quality preventative and prenatal care, including high quality primary care, for many women, especially those in low-income, underserved, and disinvested communities, as well as communities of color. [Footnote 13 Munira Z. Gunja et al., Health and Health Care for Women of Reproductive Age: How the United States Compares with Other High-Income Countries, Issue Brief, Commonwealth Fund, April 5, 2022, https://www.commonwealthfund.org/publications/issue-briefs/2022/apr/health-and-health-care-women- reproductive-age (last visited September 21, 2022).]

While these groups already face worse and often tragic outcomes as a result of lack of access to care, the Supreme Court's recent decision in [italics: Dobbs v. Jackson] will almost certainly make these disparities even worse. After the Court overturned [italics: Roe v. Wade] and enabled states to restrict or ban access to abortion, many states have indeed begun imposing severe limitations on access to abortion care, impacting health care providers' ability to care for their patients, both those seeking abortions and those needing other pregnancy-related care. [Footnote 14 New York Times. Tracking the States Where Abortion Is Now Banned. https://www.nytimes.com/interactive/2022/us/abortion-laws-roe-v-wade.html (last visited September 21, 2022)] In some states, the laws have even interfered in health care providers' ability to care for their patients where the patient's health or life is in danger. [Footnote 15: See, e.g., Harris Meyer, Patients and Doctors Navigate Conflicting Abortion and Emergency Care Laws, Scientific American, August 9, 2022, https://www.scientificamerican.com/article/patients-and-doctors-navigate-conflicting-abortion-and-emergency-care-laws/ (last visited September 21, 2022).]

PCDC strongly supports the inclusion of pregnancy, including pregnancy termination, under the definition of sex discrimination, to help prevent discrimination against patients seeking sexual and reproductive health care and providers hoping to provide it. The [italics: Dobbs] decision has already resulted in increased barriers for pregnant individuals seeking the care they need, and has

threatened access to contraception, counseling, and miscarriage care and other important care as well – only worsening an already dire situation for many women and others who can become pregnant in the United States. We appreciate the steps taken in this proposed rule to ensure that the prohibition against sex-discrimination adequately addresses pregnancy and pregnancy termination and believe this will advance health equity.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0021
All Sections: 4.3.1.2.7, 4.3.1.2.5, 4.3.1.2.1, 4.3.1.2.3
(b)(5)

Organization: Center for American Progress

Excerpt Text:
Discrimination in health care remains a widespread problem for LGBTQI+ people, especially for LGBTQI+ people of color, transgender people, and people with intersex traits [Footnote 31: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/ ; Shabab Ahmed Mirza and Caitlin Rooney, "Discrimination Prevents LGBTQ People from Accessing Health Care," (Washington: Center for American Progres, 2018), available at https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/]. LGBTQI+ individuals may experience discrimination when a health care provider refuses to provide them with care due to their sexual orientation, gender identity, or variations in sex characteristics. New data from CAP's nationally representative survey emphasize that discrimination in the form of denial of care by a health care provider is a significant concern among LGBTQI+ people. For example, in the past year [Footnote 32: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/]:

? 17 percent of LGBQ respondents reported having concerns that if they disclosed their sexual orientation to a health care provider, they could be denied good medical care.

? 49 percent of transgender or nonbinary respondents reported having concerns that if they disclosed their gender identity to a health care provider, they could be denied good medical care.

? 61 percent of intersex respondents reported having concerns that if they disclosed their intersex status to a health care provider, they could be denied good medical care.

CAP's 2022 survey also examined instances when doctors or other health care providers refused to provide care to LGBTQI+ respondents in the year prior. According to the data, overall [Footnote 33: Ibid]:

? 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 past year.

? 32 percent of transgender or nonbinary respondents, including 46 percent of transgender or nonbinary respondents of color, reported that, in the past year, they experienced at least one kind of care refusal by a health care provider.

? 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.

Not only does health care discrimination directly negatively affect the mental and physical health of LGBTQI+ people, but it also engenders avoidance behavior, delays, or denials of care that exacerbate health disparities among LGBTQI+ populations [Footnote 34: See National Academies of Sciences, Engineering, and Medicine, "Understanding the Well-Being of LGBTQI+ Populations" (Washington: 2020), available at https://www.nap.edu/read/25877/chapter/1]. For example, according to CAP's nationally representative survey data from 2022 [Footnote 35: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/]:

? 23 percent of LGBTQI+ people - including 27 percent of LGBTQI+ respondents of color, 32 percent of LGBTQI+ respondents with disabilities, 37 percent of transgender or nonbinary respondents, and 50 percent of intersex respondents - 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. By comparison, 7 percent of non-LGBTQI+ people reported the same.

? 21 percent of LGBTQI+ people - including 26 percent of LGBTQI+ respondents of color, 28 percent of LGBTQI+ respondents with disabilities, 41 percent of transgender or nonbinary respondents, and 42 percent of intersex respondents - reported that in the past year they postponed or avoided getting preventive screenings due to disrespect or discrimination from doctors or other health care providers. By comparison, 7 percent of non-LGBTQI+ people reported the same.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0025
All Sections: 4.3.1.2.3, 2

(b)(5)

Organization: Center for American Progress

Excerpt Text:

Federal law, including Title IX, recognizes that protections against sex discrimination include termination of pregnancy [Footnote 39: The Department of Education's Title IX regulations prohibit discrimination related to "termination of pregnancy or recovery therefrom." 34 C.F.R. § 106.40(b)(1)]. Discrimination in health care based on termination of pregnancy can show up in many ways. For example, patients needing emergency abortion care have been denied care at hospitals. Patients have reported being denied medical care unrelated to abortion because their medical history includes a prior abortion. Pharmacies have refused to fill prescriptions needed to manage a miscarriage or complications from pregnancy loss because these medications can also be used to terminate a pregnancy.

Often, discrimination based on termination of pregnancy is rooted in abortion stigma [Footnote 40: Alison Norris et al., Abortion Stigma: A Reconceptualization of Constituents, Causes, and Consequences, 21 WOMEN'S HEALTH ISSUES 1, 6 (2011), https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/Abortion-Stigma.pdf; Anuradha Kumar et al., Conceptualising Abortion Stigma, 11 CULTURE, HEALTH & SEXUALITY 625, 628–29 (2009)]. This stigma is experienced by a majority of people seeking abortion and is rooted in sex-based conventions that women are: inherently nurturing and maternal; expected by society to be chaste (which an unwanted pregnancy is seen as diametrically opposed to); and expected to biologically desire to birth children and fulfill traditional roles of homemaker and child caretaker within the nuclear family structure [Footnote 41: See Paula Abrams, The Scarlet Letter: The Supreme Court and the Language of Abortion Stigma, 19 MICH. J. GENDER & L. 293, 328–29 (2013); M. ANTONIA BIGG ET AL., PERCEIVED ABORTION STIGMA AND PSYCHOLOGICAL WELL-BEING OVER FIVE YEARS AFTER RECEIVING OR BEING DENIED AN ABORTION 2 (Whitney S. Rice ed., 2020) (finding that most people considering abortion perceive some stigma related to their decision)] [Footnote 42: Norris, supra note 5, at 6;; Kumar, supra note 5, at 628-29]. The stigmatization of abortion also stems from a misperception that abortion is an immoral act as opposed to a personal medical decision [Footnote 43: COCKRILL K ET AL., ADDRESSING ABORTION STIGMA THROUGH SERVICE DELIVERY: A WHITE PAPER 17(2013); https://www.ibisreproductivehealth.org/publications/addressing-abortion-stigma-through-service-delivery-white-paper].

Abortion stigma often shapes the experiences of patients seeking all forms of medical care, simply because they present as capable of pregnancy [Footnote 44: Transgender, nonbinary, and gender-expansive people who were assigned female or intersex at birth experience pregnancy, have abortions, and are underrepresented and underserved in abortion policy discourse. See e.g. Heidi Moseson et al., Abortion Experiences and Preferences of Transgender, Nonbinary, and Gender-expansive People in the United States, AM. J. OBSTET GYNECOL, Sep. 2020, at 1, 1-2]. Sex-based discrimination in health care—including abortion care—has a disproportionate impact on women, trans, and non-binary individuals in comparison to cis men [Footnote 45: See Emily Paulsen, Recognizing, Addressing Unintended Gender Bias in Patient Care, DUKE HEALTH (Jan. 14, 2020), https://physicians.dukehealth.org/articles/recognizing-addressing-unintended-gender-bias-patient-care]. When reproductive health care is marred by abortion stigma, the stigma "diminishes the trust that is essential to the patient-provider relationship and undermines women's ability to make informed medical decisions" [Footnote 46: NAT'L P'SHIP FOR WOMEN & FAMS., BAD MEDICINE: HOW POLITICAL AGENDA IS

UNDERMINING ABORTION CARE AND ACCESS 2 (2019), https://www.nationalpartnership.org/our-work/repro/reports/bad-medicine-oklahoma.html]. These experiences are precisely the discriminatory conduct that Section 1557 protects against.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0028
All Sections: 4.3.1.2.2, 4.3.1.2.7, 4.3.1.2.1, 5.11, 4.3.1.2.3
(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
[Bold: B. The final rule must require disaggregated data collection]

The availability 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: 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 & Mark V. Johnston, Relationships between level of disability and receipt of preventive health services, Archives of Physical Medicine and Rehabilitation, 749 (2004).] Racial and ethnic minorities with disabilities experience greater disparities in diagnoses and utilization of assistive

technology. [Footnote 22: D.S. Mandell et al., Racial/ethnic disparities in the identification of children with autism spectrum disorders, Am. J. Public Health 493 (2009); H.S. Kaye, P. Yeager & M. Reed, Disparities in usage of assistive technology among people with disabilities, 20 Assist. Technol. 194 (2008).]

While investigations of alleged discrimination sometimes focus on variations based on a single demographic variable, in our increasingly multicultural society, it is imperative that HHS's civil rights enforcement should support these types of analyses. This requires standardized categories and definitions for all these demographic variables and relevant combinations. The department must act decisively and require covered entities to collect demographic data, as existing data collection efforts are insufficient.

Additionally, the department must ensure that data collected is maintained safely and securely by the appropriate entities. Strict standards must be adopted to make clear that data cannot be used for negative actions such as immigration or law enforcement, redlining, or targeting of specific groups. While requests for data should be required, individuals' responses must be voluntary and should be self-reported to ensure accuracy. It is critical to train relevant staff on the collection of demographic data, including how to explain why data is being collected. These policies will help to ensure that data collected can be best utilized to prevent discrimination and disparities in health care access and outcomes.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0029
All Sections: 4.3.1.2.1, 7.7.1, 7.6.1, 4.3.1.2.3
(b)(5)
Organization: Center for American Progress

Excerpt Text:
iv. The Final Rule must enumerate specific forms of discrimination related to pregnancy or other related conditions, including termination of pregnancy.

Throughout the Final Rule, we urge the Department to specifically name and include – both in the text and preamble, including the language specified in § 92.206 and § 92.207 – examples of discrimination related to the full range of reproductive health care and type of services. The Final Rule must name the full range of reproductive health care protected from discrimination. Section 1557's protection against sex discrimination includes protections against discrimination relating to all reproductive health decisions. Specifically, the Final Rule must explicitly name that Section 1557 reaches discrimination related to fertility care, contraception, mistreatment in maternity care, and sex discrimination in access to medications and treatments for disabilities and emergency medical conditions.

With respect to discrimination against people seeking or accessing fertility treatment, it is essential that the Final Rule explicitly name that Section 1557's protects against discrimination on this basis because discrimination persists in the context of accessing infertility diagnosis, treatment, and services including assisted reproductive technology. Sex discrimination in the context of fertility care can take many forms. Some insurance companies refuse to cover certain types of care that are traditionally used by women (e.g., in vitro fertilization (IVF)) [Footnote 48: Gabriela Weigel et al., Kaiser Family Foundation, Coverage and Use of Fertility Services in the U.S. (2020), https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/. These benefit exclusions disproportionately affect women of color due to racial disparities in the rate of certain diseases that may cause infertility. See Jennifer O'Hara, Mayo Clinic Q&A Podcast: The Link Between Racial Disparities and Cervical Cancer, Mayo Clinic News Network (Jan. 10, 2022), https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-qa-podcast-the-link-between-racial-disparities-and-cervical-cancer/#:~:text=Hispanic%20women%20have%20the%20highest,Race%20is%20a%20social%20construct(describing that Hispanic women have the highest incidence rate of cervical cancer, followed by non-Hispanic Black women)]. Even in those states that do require insurance providers to provide IVF, some insurance providers require that patients use their "spouse's sperm" to fertilize their eggs to be eligible for IVF insurance coverage, discriminating against patients based on their marital status, sexual orientation, and gender identity [Footnote 49: E.g., Haw. Rev. Stat. § 431:10A-116.5 (1987); Ark. Code R. 054.00.1–5(B) (1991). Furthermore, Texas, which only requires insurance providers to offer IVF insurance, also includes this same eligibility requirement. See Tex. Ins. Code Ann. § 1366.005]. In a recent example of discrimination on the basis of sexual orientation and marital status, OSF HealthCare, a self-insured Catholic hospital system with facilities in Illinois and Michigan, recently adopted an insurance policy for its employees that limits IVF coverage to "married couple[s] of opposite sex spouses" [Footnote 50: Shira Stein, Hospital Chain Blocks Fertility Coverage for Its LGBTQ Employees, Bloomberg L. (July 18, 2022), https://news.bloomberglaw.com/health-law-and-business/hospital-chain-blocks-fertility-coverage-for-its-lgbt-employees https://www.bgov.com/core/news_articles/RF7N4HT0G1LX].

Additionally, public and private insurers often discriminate against patients based on sex by requiring that they meet outdated and heteronormative definitions of infertility before providing IVF coverage. For example, relying on a 2013 definition of infertility that has since been rescinded by the American Society of Reproductive Medicine, many insurer require simply that patients in different-sex relationships attest that they have unsuccessfully tried to become pregnant by having unprotected sex for six months or a year, depending on their age, but require same-sex couples and single individuals to undergo six to twelve unsuccessful cycles of intrauterine insemination (IUI) at their own expense before deeming them eligible for IVF coverage [Footnote 51: Compare Practice Committee of the American Society for Reproductive Medicine, Definitions of Infertility and Recurrent Pregnancy Loss: A Committee Opinion, 99 Fertility & Sterility 63, 63 (2013) (defining infertility as "a disease defined by failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination," with Practice Committee of the American Society for Reproductive Medicine, Definitions of Infertility and Recurrent Pregnancy Loss: A Committee Opinion, 113 Fertility & Sterility 533, 533 (2020) (defining infertility as "a disease historically

defined by the failure to achieve a successful pregnancy after 12 months or more of regular, unprotected sexual intercourse or due to an impairment of a person's capacity to reproduce either as an individual or with her/his partner")]. These patients are thereby forced to absorb exorbitant costs out of pocket and are delayed or denied access to IVF coverage benefits solely due to their sexual orientation [Footnote 52: See Goidel complaint, supra note TK, at ¶ 8 (describing that a patient was forced to pay out of pocket $45,000 to achieve a successful pregnancy after she was denied coverage for the benefits in her plan because, as a queer woman, she could not attest to engaging in heterosexual sex)].

Studies have found that physicians may consciously or unconsciously block patients from accessing fertility treatment by making assumptions or possessing biases about who can or deserves to be a parent and who wants or deserves fertility treatment. For example, women of color "have reported 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 53: The Ethics Committee of the American Society for Reproductive Medicine, Disparities in Access to Effective Treatment for Infertility in the United States: An Ethics Committee Opinion, 116 FERTILITY & STERILITY 54, 57 (2021) (discussing the various inequitable barriers to fertility care), 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]. We urge the Department to clarify in the regulatory text that such discrimination in health care, including in the context of seeking or accessing fertility care, is impermissible discrimination on the basis of sex under Section 1557, and to include examples of a broad range of impermissible sex discrimination in the context of seeking or accessing fertility care in the Final Rule.

With respect to contraception, the Final Rule must make clear that Section 1557 prohibits discrimination against those seeking contraception or specific types of contraception. The Final Rule also should include the examples included in the guidance that the Department issued on July 13, 2022, to retail pharmacies, responding to incidents occurring after Dobbs, and explicit clarification of other types of discrimination against those seeking contraception [Footnote 54: U.S. DEPT. OF HEALTH & HUM. SERVS., GUIDANCE TO NATION'S RETAIL PHARMACIES: OBLIGATIONS UNDER FED. C.R. L. TO ENSURE ACCESS TO COMPREHENSIVE REPRODUCTIVE HEALTH CARE SERVS. (Jul. 13, 2022), https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html#:~:text=Pharmacies%2C%20therefore%2C%20may%20not%20discriminate,medications%20and%20how%20to%20take]. Additional examples could include: a state program that otherwise provides coverage of contraceptives but excludes a specific contraceptive because of an assertion that the contraception causes an abortion or a provider network that would only include facilities that refuse to perform female sterilization procedures [Footnote 55: In addition to violating section 1557, a state program in this instance may also be violating the ACA contraceptive coverage requirement. The Department has already made clear that the ACA contraceptive coverage requirement is a floor for coverage. Should a state restriction on contraceptives make compliance with the ACA's contraceptive coverage requirement impossible, the federal government will step in to enforce the ACA. Dep'ts of Lab., Health &

Hum. Serv., & Treasury, FAQs About Affordable Care Act Implementation Part 54 (July 28, 2022) at 7, https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf]. The Department must also specify that items or services related to contraception are also protected [Footnote 56: In the context of insurance coverage requirements, the Department already recognizes that any item or service necessary to access contraception is part of contraception. Dep'ts of Lab., Health & Hum. Serv., & Treasury, supra note 22, at 10]. Additional medications or services are often needed to facilitate use of contraception, such as anesthetics for insertion of long-acting reversible contraceptives. For example, a pharmacy refusal to provide misoprostol to a patient who was prescribed it in order to make IUD insertion easier could be a Section 1557 violation.

Additionally, the Final Rule must make clear that Section 1557 prohibits discrimination where a patient is denied medications or treatments for care unrelated to abortion because the medicine is also used for abortion care. Dobbs emboldened covered entities to start denying medications and treatments for chronic health conditions and other disabilities that could prevent, complicate, or end pregnancies or fertility. As the Department has already recognized in its July 13, 2022 guidance, Section 1557 prohibits discrimination in the form of refusing to fill prescriptions for medications that are considered "abortifacients" but may be prescribed to treat other health conditions, such as cancer, arthritis, and ulcers [Footnote 57: U.S. DEPT. OF HEALTH & HUM. SERVS., supra note 21]. This form of discrimination has occurred in states where abortion is now banned [Footnote 58: Katie Shepherd & Frances Stead Sellers, Abortion Bans Complicate Access to Drugs for Cancer, Arthritis, Even Ulcers, WASH POST (Aug. 8, 2022), https://www.washingtonpost.com/health/2022/08/08/abortion-bans-methotrexate-mifepristone-rheumatoid-arthritis/]. Similarly, the drug mifepristone is currently being tested for treating breast cancer, brain cancer, prostate cancer, alcoholism, post-traumatic stress disorder, and depression, among other conditions [Footnote 59: Caroline Hopkins, The 'Abortion Pill' May Treat Dozens of Diseases, but Roe Reversal Might Upend Research, ABC NEWS (June 25, 2022), https://www.nbcnews.com/health/health-news/abortion-pill-may-treat-dozens-diseases-roe-reversal-might-upend-resea-rcna34812]. It also is approved for termination of pregnancies. Following the Dobbs decision, patients who could be pregnant are at risk when seeking mifepristone for purposes besides abortion. Patients being refused any form of health care—because of stereotyping that the patient could be pregnant and having an abortion—falls under Section 1557's protections. To this end, the Final Rule must include language in § 92.206 and § 92.207 addressing the denial of medications or treatments that could prevent, complicate, or end pregnancies yet are prescribed for purposes beyond sexual and reproductive health care, including treatment for severe chronic conditions [Footnote 60: See U.S. DEPT. OF HEALTH & HUM. SERVS., supra note 21; see also Shepherd & Sellers, supra note 25].

The Final Rule should make clear that Section 1557 protects against discriminatory refusals to provide information or referrals about abortion and other reproductive health care. Section 1557 prohibits refusing to provide information, resources, or referrals about abortion care and other reproductive health care. Such discriminatory refusal of care constitutes discrimination based on pregnancy or related conditions. For example, many Indigenous individuals rely on Indian Health Service for health care, but IHS facilities often fail to provide information to patients about abortion care or counseling about pregnancy options [Footnote 61: Ex. F Decl. of Rachael Lorenzo 15, Nov. 18, 2020, 1:20-cv-11297-PBS]. These are forms of sex-based discrimination

that Section 1557 protects against. Providers who operate in states that ban abortion may also be emboldened to deny information about abortion that a patient can receive outside of their state, even if such information is not unlawful to provide. It is critical for the Final Rule to make clear to providers, hospitals, and other entities subject to Section 1557 requirements their responsibility to continue providing information and referrals relating to a pregnancy, including termination of pregnancy.

The Final Rule should also make clear that Section 1557 protects against discrimination based on a person's actual or perceived decision relating to abortion care. In the preamble discussion of § 92.206, the Department should include examples making clear that it is discriminatory to refuse to provide health care because of a patient's actual or perceived abortion care history, because doing so is discrimination based on sex. Patient health suffers when a provider's own biases against abortion are substituted for necessary medical care. Not only is the patient denied the immediate care they need, but also the patient's trust in the health care system erodes when they do not feel safe with their providers and may even fear consequences for disclosing their medical history. This is precisely the discrimination that Section 1557 was meant to address.

Additionally, the Final Rule should make clear that Section 1557 prohibits discrimination related to discrimination in maternity care. Pregnant Black, Indigenous, Latina/x, 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 mistreatment during labor and delivery [Footnote 62: Saraswathi Vedam, et al. The Giving Voice to Mothers study: inequity and mistreatment during pregnancy and childbirth in the United States. Reprod Health 16, 77 (2019). https://doi.org/10.1186/s12978-019-0729-2]. For example, in a 2018 California survey, Black, Asian, and Pacific Islander women who gave birth in hospitals reported higher rates of unfair treatment, harsh language, and rough handling than white women [Footnote 63: Carol Sakala et al., National Partnership for Women & Families, Listening to Mothers in California: A Population-Based Survey of Women's Childbearing Experiences, Full Survey Report, 64-65 (Sept. 2018) https://www.chcf.org/wp-content/uploads/2018/09/ListeningMothersCAFullSurveyReport2018.pdf]. Among subspecialty provider offices, 44 percent of gynecology offices were inaccessible due to factors such as inaccessible equipment and lack of transfer assistance, leaving wheelchair users unable to access abortion or maternal care [Footnote 64: Tara Lagu, MD, MPH, et al. Access to Subspecialty Care for Patients With Mobility Impairment, Annals of Internal Medicine, (2013). https://www.acpjournals.org/doi/10.7326/0003-4819-158-6-201303190-00003]. Section 1557 implementing regulations must address this discrimination.

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0003
All Sections: 4.3.1.2.3

(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:
Furthermore, as we grapple with the fallout of the Supreme Court's decision in [Italics: Dobbs v. Jackson Women's Health Organization], it is essential for the Administration's Proposed Rule to robustly protect patients from discrimination related 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 rippling across the country, people of color, people with low incomes, people who are 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0003
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 4.3.1.1, 4.3.1.2.3

(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
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-lgbtqi-communities/)] by Center for American Progress. 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66854-0003
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)

Organization: Wisconsin Primary Health Care Association

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-39726-0003
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)

Organization: Family Equality

Excerpt Text:
The National Institute for Health has determined that LGBTQI+ individuals experience worse physical health compared to their heterosexual and cis-gender counterparts [Footnote 4: KFF (2018), Health and Access to Care and Coverage LGBT Individuals in the US – Health Challenges, https://www.kff.org/report-section/health-and-access-to-care-and-coverage-lgbt-individuals-in-the-us-health-challenges/]. While historically HIV/AIDS has been a devastating health issue for the LGBTQI+ community, the range of health issues which disproportionately affect the community are much more varied, including chronic conditions, early onset disabilities, cancer, and cardiovascular disease [Footnote 5: Id]

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0034
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)

Organization: Justice in Aging

Excerpt Text:
[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. 47,824, 47,916 (§ 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 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 LGBTQI+ 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 I. 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/#S1title.]

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0035
All Sections: 4.3.1.2.1, 7.7.1, 7.6.1, 4.3.1.2.3
(b)(5)
Organization: Center for American Progress

Excerpt Text:
b. Addressing Critical Gaps in the Forms of Prohibited Sex Discrimination Enumerated

We appreciate HHS' enumeration of specific forms of sex discrimination prohibited in § 92.206(b) and § 92.207(b). 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 not refuse gender-affirming care to a patient based on a personal 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(b) and § 92.207(b) to prevent covered entities from using state or local laws that ban 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 Dobbs, we also urge you to add enumerated specific forms of discrimination related to pregnancy and related conditions. In this section of our comments, we offer analysis on how discrimination related to pregnancy and related conditions undermines program access and recommend amendments to the proposed regulatory text. Under § 92.207, we build on this analysis and recommend amendments to address discrimination related to pregnancy and related conditions in health insurance and other health-related coverage.

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, 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, 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 mistreatment during labor and delivery [Footnote 75: Vedam, S., Stoll, K., Taiwo, T.K. et al. The Giving Voice to Mothers study: inequity and mistreatment during pregnancy and childbirth in the United States. Reprod Health 16, 77 (2019). https://doi.org/10.1186/s12978-019-0729-2]. People with disabilities often experience multiple barriers to sexual and reproductive health care [Footnote 76: Agaronnik N, Pendo E, Lagu T, DeJong C, Perez-Caraballo A, Iezzoni LI. Ensuring the Reproductive Rights of Women with Intellectual Disability. J Intellect Dev Disabil. 2020;45(4):365-376. doi: 10.3109/13668250.2020.1762383. Epub 2020 Jun 10. PMID: 35046755; PMCID: PMC8765596. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8765596/]. For example, among subspecialty provider offices, 44 percent of gynecology offices were inaccessible due to factors such as inaccessible equipment and lack of transfer assistance, leaving wheelchair users unable to access abortion or maternal care [Footnote 77: Lagu, Tara, et al. "Access to subspecialty care for patients with mobility impairment: a survey." Annals of Internal Medicine 158.6 (2013): 441-446, available at https://www.acpjournals.org/doi/10.7326/0003-4819-158-6-201303190-00003]. Discrimination persists for many people when accessing infertility diagnosis, treatment, and services, including assisted reproductive technology. It is essential that the Final Rule explicitly name this as prohibited sex discrimination.

When the Supreme Court overturned the constitutional right to abortion in Dobbs, it provoked covered entities to begin discriminatorily denying or erecting barriers to medications and treatments that can prevent, complicate, or end pregnancies. Covered entities are struggling to understand their compliance with rapidly changing state laws. The impacts of Dobbs are compounding preexisting barriers to abortions, contraception, miscarriage management, fertility care, and other sexual and reproductive health care, particularly for communities of color, people with disabilities, the LGBTQI+ community (especially transgender people), and more [Footnote 78: Bella Isaacs-Thomas, "For many pregnant trans people, competent medical care is hard to find," PBS News Hour, May 26, 2021, available at https://www.pbs.org/newshour/health/for-many-pregnant-trans-people-competent-medical-care-is-hard-to-find]. For example, people with

disabilities are increasingly denied or subjected to unconscionable barriers to methotrexate, which is regularly used to treat cancer and autoimmune conditions [Footnote 79: Laura Weiss, "Pharmacists and Patients Are Freaking Out Over New Medication Restrictions Post-Roe" The New Republic, July 27, 2022, available at https://newrepublic.com/article/167165/dobbs-pharmacists-walgreens-methotrexate]. We expect that under Dobbs, people with disabilities will face increasing discriminatory denials of and barriers to the vast array of medications and treatments prescribed for their conditions that happen to prevent, complicate, or end pregnancies or fertility. Accordingly, we urge you to amend proposed § 92.206(b) as follows:

(3) 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, italic: 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, [bold, italic: fertility care, or any health services], [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, [bold, underline: transgender status] or gender otherwise recorded.

(5) [Bold, italic: 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, that could 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].

In addition, HHS must strengthen the language pertaining to providers complying with a state or local law as a justification for denying gender-affirming care, abortions, or other reproductive or sexual health care to state unequivocally that Section 1557, as federal law, preempts any such state or local law restricting access to this care.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0037
All Sections: 4.3.1.2.4, 4.3.1.2.1, 4.3.1.2.3, 2

(b)(5)

Organization: Center for American Progress

Excerpt Text:

b. Sex Discrimination in Coverage

U.S. health insurance and other health-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 certain types of care that are traditionally used by women, such as in vitro fertilization (IVF) [Footnote 83: Gabriela Weigel and others, "Coverage and Use of Fertility Services in the U.S." (San Francisco: Kaiser Family Foundation, 2020), available at https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/]. 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 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 that providers do not take their fertility concerns seriously, instead "emphasiz[ing] birth control over procreation" [Footnote 84: Ethics Committee of the American Society for Reproductive Medicine. "Disparities in access to effective treatment for infertility in the United States: an Ethics Committee opinion." Fertility and Sterility 104.5 (2015): 1104-1110, available at 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].

As the 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 from their state family planning programs and contraceptive coverage mandates [Footnote 85: Guttmacher Institute, "Emergency Contraception," available at https://www.guttmacher.org/state-policy/explore/emergency-contraception (last accessed September 2022)]. This results in discrimination against people of color and people with low-incomes who face higher rates of unintended pregnancy and adverse reproductive health outcomes due to these barriers [Footnote 86: American College of Obstetricians and Gynecologists, "Access to Contraception" available at https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception (last accessed September 2022)]. Robust enforcement of Section 1557 is necessary to ensure health entities and providers do not perpetuate discriminatory policies against contraceptive care.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0004
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 4.3.1.2.3

(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0047
All Sections: 4.3.1.2.5, 4.3.1.2.4, 8.4, 4.3.1.2.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:
XVIII. Notification of Views Regarding Application of Federal Conscience and Religious Freedom Laws (§ 92.302)

The federal government has a compelling interest in preventing discrimination in health care. The very purpose of Section 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.

It is crucial that the Department's Final Rule includes the Proposed Rule's revised approach to religious exemptions. Expansion of religious exemptions in health care settings disproportionately harms vulnerable populations including women - especially women of color - and LGBTQI+ individuals who are seeking a wide range of care, including gender-affirming and reproductive care [Footnote 101: Emily London and Maggie Siddiqi, "Religious Liberty Should Do No Harm," (Washington: Center for American Progress, 2019) available at https://www.americanprogress.org/article/religious-liberty-no-harm/].

Data from CAP's 2022 nationally representative survey shed light on occurrences when doctors and other health care providers refuse to provide care for religious reasons. For example [Footnote 102: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/]:

? 8 percent of LGBQ respondents (including 14 percent of LGBQ respondents of color), 12 percent of transgender or nonbinary respondents (including 20 percent of transgender or nonbinary respondents of color), and 53 percent of intersex respondents reported that, in the past year, a health care provider refused to see them due to the provider's religious beliefs or the stated religious tenets of the hospital or health care facility.

Denial of medical care for religious purposes negatively affects patients who require the denied care, not only by creating delays that may result in harm but also because the stress of being denied care and fear of encountering similar denials is detrimental and can engender avoidance behavior [Footnote 103: National Academies of Sciences, Engineering, and Medicine, "Understanding the Well-Being of LGBTQI+ Populations" (Washington: 2020), available at https://www.nap.edu/read/25877/chapter/1]. The 2020 version of Section 1557 disregarded those harms by implementing regulations that improperly incorporated a religious exemption that violated the plain language of the statute and is contrary to the express purpose of Section 1557. We strongly support the Proposed Rule's case-by-case process, which 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0049
All Sections: 4.3.1.2.2, 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 5.11, 4.3.1.2.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:

b. Data Collection

We appreciate that the Department recognizes the importance of demographic data collection to understand program populations and advance health equity and that the Proposed Rule acknowledges that demographic data collection and civil rights enforcement are inextricably linked [Footnote 104: HHS has incorporated demographic data collection into its 2022 Equity Action Plan, U.S. Dep't of Health & Hum. Svcs., Equity Action Plan (Apr. 2022), available at https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf, and demographic data collection has long been a stated priority for its subagencies; see, e.g., Ctrs. for Medicare & Medicaid Svcs., The CMS Equity Plan for Improving Quality in Medicare (Sept. 2015), available at https://www.cms.gov/about-cms/agency-information/omh/omh_dwnld-cms_equityplanformedicare_090615.pdf; Ctrs. for Medicare & Medicaid Svcs., CMS Framework for Health Equity 2022-2032 (Apr. 2022); available at https://www.cms.gov/files/document/cms-framework-health-equity.pdf; Ctrs. for Medicare & Medicaid Svcs., CMS Strategic Plan, Pillar: Health Equity (Aug. 2022), available at https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf].

While the Department considered a demographic data collection requirement outside of Section 1557 regulations, we encourage the Department to adopt a basic demographic data requirement in the Final Rule. Establishing a clear requirement will improve demographic data collection across the agency, enhance civil rights enforcement, and further the Department's goal of advancing health equity.

Investing in demographic data collection across programs and activities used by the public will better equip the Department to equitably serve all people, especially members of historically underserved populations. Establishing demographic data as a function of civil rights monitoring across the agency will also help to ensure and demonstrate compliance with the civil rights requirements of Section 1557.

Currently, health data stratified by key demographic variables such as race, ethnicity, disability, sexual orientation, gender identity, and variations in sex characteristics remains incomplete or inadequate [Footnote 105: For example, see Nat'l Acad. of Sciences, Engineering & Medicine, Understanding the Well-Being of LGBTQI+ Populations 75-81 (White, J., Sepulveda M.J., & Patterson C.J., eds., 2020), available at https://www.ncbi.nlm.nih.gov/books/NBK563325/pdf/Bookshelf_NBK563325.pdf and Bonnelin Swenor, A Need for Disability Data Justice, Health Affairs (Aug. 22, 2022), available at https://www.healthaffairs.org/content/forefront/need-disability-data-justice]. Studies have

overwhelmingly shown high acceptability among patients and enrollees in self-reporting race and ethnicity, sexual orientation and gender identity, and other demographic information, given that appropriate steps are taken to support data collection activities [Footnote 106: David Baker et al., Patients' attitudes toward health care providers collecting information about their race and ethnicity, 20 J. Gen. Intern. Med. 895-900 (2005), available at https://pubmed.ncbi.nlm.nih.gov/16191134/; David W. Baker, Romana Hasnain-Wynia, Namratha R. Kandula, Jason A. Thompson, and E. Richard Brown, Attitudes Toward Health Care Providers, Collecting Information About Patients' Race, Ethnicity, and Language, 45 Med. Care 1034 (Nov. 2007)] [Footnote 107: Sean Cahill et al., Do Ask Do Tell: High Levels of Acceptability by Patients of Routine Collection of Sexual Orientation and Gender Identity Data in Four Diverse American Community Health Centers, PLoS One (2014), available at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0107104] [Footnote 108: See, e.g., Chris Grasso et al., Planning and implementing sexual orientation and gender identity data collection in electronic health records, 26 J. Am. Med. Inform. Assoc. 66-70 (2019), available at https://pubmed.ncbi.nlm.nih.gov/30445621/; Pittman et al., Who, When, and How: The Current State of Race, Ethnicity, and Primary Language Data Collection in Hospitals, The Commonwealth Fund (2004), available at https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2004_may_who__when__and_how__the_current_state_of_race__ethnicity__and_primary_language_data_collection_in_ho_hasnain_wynia_whowhenhow_726_pdf.pdf]. Information gathered through these data collections have shaped policy interventions to address disparities and improve access to health care for underserved communities [Footnote 109: See, e.g., U.S. Dep't of Health & Hum. Svcs., HHS Initiatives to Address the Disparate Impact of COVID-19 on African Americans and Other Racial and Ethnic Minorities (2020), available at https://www.hhs.gov/sites/default/files/hhs-fact-sheet-addressing-disparities-in-covid-19-impact-on-minorities.pdf].

We recognize the Department's concern about dynamic and responsive data collection methods and standards given the fluctuating nature of populations and that understandings of identity continue to evolve. However, the Department's proposal to adopt an approach modeled after the U.S. Department of Education (ED), may not be the most effective means of collecting these data. While we agree that HHS has the authority to require data collection and reporting for compliance reporting under Section 1557 as well as other civil rights statutes, a sub-regulatory approach has thus far not yielded sufficient progress toward standardized demographic data collection within HHS [Footnote 110: See Charly Gilfoil, Nat'l Health L. Prog., Demographic Data Collection in Medicaid & CHIP: CMS Authority to Collect Race & Ethnicity Data (Sept. 7, 2022), available at https://healthlaw.org/resource/demographic-data-collection-in-medicaid-chip-cms-authority-to-collect-race-ethnicity-data/]. Additionally, ED's civil rights data collection program is not an ideal proxy for how the Department could collect demographic data since the Department's scope of demographic data to collect will be larger, it will need to collect these data from more entities, and each entity engages with patients, enrollees, and grantees using different methods and at different frequencies. These differences may pose significant challenges for the Department to standardize and coordinate demographic data collection and report across the agency's many programs and activities.

For these reasons, we believe that a better approach would be for the Department to set a baseline demographic data collection requirement within the 2022 Final Rule and direct each sub-agency or program to set its own requirements and methods for data collection with a specific timeline for implementation. Notably, 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. HHS has already established or acknowledged recommended practices for engaging in demographic data collection in each of these demographic categories. HHS should adopt those existing data collection practices and engage in additional research where necessary.

Whether the Department includes a demographic data collection requirement in the 2022 Final Rule, engages in further rulemaking, or issues sub-regulatory guidance, we offer the following recommendations for principles to guide demographic data collection. Specifically, the Department should develop resources and toolkits for collecting demographic data; provide appropriate training and technical assistance to programs and grantees; adopt clear privacy and nondiscrimination protections; ensure that data collected is maintained safely and securely by the appropriate entities; ensure requests for data are required but that providing demographic data is voluntary and self-reported; set, review, and update minimum standard variables for each demographic category; support analyses based on multiple demographic variables; conduct regular review and meaningfully engage in community feedback; ensure public reporting of data and analysis. It is also essential that strict standards are adopted to make clear that data cannot be used for negative actions such as immigration or law enforcement, redlining or targeting of specific groups.

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0005
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 4.3.1.2.3
(b)(5)
Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
As a result of discriminatory government policies and bias in the health care 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 THURGOOD MARSHALL INST. & INST. ON ASSETS AND SOC. POL'Y AT BRANDEIS UNIV. THE BLACK-WHITE RACIAL WEALTH GAP (2019), https://tminstituteldf.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. 10, 2022), https://www.npr.org/2022/03/10/1085882933/redlining-pollution-racism; Daniel Cusick, 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, MILBANK Q., Jun. 2005, at 247, 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 C. Arcaya & Alina Schnake-Mahl, Health in the Segregated City, NYU FURMAN CTR. (Oct. 2017), https://furmancenter.org/research/iri/essay/health-in-the-segregated-city] Black households also struggle to access healthy food: One out of every five Black households is situated in a food desert, [Footnote 15 Michael Chui, et al., A $300 billion opportunity: Serving the emerging Black consumer, MCKINSEY Q. (Aug. 6, 2021), https://www.mckinsey.com/featured-insights/diversity-and-inclusion/a-300-billion-dollar-opportunity- serving-the-emerging-black-american-consumer.] and communities of color have fewer large supermarkets than predominantly white neighborhoods, even when controlling for income. [Footnote 16 Kelly Brooky, Research Shows Food Deserts More Abundant in Minority Neighborhoods, JOHNS HOPKINS UNIV. MAG. (Spring 2014), https://hub.jhu.edu/magazine/2014/spring/racial-food-deserts/.]

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0005
All Sections: 4.3.1.2.5, 7.7.2, 7.7.4, 4.3.1.2.3

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
The Department's proposal to once again recognize Section 1557's application to private insurance continues this 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-lgbtqi-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.

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0009
All Sections: 4.3.1.2.1, 4.3.1.2.3
(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
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/10425271002/.]

Section 4.3.1.2.4 - Sexual Orientation

Comment Number: HHS-OS-2022-0012-DRAFT-5331-0001
All Sections: 4.3.1.2.4
(b)(5)

Organization:

Excerpt Text:

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 on a weekend. Obtaining prior-auth on 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 assuming 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 lifted.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4
(b)(5)
Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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 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. 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: 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 w[ill] face discriminatory care" which ultimately causes many people to not seek care.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4

(b)(5)

Organization: Colors+

Excerpt Text:
Our youth are scared. They are afraid of the present and future protections to 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, LGBTQI+ 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 health care, 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 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 w[ill] 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] This surfaces in a wide variety of contexts, including physical and mental

health care services [Hyperlink: https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people]. In a study published in Health Affairs, researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access [Hyperlink: https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.0455]. They concluded that discrimination, as well as insensitivity or disrespect on the part of health care providers, were key barriers to health care access. And a recent systematic literature review conducted by Cornell University "found robust evidence that discrimination on the basis of sexual orientation or gender identity is associated with harms to the health of LGBT people" [Hyperlink: https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-scholarly-research-say-about-the-effects-of-discrimination-on-the-health-of-lgbt-people/].

Comment Number: HHS-OS-2022-0012-DRAFT-69031-0001
All Sections: 4.3.1.2.4, 4.3.1.2.3

(b)(5)

Organization: Howard Brown Health

Excerpt Text:
Far too many LGBTQ+ and intersex people across the country continue to 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-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 55% 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/PMC5508186/]. Discrimination also takes a toll on

mental health, with LGBTQI+ patients having higher rates of mental health distress and suicidality [Footnote 6: Ibid].

Comment Number: HHS-OS-2022-0012-DRAFT-39726-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)

Organization: Family Equality

Excerpt Text:
We are pleased to submit this comment in support of the proposed changes to Section 1557 rules that HHS is now considering. Significantly, the proposed rules directly address the widespread discrimination against LGBTQI+ families in our healthcare system by restoring provisions which prevent healthcare entities and insurance companies from discriminating against anyone based on sex and reaffirms that discrimination based on sexual orientation and gender identity is considered unlawful discrimination. These rules are consistent with the Bostock decision and with current legal precedent, and they ensure that discrimination on the basis of association also is expressly prohibited. This means that children and other family members of LGBTQI+ people are explicitly protected from unlawful refusal of care. Addressing this discrimination, which often puts the health of children at risk, is vital to address ongoing health disparities and to improve the nation's overall health outcomes.

Comment Number: HHS-OS-2022-0012-DRAFT-66033-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4
(b)(5)

Organization: Legacy Community Health

Excerpt Text:
It is clear from the experiences of our patients that anti-LGBTQIA+ discrimination in healthcare is still very common, and this discrimination leads to worse health outcomes and additional barriers to care. We routinely care for patients who reside outside our usual service areas because they do not have access to care in their own communities. Sometimes, patients will spend an entire day traveling to one of our clinic locations to receive care. We know that there are many more patients who do not have the resources or ability to travel to one of our health centers, and instead opt to forego healthcare altogether.

All healthcare providers must fulfill their obligations to provide affirming, competent, nondiscriminatory healthcare. This proposed rule is a critically important step in this direction. Healthcare is a human right, and all people should be able to access affirming and nondiscriminatory care wherever they choose to receive it. We strongly support this proposed rule, and we urge for its swift finalization.

Comment Number: HHS-OS-2022-0012-DRAFT-68054-0001
All Sections: 4.3.1.2.2, 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)
Organization: Washington Health Benefit Exchange

Excerpt Text:
The proposed rule strengthens our state's ability to make progress toward these goals and preserves the gains our state has made to reduce the uninsured rate and improve access to care, particularly for underserved communities, women, LGBTQ Washingtonians, pregnant women, and individuals with limited English proficiency (LEP). The proposed rule aligns with the Supreme Court's 2020 Bostock v. Clayton County opinion which established clear federal protections against employment discrimination based on sexual orientation and gender identity discrimination.

WAHBE supports the overall approach of the proposed rule. It comprehensively addresses discrimination that can contribute to health disparities. The proposed rule reinstates essential protections announced in 2016 and eliminates the confusion and uncertainty created by the later 2020 rulemaking. The 2020 changes excluded many insurers, third-party administrators, and lines of business from being bound by 1557 protections; reduced language access requirements; narrowed the definition of sex as a basis for discrimination; and reduced the scope and applicability of Section 1557 to exclude a variety of HHS programs.

Comment Number: HHS-OS-2022-0012-DRAFT-65682-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)
Organization: Primary Care Development Corporation

Excerpt Text:
I. PCDC Supports the Reinstatement of Nondiscrimination Protections for LGBTQ Individuals

The proposed rule will reduce incidents of discrimination towards members of the LGBTQ community by reinstating nondiscrimination protections for LGBTQ individuals that were removed by the Trump administration's 2020 Final Rule and expanding on the original protections found in the Obama administration's 2016 Final Rule. Members of the LGBTQ community were disproportionally affected by Trump administration's revision of the 2016 Section 1557 Final Rule – especially as it relates to primary care access.

We appreciate and want to emphasize the Biden administration's acknowledgment that LGBTQ people "face pervasive health disparities and barriers in accessing needed health care." LGBTQ patients are more likely than their heterosexual counterparts to encounter stigma and

discrimination and are at increased risk for physical and emotional health challenges. [Footnote 2: St. Catherine University, How Discrimination Impacts LGBTQ Healthcare, https://www.stkate.edu/academics/healthcare-degrees/lgbtq-health-discrimination, (last visited September 21, 2022)] For example, transgender individuals are less likely to have health insurance, [Footnote 3: Luisa Kcomt et al., Healthcare avoidance due to anticipated discrimination among transgender people: A call to create trans-affirmative environments, SSM Popul. Health, August 11, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7276492/. (last visited September 21, 2022).] and as a result, face significant barriers in accessing health care, including primary care. [Footnote 4: Hudaisa Hafeez et al., Health Care Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review, Cureus, April 17, 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478215/. (last visited September 21, 2022)] Similarly, lesbian women are less likely to access preventive cancer screening, a routine part of primary care, due in part to poor patient experiences seeking health care and in part due to both patient's and provider's lack of knowledge about cancer risk. [Footnote 5: Id]. This lack of access to general and preventative care correlates with the LGBTQ community's higher prevalence of mental health issues and sexually transmitted infections (STIs), including HIV. [Footnote 6: Id].

Although most primary care providers and other health care providers aspire to provide non-discriminatory person-centered, comprehensive care, as was clear from the groundswell of opposition from established medical organizations when the Trump Administration's rollback of protections was proposed, [Footnote 7: See, e.g., Todd Shryock, Physician groups oppose rollback of anti-discrimination protections, Medical Economics, May 30, 2019, https://www.medicaleconomics.com/view/physician-groups-oppose-rollback-anti-discrimination- protections (describing a joint letter in opposition to the rule change signed by American Medical Association, American College of Physicians, American Academy of Nursing, American Academy of PAs, American Nurses Association, American Academy of Pediatrics, American Psychiatric Association, American Psychological Association, and others).] nonetheless many transgender patients specifically report experiencing discrimination when accessing health care. When polled about their experiences with primary care, for example, transgender and gender nonconforming respondents reported experiencing the highest rates of discrimination and barriers to care. To underscore this point, about 10% of respondents reported that health care professionals used harsh language towards them, 11% reported that health professionals refused to touch them or used excessive precautions, and more than 12% of respondents reported being blamed for their health status. [Footnote 8: Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV, Report, 2010, available at https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt- caring.pdf.] The anti-discrimination provisions in the proposed rule have the potential to reduce these incidents by clarifying the obligations of both providers and insurers.

Reducing discrimination on the basis of sex, including sexual orientation and gender identity, are necessary steps towards achieving health equity for all communities. We strongly support the rule change and believe that the provisions mentioned will help ensure that members of LGBTQ community are able to access a full range of necessary health care, including primary care.

Comment Number: HHS-OS-2022-0012-DRAFT-68873-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: Fenway Community Health Center

Excerpt Text:

Discrimination based on sexual orientation and gender identity (SOGI) negatively affects the health of LGBTQIA+ people and functions as a barrier to care [Footnote 1: Gruberg S, Mahowald L, Halpin J. The state of the LGBTQ community in 2020. A national public opinion study. Washington, DC: Center for American Progress. 2020, October 6. https://www.americanprogress.org/issues/lgbtq- rights/reports/2020/10/06/491052/state-lgbtq-community-2020/]. Discrimination in health care may cause sexual and gender minority patients to have higher rates of medical mistrust, which may constitute a barrier to accessing care [Footnote 2: Ahmed Mirza, Shabab and Rooney, Caitlin (2018). Discrimination Prevents LGBTQ People from Accessing Health Care. Washington, DC: Center for American Progress]. LGBTQIA+ people of color experience intersectional stigma. Racism is a major barrier to care for Black lesbian and bisexual women [Footnote 3: Brenick A, Romano K, Kegler C, Eaton LA. Understanding the Influence of Stigma and Medical Mistrust on Engagement in Routine Healthcare Among Black Women Who Have Sex with Women. LGBT Health. 2017 Feb;4(1):4-10]. Anti-Black stigma is common in predominantly White LGBT settings [Footnote 4: McConnell EA, Janulis P, Phillips G 2nd, Truong R, Birkett M. Multiple Minority Stress and LGBT Community Resilience among Sexual Minority Men. Psychol Sex Orientat Gend Divers. 2018 Mar;5(1):1-12]. The long history of structural stigma and discrimination against Black people in healthcare settings contributes to medical mistrust that acts as a major barrier to accessing care for Black LGBT people [Footnote 5: Quinn KG, Christenson E, Spector A, Amirkhanian Y, Kelly JA. The Influence of Peers on PrEP Perceptions and Use Among Young Black Gay, Bisexual, and Other Men Who Have Sex with Men: A Qualitative Examination. Arch Sex Behav. 2020 Aug;49(6):2129-2143] [Footnote 6: Cahill S, Taylor SW, Elsesser SA, Mena L, Hickson D, Mayer KH. Stigma, medical mistrust, and perceived racism may affect PrEP awareness and uptake in black compared to white gay and bisexual men in Jackson, Mississippi and Boston, Massachusetts. AIDS Care. 2017 Nov;29(11):1351-1358].

Partly as a result of widespread societal discrimination, LGBT people are more likely than cisgender, straight people to live in poverty (22% vs. 16%), with transgender people (29%), bisexual women (29%), and bisexual men (19%) experiencing the highest rates of poverty [Footnote 7: Badget L, Choi S, Wilson B. (October 2019). LGBT Poverty in the United States: A study of differences between sexual orientation and gender identity groups. UCLA School of Law: The Williams Institute. Available at: https://williamsinstitute.law.ucla.edu/publications/lgbt-poverty-us/]. Furthermore, LGBT people of color had significantly higher rates of poverty compared to their White counterparts [Footnote 8: Ibid].

Lack of access to health insurance is also a key correlate of health disparities. Sexual minority women are less likely to have health insurance and a primary care provider than heterosexual women. An analysis of 2013-2015 National Health Interview Survey data found that lesbian and gay women were significantly less likely to have health insurance (80.7% of sexual minority women versus 85.2% of heterosexual women) and a usual primary care provider (79.6% of sexual minority women versus 84% of heterosexual women) compared to heterosexual women [Footnote 9: Lunn MR, Cui W, Zack MM, Thompson WW, Blank MB, Yehia BR. Sociodemographic Characteristics and Health Outcomes Among Lesbian, Gay, and Bisexual U.S. Adults Using Healthy People 2020 Leading Health Indicators. LGBT Health. 2017 Aug;4(4):283-294. doi: 10.1089/lgbt.2016.0087. Epub 2017 Jul 20. PMID: 28727950; PMCID: PMC5564038]. Striking racial/ethnic disparities in insurance coverage—with American Indians and Alaska Natives, Hispanics, and Black people less likely to be insured than White non-Hispanic and Asian Pacific Islander people—also affect LGBTQI+ people of color [Footnote 10: Artiga S, Hill L, Orgera K, Damico A. Health coverage by race and ethnicity, 2010-2019. Kaiser Family Foundation. July 16, 2021. https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/].

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0010
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
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 Mahowal, 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 Caroline Medina, 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0011
All Sections: 4.3.1.2.5, 4.3.1.2.4, 2

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
[Italics: D. Impact of Discrimination on LGBTQ+ People.]

Discrimination in healthcare settings remains a significant problem for LGBTQ+ individuals. Such discrimination adversely affects the mental and physical health of LGBTQ+ individuals and engenders the individuals' avoidance behavior, delays, or denials of care. [Footnote 9: Caroline Medina & Lindsay Mahowald, Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities, (Sept. 8, 2022), https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/.] In 2021, roughly ten percent of the LGBTQ+ survey respondents reported experiencing refusals of care by doctors and other healthcare providers. [Footnote 10: Id.] Finally, such discrimination deters LGBTQ+ people from seeking care. The 2021 survey revealed that LGBTQ+ individuals were three times more likely to postpone or avoid healthcare due to discrimination by providers than non-LGBTQ+ individuals. [Footnote 11: Id.]

Under the current iteration of the rule, LGBTQ+ individuals are more likely to avoid seeking medical care out of fear of discrimination. [Footnote 12: See, Shabab Ahmen Mirza & Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care, Ctr. for Am. Progress (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.] For example, thirty percent of LGBTQ+ Americans reported difficulty accessing healthcare services and fifteen percent reported postponing or foregoing healthcare services due to the current rule. [Footnote 13: Sharita Gruberg et al, The State of the LGBTQ Community in 2020, Ctr. for Am. Progress (Oct. 6, 2020), https://www.americanprogress.org/article/state-lgbtq-community-2020/.] This inability to access healthcare flies directly in the face of the spirit and intent of the [Italics: Patient Protection] and Affordable Care Act, specifically Section 1557: "[A]n individual shall not, on the ground prohibited under [various Civil Rights laws], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity." [Footnote 14: 111 P.L. 148, Sec. 1557.]

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0014
All Sections: 4.3.1.2.5, 4.3.1.2.4

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[Bod: 1. Sexual Orientation and Gender Identity Discrimination Harms Patients]

The Proposed Rule is an important step to address the "robust evidence that discrimination on the basis of sexual orientation or gender identity is associated with harms to the health of

LGBTQI+ people". 87 Fed. Reg. at 47,834. LGBTQ persons report experiencing barriers to receiving medical services, including disrespectful attitudes, discriminatory treatment, inflexible or prejudicial policies, and even outright refusals of essential care, leading to poorer health outcomes and often serious or even catastrophic consequences. [Footnote 15: Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV at 5–6 (2010) , https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care- isnt-caring.pdf; see also Jennifer Kates, et al., Kaiser Family Found., Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender (LGBT) Individuals in the U.S. (May 3, 2018), https://www.kff.org/report-section/health-and-access-to-care-and-coverage-lgbt-individuals-in-the-us- health-challenges.] LGBTQ individuals experience poorer physical health compared to their heterosexual and non-transgender counterparts, have higher rates of chronic conditions, and are at higher risk for certain mental health and behavioral health conditions, including depression, anxiety, and substance misuse. [Footnote 16: Lambda Legal, at 5, 8.] HHS recognizes that these harms have been further exacerbated by the COVID-19 pandemic and limited healthcare resources. 87 Fed. Reg. at 47,834.

Transgender people in particular face significant barriers to receiving both routine and gender-affirming care. [Footnote 17: See Sandy E. James et al., Nat'l Ctr. For Transgender Equal., The Report of the 2015 U.S. Transgender Survey, at 96-99 . (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Full- Report-Dec17.pdf; (transgender people in particular report hostile and disparate treatment from providers); see also Morning Consult & The Trevor Project, How COVID-19 is Impacting LGBTQ Youth at 25 (2020), https://www.thetrevorproject.org/wp-content/uploads/2020/10/Trevor-Poll_COVID19.pdf (finding that 28% of trans and nonbinary youth and 18% of LGBTQ youth overall reported wanting mental healthcare and not being able to receive it, compared with only 7% of white cisgender heterosexual youth).] These barriers create serious consequences. Among transgender people, suicide attempts are nine times more common than in the overall U.S. population (41% versus 4.6%). [Footnote 18: Ann P. Haas et al., Am. Found. For Suicide Prevention & The Williams Inst., Suicide Attempts Among Transgender and Gender Non-Conforming Adults: Findings of the National Transgender Discrimination Survey 2 (2014), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-GNC- Suicide-Attempts-Jan-2014.pdf.] Unaddressed gender dysphoria can impact quality of life and trigger decreased social functioning. [Footnote 19: See Emily Newfield et al., Female-to-Male Transgender Quality of Life, 15(9) Quality of Life Research 1447 (2006), https://www.ncbi.nlm.nih.gov/pubmed/16758113 (observing that transgender men who received gender-affirming care reported having a higher health-related quality of life than those who had not).] Transgender people are more likely to experience income insecurity, [Footnote 20: See Sharita Gruberg et al., Ctr. for Am. Progress, The State of the LGBTQ Community in 2020 (Oct. 6, 2020), https://www.americanprogress.org/article/state-lgbtq-community-2020 (showing 54% of transgender respondents reported that discrimination moderately or significantly affected their financial well-being).] more likely to experience food insecurity, [Footnote 21: Kerith J. Conron & Kathryn K. O'Neill, Univ. of Cal. Los Angeles, Food Insufficiency Among Transgender Adults During the COVID-19 Pandemic 2 (2021), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Food-Insufficiency-Dec-2021.pdf.] and more likely to be uninsured or rely on state-run programs such as Medicaid. [Footnote 22: Jaime M. Grant et al., Nat'l Ctr. For

Transgender Equal. & Nat'l Gay and Lesbian Task Force, National Transgender Discrimination Survey Report on Health & Health Care at 8 (2010), https://cancer- network.org/wp-content/uploads/2017/02/National_Transgender_Discrimination_Survey_Report_on_health_and_health_c are.pdf (23% of transgender women and 13% of transgender men report relying on public health insurance); see also Kellan Baker et al., Ctr. for Am. Progress, The Medicaid Program and LGBT Communities: Overview and Policy Recommendations (Aug. 9, 2016), https://www.americanprogress.org/article/the-medicaid-program-and-lgbt-communities-overview-and- policy-recommendations (noting that the high prevalence of poverty in LGBTQ communities, especially among transgender people and LGBTQ people of color, makes Medicaid a critical program for the health and well-being of these communities)] State programs are likely to bear the financial burden of addressing the significant consequences resulting from denying transgender people necessary healthcare. [Footnote 23: See Christy Mallory & William Tentindo, Williams Inst., Medicaid Coverage for Gender Affirming Care (Oct. 2019), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Medicaid-Gender- Care-Oct-2019.pdf (listing states that include gender affirming care in their Medicaid programs); see e.g., Wash. Admin. Code § 182-501-0060 (listing program's benefits); Cal. Code Regs. tit. 22 § 51301 et seq. (same); N.Y. Comp. Codes R. & regs. tit. 18, § 505.1 et seq. (same).] Access to gender-affirming care improves wellbeing for transgender adults. [Footnote 24: Michael Zaliznyak et al., Effects of Gender-Affirming Hormone Therapy on Sexual Function of Transgender Men and Women, 206 J. of Urology 637, 638 (2021), https://www.auajournals.org/doi/epdf/10.1097/JU.0000000000002045.06; What We Know Project, Cornell University, What Does the Scholarly Research Say about the Effect of Gender Transition on Transgender Well-Being? (2018) https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what- does-the-scholarly-research-say-about-the-well-being-of-transgender-people (online literature review); Newfield et al., supra fn. 20.]

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4

(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
Years later, the situation has not much improved. The Department's [bold/underlined: 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 [bold/underlined: wide variety of contexts,] including physical and mental health care services. In a [bold/underlined: study published in [italics: Health Affairs,]] researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access. They concluded that discrimination, as well as insensitivity or disrespect on the part of health care providers, were key barriers to health care access. And a recent [bold/underlined: systematic literature review] conducted by Cornell University "found robust evidence that

discrimination on the basis of sexual orientation or gender identity is associated with harms to the health of LGBT people."

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:
As health care providers we have witnessed first-hand the harm discrimination 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.apa.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-death-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 all Black people reporting this happens often or very often [embedded hyperlink text (https://patientengagementhit.com/news/one-quarter-of-adults-report-racial-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 [embedded hyperlink text (https://www.nationalpartnership.org/our-work/health/reports/black-womens-maternal-health.html)]to die from a pregnancy related cause than white women. For LGBTQ+ people, pervasive discrimination also discourages a significant number of patients from seeking health care. According to data from the Center for American Progress [embedded hyperlink text (https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/)], 8 percent of all LGBTQ+ people and 14 percent of those who had experienced discrimination on the basis of their sexual orientation or gender identity in the past year – avoided or postponed needed medical care. Among transgender people 22 percent reported such avoidance. The pervasive discrimination in our health care systems must be addressed through robust implementation and enforcement of Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: Colors+

Excerpt Text:
These problems persist in 2022. Data in a 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" [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 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 risk for anxiety, depression, suicidality, obesity, isolation, and bullying/assault because of how society, individuals, and organizations respond to them. This rule would be vital in not only allowing our LGBTQ+ youth to survive, but thrive as young

people and adults. We want to support our youth in becoming healthy individuals and community members with this rule, we can make a big step toward doing that.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
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 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-lgbtqi-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.

Comment Number: HHS-OS-2022-0012-DRAFT-39726-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3

(b)(5)

Organization: Family Equality

Excerpt Text:
LGBTQI+ Families and Children

LGBTQI+ people face discrimination and barriers to health care which can directly lead to disparities in health outcomes. A recently published report by the Center for American Progress highlighted 2022 data revealing the continued extent of discrimination and disparities faced by LGBTQI+ people when seeking health care.

- Fifteen 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.

- 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 refusal by a health care provider in the past year.

- 55 percent of intersex respondents reported that a health care provider refused to see them because of their sex characteristics or intersex variation, with over half of those cases being due to the religious beliefs or tenants of the hospital or health care facility.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0003
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 4.3.1.1, 4.3.1.2.3

(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
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-lgbtqi-communities/)] by Center for American Progress. 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66854-0003
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)

Organization: Wisconsin Primary Health Care Association

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-39726-0003
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)

Organization: Family Equality

Excerpt Text:
The National Institute for Health has determined that LGBTQI+ individuals experience worse physical health compared to their heterosexual and cis-gender counterparts [Footnote 4: KFF (2018), Health and Access to Care and Coverage LGBT Individuals in the US – Health Challenges, https://www.kff.org/report-section/health-and-access-to-care-and-coverage-lgbt-individuals-in-the-us-health-challenges/]. While historically HIV/AIDS has been a devastating health issue for the LGBTQI+ community, the range of health issues which disproportionately affect the community are much more varied, including chronic conditions, early onset disabilities, cancer, and cardiovascular disease [Footnote 5: Id]

Comment Number: HHS-OS-2022-0012-DRAFT-68873-0003
All Sections: 4.3.1.2.5, 4.3.1.2.4
(b)(5)

Organization: Fenway Community Health Center

Excerpt Text:
It is also critically important that, consistent with the Bostock ruling and subsquent federal agency interpretations noted in the NPRM footnote 46, nondiscrimination language be restored that to federal regulation that explicitly prohibits discrimination based on both sexual orientation and gender identity. As we have noted, such discrimination negatively impacts the health and well- being of LGBTQIA+ people, and in particular BIPOC LGBTQIA+ people, and constitutes a barrier to accessing care.

Access to health care is important to all people, and we believe that health care is a right. LGBT people are more likely to have chronic conditions such as diabetes, asthma, obesity, hypertension, and cardiovascular disease [Footnote 11: Beach LB, Elasy TA, Gonzales G. Prevalence of Self-Reported Diabetes by Sexual Orientation: Results from the 2014 Behavioral Risk Factor Surveillance System. LGBT Health. 2018 Feb/Mar;5(2):121-130] [Footnote 12: Caceres BA, Jackman KB, Edmondson D, Bockting WO. Assessing gender identity differences in cardiovascular disease in US adults: an analysis of data from the 2014-2017 BRFSS. J Behav Med. 2020 Apr;43(2):329-338] [Footnote 13: Karen I. Fredriksen-Goldsen, Hyun-Jun Kim, Chengshi Shui, and Amanda E. B. Bryan, 2017: Chronic Health Conditions and Key Health Indicators Among Lesbian, Gay, and Bisexual Older US Adults, 2013–2014. American Journal of Public Health 107, 1332_1338] [Footnote 14: Laska MN, VanKim NA, Erickson DJ, Lust K, Eisenberg ME, Rosser BR. Disparities in Weight and Weight Behaviors by Sexual Orientation in College Students. Am J Public Health. 2015 Jan;105(1):111-121] [Footnote 15: Deputy NP, Boehmer U. Weight status and sexual orientation: differences by age and within racial and ethnic subgroups. Am J Public Health. 2014;104(1):103-109. doi:10.2105/AJPH.2013.301391] [Footnote 16: Azagba S, Shan L, Latham K. Overweight and Obesity among Sexual Minority Adults in the United States. Int J Environ Res Public Health. 2019 May 23;16(10):1828] [Footnote 17: Caceres BA, Brody AA, Halkitis PN, Dorsen C, Yu G, Chyun DA. Sexual Orientation Differences in Modifiable Risk Factors for Cardiovascular Disease and Cardiovascular Disease Diagnoses in Men. LGBT Health. 2018;5(5):284-294] [Footnote 18: Jackson CL, Agénor M, Johnson DA, Austin SB, Kawachi I. Sexual orientation identity disparities in health behaviors, outcomes, and services use among men and women in the United States: a cross-sectional study. BMC Public Health. 2016;16(1):807] [Footnote 19: Fredriksen-Goldsen KI, Kim H-J, Emlet CA, et al. The Aging and Health Report: Disparities and Resilience Among Lesbian, Gay, Bisexual, and Transgender Older Adults. Seattle: University of Washington; 2011] [Footnote 20: Caceres BA, Makarem N, Hickey KT, Hughes TL. Cardiovascular Disease Disparities in Sexual Minority Adults: An Examination of the Behavioral Risk Factor Surveillance System (2014-2016). Am J Health Promot. 2019 May;33(4):576-585] [Footnote 21: Caceres BA, Jackman KB, Edmondson D, Bockting WO. Assessing gender identity differences in cardiovascular disease in US adults: an analysis of data from the 2014-2017 BRFSS. J Behav Med. 2020 Apr;43(2):329-338] [Footnote 22: Nokoff NJ, Scarbro S, Juarez-Colunga E, Moreau KL, Kempe A. Health and Cardiometabolic Disease in Transgender Adults in the United States: Behavioral Risk Factor Surveillance System 2015. J Endocr Soc. 2018 Mar 5;2(4):349-360]. LGBT people experience higher rates of cancer, and gay and bisexual men and transgender women experience disproportionate burden of HIV and other STIs [Footnote 23: Cahill SR. Legal and Policy Issues for LGBT Patients with Cancer or at

Elevated Risk of Cancer. Semin Oncol Nurs. 2018 Feb;34(1):90- 98] [Footnote 24: Centers for Disease Control and Prevention. HIV and Gay and Bisexual Men. Fact Sheet. Updated September 2021. https://www.cdc.gov/hiv/pdf/group/msm/cdc-hiv-msm.pdf] [Footnote 25: Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the Prevalence of HIV and Sexual Behaviors Among the US Transgender Population: A Systematic Review and Meta-Analysis, 2006-2017. Am J Public Health. 2019 Jan;109(1):e1-e8]. Because of these disparities, LGBTQIA+ people are in need of the critical health and social support services that HHS grantee organizations provide.

The efficacy of the Ending the HIV Epidemic initiative will be heavily influenced by this nondiscrimination rule. In this country, 69% of people living with HIV and newly diagnosed with HIV each year are gay and bisexual men [Footnote 26: Centers for Disease Control and Prevention. HIV and Gay and Bisexual Men. Fact Sheet. Updated September 2021. https://www.cdc.gov/hiv/pdf/group/msm/cdc-hiv-msm.pdf]. Transgender women are also disproportionately burdened by HIV [Footnote 27: Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the Prevalence of HIV and Sexual Behaviors Among the US Transgender Population: A Systematic Review and Meta-Analysis, 2006-2017. Am J Public Health. 2019 Jan;109(1):e1-e8]. Black and Latino gay and bisexual men and Black transgender women experience the most striking disparities in the domestic HIV epidemic [Footnote 28: CDC (2018), HIV among African American Gay and Bisexual Men. https://www.cdc.gov/hiv/group/msm/bmsm.html. Accessed January 22, 2018] [Footnote 29: Becasen et al., 2019]. Access to critical services provided by HHS grantees—including housing support, mental health and substance use treatment, and nutritional support—that help people living with HIV stay healthy and adhere to treatment hang in the balance. Treatment adherence is of critical importance in the Ending the HIV Epidemic initiative.

Homeless services, funding by HHS, are especially important to LGBT people, and especially for LGBT people of color. LGBT youth represent as much as 20-40% of homeless youth in some cities [Footnote 30: Ray, N. (2007). Lesbian, Gay, Bisexual and Transgender Youth: An Epidemic of Homelessness. National Gay and Lesbian Task Force Policy Institute, National Coalition for the Homeless. https://www.thetaskforce.org/lgbt-youth-an-epidemic-of-homelessness/]. Data from the 2015 National Transgender Discrimination Survey show that 30% of transgender Americans have experienced homeless at some point in their lives, and 12% in the past year [Footnote 31: James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). The Report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality].

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0030
All Sections: 6.2.1, 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:

The 2022 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. Proscribing discrimination on these bases will improve health care access for LGBTQI+ people of color, in particular. Further, transgender people of color face significant barriers to health care access. As noted in a 2021 CAP report, transgender people of color more frequently experience denial of care and medical abuse than white transgender people [Footnote 71: Caroline Medina and others, "Protecting and Advancing Health Care for Transgender Adult Communities" (Washington: Center for American Progress, 2021), available at https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/]. That report further notes that transphobia is often inseparable from racism and sexism in the medical system.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0034
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3

(b)(5)

Organization: Justice in Aging

Excerpt Text:
[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. 47,824, 47,916 (§ 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 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 LGBTQI+ 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 I. 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/#S1title.]

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0036
All Sections: 4.3.1.2.4, 4.3.1.2.6

(b)(5)

Organization: Justice in Aging

Excerpt Text:
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'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. 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365932/#S1title.] 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0037
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.6

(b)(5)

Organization: Justice in Aging

Excerpt Text:
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: Ivette 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 re-closet themselves to get the care they need or delay or forgo services altogether.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0037
All Sections: 4.3.1.2.4, 4.3.1.2.1, 4.3.1.2.3, 2
(b)(5)

Organization: Center for American Progress

Excerpt Text:
b. Sex Discrimination in Coverage

U.S. health insurance and other health-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 certain types of care that are traditionally used by women, such as in vitro fertilization (IVF) [Footnote 83: Gabriela Weigel and others, "Coverage and Use of Fertility Services in the U.S." (San Francisco: Kaiser Family Foundation, 2020), available at https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/]. 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 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 that providers do not take their fertility concerns seriously, instead "emphasiz[ing] birth control over procreation" [Footnote 84: Ethics Committee of the American Society for Reproductive Medicine. "Disparities in access to effective treatment for infertility in the United States: an Ethics Committee opinion." Fertility and Sterility 104.5 (2015): 1104-1110, available at 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].

As the 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 from their state family planning programs and contraceptive coverage mandates [Footnote 85: Guttmacher Institute, "Emergency Contraception," available at https://www.guttmacher.org/state-policy/explore/emergency-contraception (last accessed September 2022)]. This results in discrimination against people of color and people with low-incomes who face higher rates of unintended pregnancy and adverse reproductive health outcomes due to these barriers [Footnote 86: American College of Obstetricians and Gynecologists, "Access to Contraception" available at https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception (last accessed September 2022)]. Robust enforcement of Section 1557 is necessary to ensure health entities and providers do not perpetuate discriminatory policies against contraceptive care.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0038
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.6
(b)(5)

Organization: Justice in Aging

Excerpt Text:
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 where 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.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0004
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 4.3.1.2.3
(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-39726-0004
All Sections: 4.3.1.2.5, 4.3.1.2.4

(b)(5)

Organization: Family Equality

Excerpt Text:
HHS has acknowledged many of these issues in its preamble to its Notice of Proposed Rulemaking as well as the pressing necessity to ensure that as many Americans as possible have access to health care services in the wake of the COIVD-19 pandemic. Family Equality also would like to highlight a crucial segment of the population that is often overlooked: the children and families of LGBTQI+ individuals. Nearly 3.7 million children in the US have LGBTQ+ parents, and 77% of LGBTQ+ millennials either are already parents or are considering expanding their families in the years ahead [Footnote 6: Family Equality (2019) LGBTQ Family Building Survey. https://www.familyequality.org/fbs]. It is estimated that around 3 million

LGBTQ+ are the primary caregiver for someone over the age of 50 [Footnote 7: SAGE, Caregiving in the LGBT Community, https://www.lgbtagingcenter.org/resources/pdfs/SAGE%20Caregiver%20Guide%20Final%20Interactive.pdf]. LGBTQI+ people don't just face the prospect of a doctor refusing to treat them, they must grapple with the reality that the people that they love and care for might also be refused treatment, even in emergency situations.

For example, in 2014 a Detroit pediatrician refused to provide pediatric care to a six-day old baby, because the parents were a lesbian couple [Footnote 8: Pediatrician refuses to treat baby with lesbian parents and there's nothing illegal about it - The Washington Post]. The doctor met with the mothers during their pregnancy and agreed to take the baby as a new patient upon birth, and yet turned the family away unexpectedly and at the most vulnerable moment. This decision not only flew in the face of professional guidance and ethics, but also could have endangered the health of the child. At best, it caused extreme emotional harm and distress to new parents, left to find a new doctor for their newborn.

Similarly, the young child of a lesbian couple in Texas, experienced a delay in care due to discrimination because she had two moms. When their two-year-old daughter fell and knocked out her front tooth, one of the mothers rushed the crying, bleeding child to a pediatric dentist only to be told that "a child cannot have two mothers" and that they would not treat her child until the "real" mother (aka the mother who gave birth to the child) arrived with a birth certificate. This mother later stated that:

Although my wife and I ... expected we might face discrimination at some point in our lives ..., we never expected to face discrimination from a medical provider—especially from someone taking care of our child. I don't think anything could have prepared us for this [Footnote 9: Brief Of Amici Curiae Lambda Legal Defense And Education Fund, Inc., Family Equality Council, Et Al., In Support Of Respondents, Masterpiece Cakeshop v. Colorado Civil Rights Commission, 584 U.S. (2018), https://www.familyequality.org/wp-content/uploads/2018/07/20171030-LambdaLegal-FamEq-Amicus-Brief- Masterpiece.pdf].

Children and family members of LGBTQI+ individuals should never have their health endangered due to their association with LGBTQI+ people, nor should LGBTQI+ parents and caregivers have to live in a state of fear that their loved ones will not be able to receive necessary health treatment. The finalized Section 1557 rules must reflect that goal.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0041
All Sections: 4.3.1.2.4, 7.9
(b)(5)
Organization: Center for American Progress

Excerpt Text:
XIV. Nondiscrimination on the Basis of Association (§ 92.209)

We support the Proposed Rule's restoring explicit protections against discrimination on the basis of association. Doing so is consistent with longstanding interpretations of other anti-discrimination 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.

LGBTQI+ people may be especially vulnerable to discrimination based on association. For example, an individual in a same-sex relationship could be discriminated against based on their own and their partner's sex, whereas that same person might not be similarly mistreated if there were not in a same-sex relationship. Similar, an infant might be turned away from a pediatrician because she had same-sex parents [Footnote 90: Andrew Sattar and Sarah McBride, "Their baby was denied access to care because they are gay," (Washington: Center for American Progress, 2015) available at https://www.americanprogress.org/article/video-their-baby-was-denied-access-to-care-because-they-are-gay/]. It is important that the final rule make clear that this kind of associational discrimination is within the ambit of the rule's protections.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0047
All Sections: 4.3.1.2.5, 4.3.1.2.4, 8.4, 4.3.1.2.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:
XVIII. Notification of Views Regarding Application of Federal Conscience and Religious Freedom Laws (§ 92.302)

The federal government has a compelling interest in preventing discrimination in health care. The very purpose of Section 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.

It is crucial that the Department's Final Rule includes the Proposed Rule's revised approach to religious exemptions. Expansion of religious exemptions in health care settings disproportionately harms vulnerable populations including women - especially women of color - and LGBTQI+ individuals who are seeking a wide range of care, including gender-affirming and reproductive care [Footnote 101: Emily London and Maggie Siddiqi, "Religious Liberty Should Do No Harm," (Washington: Center for American Progress, 2019) available at https://www.americanprogress.org/article/religious-liberty-no-harm/].

Data from CAP's 2022 nationally representative survey shed light on occurrences when doctors and other health care providers refuse to provide care for religious reasons. For example [Footnote 102: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American

Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/]:

? 8 percent of LGBQ respondents (including 14 percent of LGBQ respondents of color), 12 percent of transgender or nonbinary respondents (including 20 percent of transgender or nonbinary respondents of color), and 53 percent of intersex respondents reported that, in the past year, a health care provider refused to see them due to the provider's religious beliefs or the stated religious tenets of the hospital or health care facility.

Denial of medical care for religious purposes negatively affects patients who require the denied care, not only by creating delays that may result in harm but also because the stress of being denied care and fear of encountering similar denials is detrimental and can engender avoidance behavior [Footnote 103: National Academies of Sciences, Engineering, and Medicine, "Understanding the Well-Being of LGBTQI+ Populations" (Washington: 2020), available at https://www.nap.edu/read/25877/chapter/1]. The 2020 version of Section 1557 disregarded those harms by implementing regulations that improperly incorporated a religious exemption that violated the plain language of the statute and is contrary to the express purpose of Section 1557. We strongly support the Proposed Rule's case-by-case process, which 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0049
All Sections: 4.3.1.2.2, 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 5.11, 4.3.1.2.3
(b)(5)

Organization: Center for American Progress

Excerpt Text:
b. Data Collection

We appreciate that the Department recognizes the importance of demographic data collection to understand program populations and advance health equity and that the Proposed Rule acknowledges that demographic data collection and civil rights enforcement are inextricably linked [Footnote 104: HHS has incorporated demographic data collection into its 2022 Equity Action Plan, U.S. Dep't of Health & Hum. Svcs., Equity Action Plan (Apr. 2022), available at https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf, and demographic data collection has long been a stated priority for its subagencies; see, e.g., Ctrs. for Medicare & Medicaid Svcs., The CMS Equity Plan for Improving Quality in Medicare (Sept. 2015), available at https://www.cms.gov/about-cms/agency-information/omh/omh_dwnld-cms_equityplanformedicare_090615.pdf; Ctrs. for Medicare & Medicaid Svcs., CMS Framework for Health Equity 2022-2032 (Apr. 2022); available at https://www.cms.gov/files/document/cms-framework-health-equity.pdf; Ctrs. for Medicare &

Medicaid Svcs., CMS Strategic Plan, Pillar: Health Equity (Aug. 2022), available at https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf].

While the Department considered a demographic data collection requirement outside of Section 1557 regulations, we encourage the Department to adopt a basic demographic data requirement in the Final Rule. Establishing a clear requirement will improve demographic data collection across the agency, enhance civil rights enforcement, and further the Department's goal of advancing health equity.

Investing in demographic data collection across programs and activities used by the public will better equip the Department to equitably serve all people, especially members of historically underserved populations. Establishing demographic data as a function of civil rights monitoring across the agency will also help to ensure and demonstrate compliance with the civil rights requirements of Section 1557.

Currently, health data stratified by key demographic variables such as race, ethnicity, disability, sexual orientation, gender identity, and variations in sex characteristics remains incomplete or inadequate [Footnote 105: For example, see Nat'l Acad. of Sciences, Engineering & Medicine, Understanding the Well-Being of LGBTQI+ Populations 75-81 (White, J., Sepulveda M.J., & Patterson C.J., eds., 2020), available at https://www.ncbi.nlm.nih.gov/books/NBK563325/pdf/Bookshelf_NBK563325.pdf and Bonnelin Swenor, A Need for Disability Data Justice, Health Affairs (Aug. 22, 2022), available at https://www.healthaffairs.org/content/forefront/need-disability-data-justice]. Studies have overwhelmingly shown high acceptability among patients and enrollees in self-reporting race and ethnicity, sexual orientation and gender identity, and other demographic information, given that appropriate steps are taken to support data collection activities [Footnote 106: David Baker et al., Patients' attitudes toward health care providers collecting information about their race and ethnicity, 20 J. Gen. Intern. Med. 895-900 (2005), available at https://pubmed.ncbi.nlm.nih.gov/16191134/; David W. Baker, Romana Hasnain-Wynia, Namratha R. Kandula, Jason A. Thompson, and E. Richard Brown, Attitudes Toward Health Care Providers, Collecting Information About Patients' Race, Ethnicity, and Language, 45 Med. Care 1034 (Nov. 2007)] [Footnote 107: Sean Cahill et al., Do Ask Do Tell: High Levels of Acceptability by Patients of Routine Collection of Sexual Orientation and Gender Identity Data in Four Diverse American Community Health Centers, PLoS One (2014), available at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0107104] [Footnote 108: See, e.g., Chris Grasso et al., Planning and implementing sexual orientation and gender identity data collection in electronic health records, 26 J. Am. Med. Inform. Assoc. 66-70 (2019), available at https://pubmed.ncbi.nlm.nih.gov/30445621/; Pittman et al., Who, When, and How: The Current State of Race, Ethnicity, and Primary Language Data Collection in Hospitals, The Commonwealth Fund (2004), available at https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2004_may_who__when__and_how__the_current_state_of_race__ethnicity__and_primary_language_data_collection_in_ho_hasnain_wynia_whowhenhow_726_pdf.pdf]. Information gathered through these data collections have shaped policy interventions to address disparities and improve access to health care for underserved communities [Footnote 109: See,

e.g., U.S. Dep't of Health & Hum. Svcs., HHS Initiatives to Address the Disparate Impact of COVID-19 on African Americans and Other Racial and Ethnic Minorities (2020), available at https://www.hhs.gov/sites/default/files/hhs-fact-sheet-addressing-disparities-in-covid-19-impact-on-minorities.pdf].

We recognize the Department's concern about dynamic and responsive data collection methods and standards given the fluctuating nature of populations and that understandings of identity continue to evolve. However, the Department's proposal to adopt an approach modeled after the U.S. Department of Education (ED), may not be the most effective means of collecting these data. While we agree that HHS has the authority to require data collection and reporting for compliance reporting under Section 1557 as well as other civil rights statutes, a sub-regulatory approach has thus far not yielded sufficient progress toward standardized demographic data collection within HHS [Footnote 110: See Charly Gilfoil, Nat'l Health L. Prog., Demographic Data Collection in Medicaid & CHIP: CMS Authority to Collect Race & Ethnicity Data (Sept. 7, 2022), available at https://healthlaw.org/resource/demographic-data-collection-in-medicaid-chip-cms-authority-to-collect-race-ethnicity-data/]. Additionally, ED's civil rights data collection program is not an ideal proxy for how the Department could collect demographic data since the Department's scope of demographic data to collect will be larger, it will need to collect these data from more entities, and each entity engages with patients, enrollees, and grantees using different methods and at different frequencies. These differences may pose significant challenges for the Department to standardize and coordinate demographic data collection and report across the agency's many programs and activities.

For these reasons, we believe that a better approach would be for the Department to set a baseline demographic data collection requirement within the 2022 Final Rule and direct each sub-agency or program to set its own requirements and methods for data collection with a specific timeline for implementation. Notably, 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. HHS has already established or acknowledged recommended practices for engaging in demographic data collection in each of these demographic categories. HHS should adopt those existing data collection practices and engage in additional research where necessary.

Whether the Department includes a demographic data collection requirement in the 2022 Final Rule, engages in further rulemaking, or issues sub-regulatory guidance, we offer the following recommendations for principles to guide demographic data collection. Specifically, the Department should develop resources and toolkits for collecting demographic data; provide appropriate training and technical assistance to programs and grantees; adopt clear privacy and nondiscrimination protections; ensure that data collected is maintained safely and securely by the appropriate entities; ensure requests for data are required but that providing demographic data is voluntary and self-reported; set, review, and update minimum standard variables for each demographic category; support analyses based on multiple demographic variables; conduct regular review and meaningfully engage in community feedback; ensure public reporting of data and analysis. It is also essential that strict standards are adopted to make clear that data cannot be used for negative actions such as immigration or law enforcement, redlining or targeting of specific groups.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0005
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
[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 [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.

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0005
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 4.3.1.2.3

(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
As a result of discriminatory government policies and bias in the health care 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 THURGOOD MARSHALL INST. & INST. ON ASSETS AND SOC. POL'Y AT BRANDEIS UNIV. THE BLACK-WHITE RACIAL WEALTH GAP (2019), https://tminstituteldf.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. 10, 2022), https://www.npr.org/2022/03/10/1085882933/redlining-pollution-racism; Daniel Cusick, 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, MILBANK Q., Jun. 2005, at 247, 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 C. Arcaya & Alina Schnake-Mahl, Health in the Segregated City, NYU FURMAN CTR. (Oct. 2017), https://furmancenter.org/research/iri/essay/health-in-the-segregated-city] Black households also struggle to access healthy food: One out of every five Black households is situated in a food desert, [Footnote 15 Michael Chui, et al., A $300 billion opportunity: Serving the emerging Black consumer, MCKINSEY Q. (Aug. 6, 2021), https://www.mckinsey.com/featured-insights/diversity-and-inclusion/a-300-billion-dollar-opportunity- serving-the-emerging-black-american-consumer.] and communities of color have fewer large supermarkets than predominantly white neighborhoods, even when controlling for income. [Footnote 16 Kelly Brooky, Research Shows Food Deserts More Abundant in Minority Neighborhoods, JOHNS HOPKINS UNIV. MAG. (Spring 2014), https://hub.jhu.edu/magazine/2014/spring/racial-food-deserts/.]

Comment Number: HHS-OS-2022-0012-DRAFT-68873-0007
All Sections: 4.3.1.2.5, 4.3.1.2.4
(b)(5)

Organization: Fenway Community Health Center

Excerpt Text:
As noted in the preamble to the NPRM, LGBTQI+ people face both health disparities and barriers to healthcare. More than one in three LGBTQ Americans, and more than three in five transgender people, experienced discrimination in the past year. Fifteen percent of LGBTQ Americans report postponing or avoiding medical treatment due to discrimination; nearly three in ten transgender individuals do so [Footnote 36: Gruberg S, Mahowald L, Halpin J. The state of the LGBTQ community in 2020. A national public opinion study. Washington, DC: Center for American Progress. 2020, October 6. https://www.americanprogress.org/issues/lgbtq-rights/reports/2020/10/06/491052/state-lgbtq-community-2020/]. Some 69% of those who reported discrimination said it affected their psychological well-being; 44% said it affected their physical well- being.

The 2016 final rule implementing Section 1557 of the ACA explicitly prohibits discrimination based on gender identity and sex stereotyping, which includes sexual orientation discrimination, across federally-funded health care programs. This rule was implemented to address anti-LGBT discrimination in healthcare. This discrimination, as well as the fear of experiencing it, is a barrier to seeking routine, preventive care as well as emergency care. It also negatively affects people's mental and physical health, and sense of safety and belonging in society. We thank you for restoring the original intent of Section 1557 of the ACA—to expand access to health care without fear of discrimination.

Section 4.3.1.2.5 - Gender Identity

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4
(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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 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. 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: 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 w[ill] face discriminatory care" which ultimately causes many people to not seek care.

Comment Number: HHS-OS-2022-0012-DRAFT-65934-0001
All Sections: 4.3.1.2.5
(b)(5)

Organization: Sam & Devorah Foundation for Transgender Youth

Excerpt Text:
[Bold: Healthcare discrimination has an impact on each of us:]

[Italics: "Anti-trans 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 will 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 proposed anti-trans legislation deeply troubling. I see firsthand the negative impact of having 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 healthcare that I don't wish on anyone."

"As someone involved in the medical field 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 tell my students that they have to hide their identities because the government sees their existence as 'not worthy.' My students deserve a future where they can be proud of their identities and they can access the gender-affirming care and communities they deserve."]

[Bold: Anti-trans laws serve no valid, evidence-based purpose; they only further marginalize trans and nonbinary youth and adults:]

[Italics: "Stop the anti-trans legislation. Whether it affects me indirectly or it affects others very directly, people are hurting because of these bills for little reason beyond personal beliefs and not being given a chance."

"In order to continue to progress as a country, we need to ensure that all laws and bills proposed serve to expand our human rights and prioritize our safety because it is a slippery slope to repeal rights for specific populations. No one's rights are secure when we begin to do that. We saw that by expanding the rights for gay and lesbian individuals reduced the amount of psychiatric illness in the community as well as the amount of hate crimes. The evidence is clear that by passing laws that support marginalized populations, that we can make a direct impact on their safety, my safety. Let's destigmatize being trans/gender expansive and create a safer society!"

"These bills exist not to solve a problem in our society, but to bully and further marginalize an already incredibly vulnerable population."

"Trans/gender-non-conforming folks will continue to persist, to exist, and to survive no matter if this bill or any other trans-legislation gets passed. Trans-affirming care and spaces are necessary for the mental health of trans and non-binary folks everywhere- it is suicide prevention."]

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4

(b)(5)

Organization: Colors+

Excerpt Text:
Our youth are scared. They are afraid of the present and future protections to 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, LGBTQI+ 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 health care, 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 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 w[ill] 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] This surfaces in a wide variety of contexts, including physical and mental health care services [Hyperlink: https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people]. In a study published in Health Affairs, researchers examined the intersection of gender identity, sexual orientation, race,

and economic factors in health care access [Hyperlink: https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.0455]. They concluded that discrimination, as well as insensitivity or disrespect on the part of health care providers, were key barriers to health care access. And a recent systematic literature review conducted by Cornell University "found robust evidence that discrimination on the basis of sexual orientation or gender identity is associated with harms to the health of LGBT people" [Hyperlink: https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-scholarly-research-say-about-the-effects-of-discrimination-on-the-health-of-lgbt-people/].

Comment Number: HHS-OS-2022-0012-DRAFT-43609-0001
All Sections: 4.3.1.2.5

(b)(5)

Organization: Endocrine Society

Excerpt Text:
The Endocrine Society is the world's oldest and largest organization of scientists devoted to hormone research and physicians who care for people with hormone-related conditions. Many of our 18,000 members are recognized for their expertise in transgender research and medicine, and we advocate to improve and protect 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].

Comment Number: HHS-OS-2022-0012-DRAFT-39706-0001
All Sections: 4.3.1.2.5

(b)(5)

Organization: FORGE, Inc.

Excerpt Text:
It is well-acknowledged that 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, 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/braclet [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 harasing [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] distracted and (negatively) 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 providers have improved?") Not called me 'it' – Told me what they were doing – Not tell me 'Next 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 utilize other avenues for health care when possible.

One Navy doctor refused me care when a suture 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 professional, and bad treatment at their hands can affect individuals' willingness to access law enforcement, public benefits, educational institutions, and much more.

Comment Number: HHS-OS-2022-0012-DRAFT-44558-0001
All Sections: 4.3.1.2.5

(b)(5)

Organization: Equitas Health

Excerpt Text:
As noted in the preamble to the NPRM, LGBTQI+ people face both health 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 2010 report addressing healthcare 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 their 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 w[ill] 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 access. They concluded that discrimination, as well as insensitivity or disrespect on the part of healthcare providers, were key barriers to healthcare access. In fact, a recent systematic literature review conducted by Cornell University "found robust evidence that discrimination on the basis of sexual orientation or gender identity is associated with harms to the health of LGBT people."

And unfortunately, these problems persist in 2022. Data in a new report from the Center for American Progress "reveal that LGBTQI+ 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."

Other key findings from the report include the following:

- 23% of LGBTQI+ respondents – including 27% 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 healthcare providers;

- Overall, 15% of LGBQ respondents – including 23% of LGBQ respondents of color – reported experiencing some form of care refusal by a doctor or other healthcare provider in the year prior;

- Overall, 32% of transgender or non-binary respondents – including 46% of transgender or non-binary respondents of color – reported that they experienced at least one kind of care refusal by a healthcare provider in the past year;

- 55% of intersex respondents reported that, in the past year, a healthcare provider refused to see them because of their sex characteristics and/or intersex variation;

- Overall, 30% of transgender or non-binary respondents – including 47% of transgender or non-binary respondents of color – reported experiencing one form of denial by a health insurance company in the past year;

- 28% of transgender or non-binary respondents – including 29% of transgender or non-binary respondents of color – reported that a health insurance company denied them coverage for gender affirming hormone replacement therapy (HRT) in the year prior; and

- 22% of transgender or non-binary respondents – including 30% of transgender or non-binary respondents of color – reported that a health insurance company denied them coverage for gender affirming surgery in the year prior.

These statistics are realities that our patients and members of the broader LGBTQI+ community know all too well. It should also be mentioned that there are also a number of alarming trends related to access to care for LGBTQI+ youth and young adults. As noted by The Trevor Project in their most recent annual survey of youth and young adults (ages 13-24), 82% of respondents wanted mental healthcare services in the past year, and of that group, "60% of LGBTQ youth who wanted mental health care in the past year were not able to get it." As previously mentioned, the stark realities of anti-LGBTQI+ discrimination in healthcare settings are exceptionally well-documented, and the protections offered under this proposed rule are crucial. While a federal rule will certainly not solve all of the problems related to access to care for medically underserved communities, this is an important step, and such regulations affirm the human rights of members of the LGBTQI+ community, as noted by the United Nations. This is especially true for protecting care for transgender, non-binary, gender expansive, and intersex people across the country.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0001
All Sections: 4.3.1.2.2, 4.3.1.2.7, 4.3.1.2.5

(b)(5)

Organization: Health Care For All

Excerpt Text:
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 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66750-0001
All Sections: 4.3.1.2.5, 4.3.1.2.3
(b)(5)

Organization: Jacobs Institute of Women's Health

Excerpt Text:
The [Italics: Dobbs v. Jackson Women's Health Organization] decision has been disastrous for public health, and several changes to the draft rule are necessary to limit the harm that state responses to [Italics: Dobbs] are causing to women, girls, and other people capable of becoming pregnant.

Several states have now banned abortion, leaving residents seeking abortion care a choice between spending thousands of dollars to travel elsewhere for services, risking arrest by self-managing their abortions at home, or bearing children against their will. Those with low incomes – who, because of structural racism, are disproportionately likely to be Black women or other people of color – or other barriers to travel are least likely to be able to leave their states to end their pregnancies legally. For those forced to continue their pregnancies and bear children against their will, maternal mortality risks are particularly high for Black and American Indian/Alaska Native women, [Footnote 1: Trost S, Beauregard J, Chandra Gy, Njie F, Berry J, Harvey A, Goodman DA. (2022). Pregnancy-Related Deaths: Data from Maternal Mortality Review Committees in 36 US States, 2017–2019. https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc.html] and risks of severe complications are higher among Black, Latina, and Asian women compared to White women. [Footnote 2: BlueCross BlueShield. (2022). Racial and Ethnic Disparities in Maternal Health. https://www.bcbs.com/sites/default/files/file-attachments/health-of-america-report/HOA-Maternal-Health_2022.pdf] Being pregnant in an abortion-banning state has now become even more risky, because providers in states that ban abortion, facing the threat of lawsuits, have curtailed the care they provide to people who are pregnant or could become pregnant. [Footnote 3: Arey W, Lerma K, Beasley An, Harper L, Moayedi G, White, K. (2022). A Preview of the Dangerous Future of Abortion Bans, Texas Senate Bill 8. New England Journal of Medicine, 387:388-390.] [Footnote 4: Nambiar A, Patel S, Santiago-Munoz P, Spong CY, Nelson DB. (2022). American Journal of Obstetrics & Gynecology, 27(4): 648-650.] Women experiencing miscarriages have been denied care even as their conditions threaten their health and lives. [Footnote 5: Feibel C. (2022). Because of Texas abortion law, her wanted pregnancy became a medical nightmare. NPR, July 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] [Footnote 6: CNN. (2022). Woman says Texas abortion law prevented her from getting timely miscarriage care. WIBW, July 18, 2022. https://www.wibw.com/2022/07/18/woman-says-texas-abortion-law-prevented-her-getting-timely-miscarriage-care/]

Problems extend beyond care for those who are pregnant. Women who are not pregnant and require drugs or procedures that could interfere with pregnancies have been denied the treatments they need to manage their conditions. [Footnote 7: Shepherd K & Stead Sellers F. (2022). Abortion Bans Complicate Access to Drugs for Cancer, Arthritis, Even Ulcers. Washington Post (August 8, 2022). www.washingtonpost.com/health/2022/08/08/abortion-bans-methotrexate- mifepristone-rheumatoid-arthritis/] [Footnote 8: Ollstein AM & Payne D. (2022). Patients face barriers to routine care as doctors warn of ripple effects from broad abortion bans. POLITICO, September 28, 2022. https://www.politico.com/news/2022/09/28/abortion-bans-medication-pharmacy-prescriptions-00059228] Lawmakers in some states seek to ban some forms of contraception or prohibit Medicaid from covering them. [Footnote 9: Rovner J. (2022). A GOP Talking Point Suggests Birth Control Is Not at Risk. Evidence Suggests Otherwise. KHN, August 5, 2022. https://khn.org/news/article/republican-talking-point-birth-control-risk-abortion-false-claim/] Those who have a history of abortion – or face anti-abortion providers who suspect that patients have had or might in the future obtain an abortion – could face discrimination if abortion bans embolden providers who might have curbed discriminatory practices in the past.

The Dobbs decision has exacerbated existing inequities related to pregnancy. Those who live in areas served only by religiously affiliated institutions have long been at greatest risk of being unable to receive timely, appropriate care for miscarriages and other forms of reproductive healthcare. [Footnote 10: Barry-Jester AM & Thomson-DeVeaux A. (2018). How Catholic Bishops Are Shaping Health Care In Rural America. FiveThirtyEight, July 25, 2018. https://fivethirtyeight.com/features/how-catholic-bishops-are-shaping-health-care-in-rural-america/] In many cases, women have not been aware that they could not receive appropriate care at their local facilities because of religious directives until they were in the position of needing prompt care. [Footnote 11: Catholics for Choice. (2017). Is Your Health Care Compromised? How the Catholic Directives Make for Unhealthy Choices. https://www.catholicsforchoice.org/wp-content/uploads/2017/01/2017_Catholic-Healthcare-Report.pdf] [Footnote 12: Kaye J, Amiri B, Melling L, Dalven J. (2016). Health Care Denied. American Civil Liberties Union. https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied]

Comment Number: HHS-OS-2022-0012-DRAFT-39726-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)
Organization: Family Equality

Excerpt Text:
We are pleased to submit this comment in support of the proposed changes to Section 1557 rules that HHS is now considering. Significantly, the proposed rules directly address the widespread discrimination against LGBTQI+ families in our healthcare system by restoring provisions which prevent healthcare entities and insurance companies from discriminating against anyone based on sex and reaffirms that discrimination based on sexual orientation and gender identity is

considered unlawful discrimination. These rules are consistent with the Bostock decision and with current legal precedent, and they ensure that discrimination on the basis of association also is expressly prohibited. This means that children and other family members of LGBTQI+ people are explicitly protected from unlawful refusal of care. Addressing this discrimination, which often puts the health of children at risk, is vital to address ongoing health disparities and to improve the nation's overall health outcomes.

Comment Number: HHS-OS-2022-0012-DRAFT-66033-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4

(b)(5)

Organization: Legacy Community Health

Excerpt Text:
It is clear from the experiences of our patients that anti-LGBTQIA+ discrimination in healthcare is still very common, and this discrimination leads to worse health outcomes and additional barriers to care. We routinely care for patients who reside outside our usual service areas because they do not have access to care in their own communities. Sometimes, patients will spend an entire day traveling to one of our clinic locations to receive care. We know that there are many more patients who do not have the resources or ability to travel to one of our health centers, and instead opt to forego healthcare altogether.

All healthcare providers must fulfill their obligations to provide affirming, competent, nondiscriminatory healthcare. This proposed rule is a critically important step in this direction. Healthcare is a human right, and all people should be able to access affirming and nondiscriminatory care wherever they choose to receive it. We strongly support this proposed rule, and we urge for its swift finalization.

Comment Number: HHS-OS-2022-0012-DRAFT-68054-0001
All Sections: 4.3.1.2.2, 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3

(b)(5)

Organization: Washington Health Benefit Exchange

Excerpt Text:
The proposed rule strengthens our state's ability to make progress toward these goals and preserves the gains our state has made to reduce the uninsured rate and improve access to care, particularly for underserved communities, women, LGBTQ Washingtonians, pregnant women, and individuals with limited English proficiency (LEP). The proposed rule aligns with the Supreme Court's 2020 Bostock v. Clayton County opinion which established clear federal protections against employment discrimination based on sexual orientation and gender identity discrimination.

WAHBE supports the overall approach of the proposed rule. It comprehensively addresses discrimination that can contribute to health disparities. The proposed rule reinstates essential protections announced in 2016 and eliminates the confusion and uncertainty created by the later 2020 rulemaking. The 2020 changes excluded many insurers, third-party administrators, and lines of business from being bound by 1557 protections; reduced language access requirements; narrowed the definition of sex as a basis for discrimination; and reduced the scope and applicability of Section 1557 to exclude a variety of HHS programs.

Comment Number: HHS-OS-2022-0012-DRAFT-65682-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3

(b)(5)

Organization: Primary Care Development Corporation

Excerpt Text:

I. PCDC Supports the Reinstatement of Nondiscrimination Protections for LGBTQ Individuals

The proposed rule will reduce incidents of discrimination towards members of the LGBTQ community by reinstating nondiscrimination protections for LGBTQ individuals that were removed by the Trump administration's 2020 Final Rule and expanding on the original protections found in the Obama administration's 2016 Final Rule. Members of the LGBTQ community were disproportionally affected by Trump administration's revision of the 2016 Section 1557 Final Rule – especially as it relates to primary care access.

We appreciate and want to emphasize the Biden administration's acknowledgment that LGBTQ people "face pervasive health disparities and barriers in accessing needed health care." LGBTQ patients are more likely than their heterosexual counterparts to encounter stigma and discrimination and are at increased risk for physical and emotional health challenges. [Footnote 2: St. Catherine University, How Discrimination Impacts LGBTQ Healthcare, https://www.stkate.edu/academics/healthcare-degrees/lgbtq-health-discrimination, (last visited September 21, 2022)] For example, transgender individuals are less likely to have health insurance, [Footnote 3: Luisa Kcomt et al., Healthcare avoidance due to anticipated discrimination among transgender people: A call to create trans-affirmative environments, SSM Popul. Health, August 11, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7276492/. (last visited September 21, 2022).] and as a result, face significant barriers in accessing health care, including primary care. [Footnote 4: Hudaisa Hafeez et al., Health Care Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review, Cureus, April 17, 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478215/. (last visited September 21, 2022)] Similarly, lesbian women are less likely to access preventive cancer screening, a routine part of primary care, due in part to poor patient experiences seeking health care and in part due to both patient's and provider's lack of knowledge about cancer risk. [Footnote 5: Id]. This lack of access to general and preventative care correlates with the LGBTQ community's higher prevalence of mental health issues and sexually transmitted infections (STIs), including HIV. [Footnote 6: Id].

Although most primary care providers and other health care providers aspire to provide non-discriminatory person-centered, comprehensive care, as was clear from the groundswell of opposition from established medical organizations when the Trump Administration's rollback of protections was proposed, [Footnote 7: See, e.g., Todd Shryock, Physician groups oppose rollback of anti-discrimination protections, Medical Economics, May 30, 2019, https://www.medicaleconomics.com/view/physician-groups-oppose-rollback-anti-discrimination- protections (describing a joint letter in opposition to the rule change signed by American Medical Association, American College of Physicians, American Academy of Nursing, American Academy of PAs, American Nurses Association, American Academy of Pediatrics, American Psychiatric Association, American Psychological Association, and others).] nonetheless many transgender patients specifically report experiencing discrimination when accessing health care. When polled about their experiences with primary care, for example, transgender and gender nonconforming respondents reported experiencing the highest rates of discrimination and barriers to care. To underscore this point, about 10% of respondents reported that health care professionals used harsh language towards them, 11% reported that health professionals refused to touch them or used excessive precautions, and more than 12% of respondents reported being blamed for their health status. [Footnote 8: Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV, Report, 2010, available at https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt- caring.pdf.] The anti-discrimination provisions in the proposed rule have the potential to reduce these incidents by clarifying the obligations of both providers and insurers.

Reducing discrimination on the basis of sex, including sexual orientation and gender identity, are necessary steps towards achieving health equity for all communities. We strongly support the rule change and believe that the provisions mentioned will help ensure that members of LGBTQ community are able to access a full range of necessary health care, including primary care.

Comment Number: HHS-OS-2022-0012-DRAFT-68873-0001
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: Fenway Community Health Center

Excerpt Text:
Discrimination based on sexual orientation and gender identity (SOGI) negatively affects the health of LGBTQIA+ people and functions as a barrier to care [Footnote 1: Gruberg S, Mahowald L, Halpin J. The state of the LGBTQ community in 2020. A national public opinion study. Washington, DC: Center for American Progress. 2020, October 6. https://www.americanprogress.org/issues/lgbtq- rights/reports/2020/10/06/491052/state-lgbtq-community-2020/]. Discrimination in health care may cause sexual and gender minority patients to have higher rates of medical mistrust, which may constitute a barrier to accessing care [Footnote 2: Ahmed Mirza, Shabab and Rooney, Caitlin (2018). Discrimination Prevents LGBTQ People from Accessing Health Care. Washington, DC: Center for American Progress].

LGBTQIA+ people of color experience intersectional stigma. Racism is a major barrier to care for Black lesbian and bisexual women [Footnote 3: Brenick A, Romano K, Kegler C, Eaton LA. Understanding the Influence of Stigma and Medical Mistrust on Engagement in Routine Healthcare Among Black Women Who Have Sex with Women. LGBT Health. 2017 Feb;4(1):4-10]. Anti-Black stigma is common in predominantly White LGBT settings [Footnote 4: McConnell EA, Janulis P, Phillips G 2nd, Truong R, Birkett M. Multiple Minority Stress and LGBT Community Resilience among Sexual Minority Men. Psychol Sex Orientat Gend Divers. 2018 Mar;5(1):1-12]. The long history of structural stigma and discrimination against Black people in healthcare settings contributes to medical mistrust that acts as a major barrier to accessing care for Black LGBT people [Footnote 5: Quinn KG, Christenson E, Spector A, Amirkhanian Y, Kelly JA. The Influence of Peers on PrEP Perceptions and Use Among Young Black Gay, Bisexual, and Other Men Who Have Sex with Men: A Qualitative Examination. Arch Sex Behav. 2020 Aug;49(6):2129-2143] [Footnote 6: Cahill S, Taylor SW, Elsesser SA, Mena L, Hickson D, Mayer KH. Stigma, medical mistrust, and perceived racism may affect PrEP awareness and uptake in black compared to white gay and bisexual men in Jackson, Mississippi and Boston, Massachusetts. AIDS Care. 2017 Nov;29(11):1351-1358].

Partly as a result of widespread societal discrimination, LGBT people are more likely than cisgender, straight people to live in poverty (22% vs. 16%), with transgender people (29%), bisexual women (29%), and bisexual men (19%) experiencing the highest rates of poverty [Footnote 7: Badget L, Choi S, Wilson B. (October 2019). LGBT Poverty in the United States: A study of differences between sexual orientation and gender identity groups. UCLA School of Law: The Williams Institute. Available at: https://williamsinstitute.law.ucla.edu/publications/lgbt-poverty-us/]. Furthermore, LGBT people of color had significantly higher rates of poverty compared to their White counterparts [Footnote 8: Ibid].

Lack of access to health insurance is also a key correlate of health disparities. Sexual minority women are less likely to have health insurance and a primary care provider than heterosexual women. An analysis of 2013-2015 National Health Interview Survey data found that lesbian and gay women were significantly less likely to have health insurance (80.7% of sexual minority women versus 85.2% of heterosexual women) and a usual primary care provider (79.6% of sexual minority women versus 84% of heterosexual women) compared to heterosexual women [Footnote 9: Lunn MR, Cui W, Zack MM, Thompson WW, Blank MB, Yehia BR. Sociodemographic Characteristics and Health Outcomes Among Lesbian, Gay, and Bisexual U.S. Adults Using Healthy People 2020 Leading Health Indicators. LGBT Health. 2017 Aug;4(4):283-294. doi: 10.1089/lgbt.2016.0087. Epub 2017 Jul 20. PMID: 28727950; PMCID: PMC5564038]. Striking racial/ethnic disparities in insurance coverage—with American Indians and Alaska Natives, Hispanics, and Black people less likely to be insured than White non-Hispanic and Asian Pacific Islander people—also affect LGBTQI+ people of color [Footnote 10: Artiga S, Hill L, Orgera K, Damico A. Health coverage by race and ethnicity, 2010-2019. Kaiser Family Foundation. July 16, 2021. https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/].

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0010
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
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 Mahowal, 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 Caroline Medina, 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0011
All Sections: 4.3.1.2.5, 4.3.1.2.4, 2

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
[Italics: D. Impact of Discrimination on LGBTQ+ People.]

Discrimination in healthcare settings remains a significant problem for LGBTQ+ individuals. Such discrimination adversely affects the mental and physical health of LGBTQ+ individuals and engenders the individuals' avoidance behavior, delays, or denials of care. [Footnote 9: Caroline Medina & Lindsay Mahowald, Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities, (Sept. 8, 2022), https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/.] In 2021, roughly ten percent of the LGBTQ+ survey respondents reported experiencing refusals of care by doctors and other healthcare providers. [Footnote 10: Id.] Finally, such discrimination deters LGBTQ+ people from seeking care. The 2021 survey revealed that LGBTQ+ individuals were three times more likely to postpone or avoid healthcare due to discrimination by providers than non-LGBTQ+ individuals. [Footnote 11: Id.]

Under the current iteration of the rule, LGBTQ+ individuals are more likely to avoid seeking medical care out of fear of discrimination. [Footnote 12: See, Shabab Ahmen Mirza & Caitlin

Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care, Ctr. for Am. Progress (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.] For example, thirty percent of LGBTQ+ Americans reported difficulty accessing healthcare services and fifteen percent reported postponing or foregoing healthcare services due to the current rule. [Footnote 13: Sharita Gruberg et al, The State of the LGBTQ Community in 2020, Ctr. for Am. Progress (Oct. 6, 2020), https://www.americanprogress.org/article/state-lgbtq-community-2020/.] This inability to access healthcare flies directly in the face of the spirit and intent of the [Italics: Patient Protection] and Affordable Care Act, specifically Section 1557: "[A]n individual shall not, on the ground prohibited under [various Civil Rights laws], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity." [Footnote 14: 111 P.L. 148, Sec. 1557.]

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0014
All Sections: 4.3.1.2.5

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:

The cornerstone of gender-affirming care is affirming an individual's self-identified gender and responding to self-identified needs and treatment goals—such as treating any existing gender dysphoria—consistent with evidence-based care. [Footnote 25: Coleman, E., et al., Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, 23 INT'L J. TRANSGENDER HEALTH S1 (2022). defining "gender affirmation" and "gender affirmation surgery" in relation to "a person's gender identity."] Consequently, gender-affirming care does not include harmful practices that attempt to impose or change an individual's gender identity or sexual orientation through so-called "conversion therapies," or to impose or influence a sex assignment, gender identity, or sexual orientation through medical intervention on an individual unable to give informed consent or assent.

The World Professional Association for Transgender Health (WPATH) Standards of Care thus provide that "gender-affirming interventions may be considered" when "people experience gender incongruence," and recommend "gender-affirming" surgeries be performed only when "the individual can decide for him/her/themselves." [Footnote 26: Id. at S101-02.] Performing non-emergent gonadal or genital surgeries on patients unable to participate in—lead alone lead—decisionmaking due to their age is starkly inconsistent with the patient-centered, evidence-based principles that define gender-affirming care. Such practices are not responsive to (and often conflict with) an individual's self-identified gender and bodily self-determination; they are not evidence-based; and they often lack or are inconsistent with the meaningful informed consent or assent of the individual.

Recently, however, some proponents of such harmful "conversion" or "normalizing" practices on LGBTQI+ children, youth and adults have responded to clinical criticism and regulation by seeking to recast such practices as "gender-affirming." [Footnote 27: See, e.g.,Meyer-Bahlburg H. F. L., The Timing of Genital Surgery in Somatic Intersexuality: Surveys of Patients' Preferences, 95 HORM RES PAEDIATR 12 (2022) (summarizing clinical convenience-sample surveys of patients who received surgery in infancy or childhood and referring to "diversity in opinions regarding the timing of gender-affirming genital surgery," i.e., in early childhood or later). Reflecting this potential confusion, even researchers who urge delaying genital surgeries until patients can participate in decisionmaking sometimes use "gender assigning" and "gender affirming" in this context. See, e.g., Ellerkamp, V. et al., Techniques of Primary Vaginoplasty in Young Adults with Differences of Sex Development and Female Identification, 11 J. CLIN. MED. 3688 (2022).] To avoid such misinterpretation, HHS should make clear that nothing in the Section 1557 statute or this rule may be construed to prohibit policies or practices that seek to protect patient autonomy and safety and that do not discriminate based on sex. For example, consistent with Section 1557, a hospital may adopt a policy prohibiting its staff from performing (and an insurer may adopt a policy prohibiting its plans from covering) non-emergent genital surgeries and gonadectomies on patients too young to provide informed consent or assent. Moreover, as previously discussed, Section 1557 itself may prohibit such harmful practices in many circumstances. Thus, to prevent bad actors from asserting that Section 1557 forbids policies and practices that actually protect patients from discriminatory harms, we urge the Department to add clarifying language to the final rule preamble.

We recommend adding the following preamble language with respect to sections 92.206 and 92.207:
[Underline: As used in the final rule and this preamble, "gender-affirming care" does not include any practice involving discriminatory harm, such as efforts to change a young person's gender identity or sexual orientation or to alter or remove genitals or gonads of a child unable to participate in healthcare decisionmaking.]

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0014
All Sections: 4.3.1.2.5, 4.3.1.2.4

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[Bod: 1. Sexual Orientation and Gender Identity Discrimination Harms Patients]

The Proposed Rule is an important step to address the "robust evidence that discrimination on the basis of sexual orientation or gender identity is associated with harms to the health of LGBTQI+ people". 87 Fed. Reg. at 47,834. LGBTQ persons report experiencing barriers to receiving medical services, including disrespectful attitudes, discriminatory treatment, inflexible or prejudicial policies, and even outright refusals of essential care, leading to poorer health

outcomes and often serious or even catastrophic consequences. [Footnote 15: Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV at 5–6 (2010) , https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care- isnt-caring.pdf; see also Jennifer Kates, et al., Kaiser Family Found., Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender (LGBT) Individuals in the U.S. (May 3, 2018), https://www.kff.org/report-section/health-and-access-to-care-and-coverage-lgbt-individuals-in-the-us- health-challenges.] LGBTQ individuals experience poorer physical health compared to their heterosexual and non-transgender counterparts, have higher rates of chronic conditions, and are at higher risk for certain mental health and behavioral health conditions, including depression, anxiety, and substance misuse. [Footnote 16: Lambda Legal, at 5, 8.] HHS recognizes that these harms have been further exacerbated by the COVID-19 pandemic and limited healthcare resources. 87 Fed. Reg. at 47,834.

Transgender people in particular face significant barriers to receiving both routine and gender-affirming care. [Footnote 17: See Sandy E. James et al., Nat'l Ctr. For Transgender Equal., The Report of the 2015 U.S. Transgender Survey, at 96-99 . (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Full- Report-Dec17.pdf; (transgender people in particular report hostile and disparate treatment from providers); see also Morning Consult & The Trevor Project, How COVID-19 is Impacting LGBTQ Youth at 25 (2020), https://www.thetrevorproject.org/wp-content/uploads/2020/10/Trevor-Poll_COVID19.pdf (finding that 28% of trans and nonbinary youth and 18% of LGBTQ youth overall reported wanting mental healthcare and not being able to receive it, compared with only 7% of white cisgender heterosexual youth).] These barriers create serious consequences. Among transgender people, suicide attempts are nine times more common than in the overall U.S. population (41% versus 4.6%). [Footnote 18: Ann P. Haas et al., Am. Found. For Suicide Prevention & The Williams Inst., Suicide Attempts Among Transgender and Gender Non-Conforming Adults: Findings of the National Transgender Discrimination Survey 2 (2014), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-GNC- Suicide-Attempts-Jan-2014.pdf.] Unaddressed gender dysphoria can impact quality of life and trigger decreased social functioning. [Footnote 19: See Emily Newfield et al., Female-to-Male Transgender Quality of Life, 15(9) Quality of Life Research 1447 (2006), https://www.ncbi.nlm.nih.gov/pubmed/16758113 (observing that transgender men who received gender-affirming care reported having a higher health-related quality of life than those who had not).] Transgender people are more likely to experience income insecurity, [Footnote 20: See Sharita Gruberg et al., Ctr. for Am. Progress, The State of the LGBTQ Community in 2020 (Oct. 6, 2020), https://www.americanprogress.org/article/state-lgbtq-community-2020 (showing 54% of transgender respondents reported that discrimination moderately or significantly affected their financial well-being).] more likely to experience food insecurity, [Footnote 21: Kerith J. Conron & Kathryn K. O'Neill, Univ. of Cal. Los Angeles, Food Insufficiency Among Transgender Adults During the COVID-19 Pandemic 2 (2021), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Food-Insufficiency-Dec-2021.pdf.] and more likely to be uninsured or rely on state-run programs such as Medicaid. [Footnote 22: Jaime M. Grant et al., Nat'l Ctr. For Transgender Equal. & Nat'l Gay and Lesbian Task Force, National Transgender Discrimination Survey Report on Health & Health Care at 8 (2010), https://cancer- network.org/wp-content/uploads/2017/02/National_Transgender_Discrimination_Survey_Report_on_health_and

_health_c are.pdf (23% of transgender women and 13% of transgender men report relying on public health insurance); see also Kellan Baker et al., Ctr. for Am. Progress, The Medicaid Program and LGBT Communities: Overview and Policy Recommendations (Aug. 9, 2016), https://www.americanprogress.org/article/the-medicaid-program-and-lgbt-communities-overview-and- policy-recommendations (noting that the high prevalence of poverty in LGBTQ communities, especially among transgender people and LGBTQ people of color, makes Medicaid a critical program for the health and well-being of these communities)] State programs are likely to bear the financial burden of addressing the significant consequences resulting from denying transgender people necessary healthcare. [Footnote 23: See Christy Mallory & William Tentindo, Williams Inst., Medicaid Coverage for Gender Affirming Care (Oct. 2019), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Medicaid-Gender- Care-Oct-2019.pdf (listing states that include gender affirming care in their Medicaid programs); see e.g., Wash. Admin. Code § 182-501-0060 (listing program's benefits); Cal. Code Regs. tit. 22 § 51301 et seq. (same); N.Y. Comp. Codes R. & regs. tit. 18, § 505.1 et seq. (same).] Access to gender-affirming care improves wellbeing for transgender adults. [Footnote 24: Michael Zaliznyak et al., Effects of Gender-Affirming Hormone Therapy on Sexual Function of Transgender Men and Women, 206 J. of Urology 637, 638 (2021), https://www.auajournals.org/doi/epdf/10.1097/JU.0000000000002045.06; What We Know Project, Cornell University, What Does the Scholarly Research Say about the Effect of Gender Transition on Transgender Well-Being? (2018) https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what- does-the-scholarly-research-say-about-the-well-being-of-transgender-people (online literature review); Newfield et al., supra fn. 20.]

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0015
All Sections: 4.3.1.2.5, 4.3.1.2.6, 2

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[Bold: a. Impacts on Transgender Youth]

LGBTQ youth are especially vulnerable. 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/PMC5478215.] 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/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 M. 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 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: Ximena 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 social support and gender-affirming healthcare experience mental health outcomes equivalent to their cisgender peers. [Footnote 29: Dominic J. Gibson et al., Evaluation of Anxiety and Depression in a Community Sample of Transgender Youth, 4(4) J. Am. Med. Ass'n Open 1, 1–2 (Apr. 7, 2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2778206 (finding no significant group differences in self and parent reported depressive and anxiety symptoms among "socially transitioned transgender youth, their siblings, and age- and gender-matched control participants"); Lily Durwood et al., Social Support and Internalizing Psychopathology in Transgender Youth, 50 J. of Youth and Adolescence 841 (2021), https://link.springer.com/article/10.1007%2Fs10964-020-01391-y ("Parents who reported higher levels of family, peer, and school support for their child's gender identity also reported fewer internalizing symptoms."); Kristina R Olson et al., Mental Health of Transgender Children Who Are Supported in Their Identities, 137(3) Pediatrics 1, 1 (2016), https://pubmed.ncbi.nlm.nih.gov/26921285 (similar); Anna I. R. van der Miesen et al., Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender General Population Peers, 66 J. Adolescent Health 699, 703 (2020), https://pubmed.ncbi.nlm.nih.gov/32273193 (similar); see also Jack L. Turban et al., Access To Gender- Affirming Hormones During Adolescence and Mental Health Outcomes Among Transgender Adults 17 PLOS One 1, 8 (2022), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0261039 (access to gender-affirming hormones during adolescence was associated with lower rates of past-month severe psychological distress, past-year suicidal ideation, past month binge drinking, and lifetime illicit drug use when compared to access to gender-affirming hormones during adulthood).] And for teens under the age of eighteen, use of gender-affirming hormone therapy was associated with 39% lower odds of recent depression and 38% lower odds of attempting suicide compared to adolescents who wanted, but did not receive, such therapy. [Footnote 30: Amy E. Green et al., Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth, 70 J. Adolescent Health 643, 647–48 (2022), https://doi.org/10.1016/j.jadohealth.2021.10.036; see also Diana M. Tordoff, et al., Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care, 5 J. Am. Med. Ass'n Network Open 1, 1 (2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789423 (access to gender

affirming care associated with improved mental health outcomes in youths).] Adolescents who begin gender-affirming treatment at later stages of puberty are over five times more likely to have been diagnosed with depression and over four times more likely to have anxiety disorders than adolescents who seek treatment in early puberty. [Footnote 31: Julia C. Sorbara et al., Mental Health and Timing of Gender-Affirming Care, 146 Pediatrics 1, 5 (2020), https://publications.aap.org/pediatrics/article/146/4/e20193600/79683/Mental-Health-and-Timing- of-Gender-Affirming-Care.]

In addition to improved mental health outcomes, access to gender-affirming treatment improves overall well-being in transgender teenagers and young adults. A longitudinal study that followed transgender adolescents from their intake at a gender clinic into young adulthood found that gender-affirming treatment resulted in significant improvement in global functioning and psychological wellbeing. [Footnote 32: Annelou L.C. de Vries et al., Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment, 134 Pediatrics 696, 702 (2014), https://doi.org/10.1542/peds.2013-2958.] The study reported that post-treatment, participants had "rates of clinical problems that are indistinguishable from general population samples," and that their life satisfaction, quality of life, and subjective happiness were comparable to their same-age cisgender peers. [Footnote 33: Id.] Another study found significant improvement in teens' self-worth and perceived physical appearance after starting hormone replacement therapy. [Footnote 34: Marijn Arnoldussen et al., Self-Perception of Transgender Adolescents After Gender-Affirming Treatment: A Follow-Up Study Into Young Adulthood, 9 LGBT Health 238 (2022), https://www.liebertpub.com/doi/epdf/10.1089/lgbt.2020.0494; see also Mona Ascha et al., Top Surgery and Chest Dysphoria Among Transmasculine and Nonbinary Adolescents and Young Adults, JAMA Pediatr. (forthcoming 2022), doi:10.1001/jamapediatrics.2022.3424 (reconstructive chest surgery associated with statistically significant improvement in chest dysphoria, gender congruence, and body image at three months follow-up).]

[Bold: b. Impacts on Transgender Elders]

LGBTQ elders are also particularly vulnerable to discrimination. In a survey of 2,560 LGBTQ older adults in the United States, nearly half of respondents were living at or below 200 percent of the federal poverty line. [Footnote 35: Karen I. Fredriksen-Goldsen et al., The Aging and Health Report: Disparities and Resilience Among Lesbian, Gay, Bisexual, and Transgender Older Adults Institute for Multigenerational Health 4 (2011), https://www.lgbtagingcenter.org/resources/pdfs/LGBT%20Aging%20and%20Health%20Report_final.pdf; see also Karen I. Fredriksen-Goldsen et al., Iridescent Life Course: LGBTQ Aging Research and Blueprint for the Future: A Systematic Review 65 Gerontology 253 (2019), https://pubmed.ncbi.nlm.nih.gov/30826811 (discussing state of literature).] More than one in ten LGBTQ older adults (13%) who participated in the project have been denied healthcare or provided with inferior care. [Footnote 36: Fredriksen-Goldsen et al. (2011), supra note 35, at 4.] Fifteen percent of LGBTQ older adults fear accessing healthcare outside the LGBTQ community, and 8% fear accessing healthcare inside the community. [Footnote 37: Id.] More than 21% of LGBTQ older adults have not revealed their sexual orientation or gender identity to their primary physician, and bisexual older women and men are less likely to disclose than lesbian and gay older adults. [Footnote 38: Id. at 4–5.]

Nationally, 40% of transgender seniors reported being denied healthcare or facing discrimination by healthcare providers. [Footnote 39: Id. at 31; see also Annie Snow et al., Barriers to Mental Health Care for Transgender and Gender-Nonconforming Adults: A Systematic Literature Review 44 Health & Social Work 149–55 (2019), https://pubmed.ncbi.nlm.nih.gov/31359065.] Transgender older adults are at significantly higher risk of poor physical health, disability, depressive symptomatology, and perceived stress, and suffer from fear of accessing health services, lack of physical activity, internalized stigma, victimization, and lack of social support. [Footnote 40: Karen I. Fredriksen-Goldsen et al., The Physical and Mental Health of Transgender Older Adults: An At-Risk and Underserved Population 54 The Gerontologist 488 (2014), https://pubmed.ncbi.nlm.nih.gov/23535500; see also Vanessa D. Fabbre & Eleni Gaveras, The Manifestation of Multilevel Stigma in the Lived Experiences of Transgender and Gender Nonconforming Older Adults 90 Am. J. of Orthopsychiatry 350 (2020), https://pubmed.ncbi.nlm.nih.gov/31971406; Kristen E. Porter et al., Providing Competent and Affirming Services for Transgender and Gender Nonconforming Older Adults 39 Clinical Gerontologist 366 (2016), https://pubmed.ncbi.nlm.nih.gov/29471769 Charles P. Hoy-Ellis & Karen I. Fredriksen-Goldsen, Depression Among Transgender Older Adults: General and Minority Stress 59 Am. J. of Cmty. Psychology 295 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5474152.] Discrimination in a long-term care setting and the related anxiety anticipating it are associated with negative health outcomes. [Footnote 41: Jaclyn White Hughto & Sari Reisner, Social Context of Depressive Distress in Aging Transgender Adults 37 J. of Applied Gerontology 1517 (2018), https://pubmed.ncbi.nlm.nih.gov/28380703; see also Dagfinn Nåden et al., Aspects of Indignity in Nursing Home Residences as Experienced by Family Caregivers 20 Nursing Ethics 748 (2013), https://pubmed.ncbi.nlm.nih.gov/23462504.] At least one recent study has shown that LGBTQ older adults reported a higher likelihood of moving to a long-term care facility, as compared to heterosexual older adults. [Footnote 42: Mekiayla Singleton et al., Anticipated Need for Future Nursing Home Placement by Sexual Orientation: Early Findings from the Health and Retirement Study 19 Sexuality Research & Soc. Policy 656 (2022), https://doi.org/10.1007/s13178-021-00581-y.] A survey of LGBTQ elders and their families by Justice in Aging also found that 89% of respondents predicted that staff would discriminate against an openly LGBTQ elder. [Footnote 43: Justice in Aging, Stories from the Field: LGBT Older Adults in Long-Term Care Facilities 8 (2d. ed. 2015), https://www.justiceinaging.org/wp-content/uploads/2015/06/Stories-from-the-Field.pdf.] A majority also thought that other residents would discriminate (81%) and, more specifically, that other residents would isolate an LGBTQ resident (77%). [Footnote 44: Id.] More than half also predicted that staff would abuse or neglect the person (53%). [Footnote 45: Id.]

These facts demonstrate the need for robust LGBTQ protections under Section 1557 and the harm caused by the 2020 Rule's departure from proper statutory interpretation. "[T]he unmistakable basis for HHS's action was a rejection of the position taken in the 2016 Rules that sex discrimination includes discrimination based on gender identity and sex stereotyping." [Italics: Walker], 480 F. Supp. 3d at 430. "[W]hether by design or bureaucratic inertia, the fact remains that HHS finalized the 2020 Rules without addressing the impact of the Supreme Court's decision in [Italics: Bostock]." Id. Instead, the 2020 Rule drew "from the Government's losing litigating position in [Italics: Bostock]" to justify stripping away needed protections. [Italics: Whitman-Walker Clinic], 485 F. Supp. 3d at 41 (citing 85 Fed. Reg. at 37,178-79).

Abundant evidence of harm, discrimination, and health disparities experienced by LGBTQ people demands reversal. It is critical for HHS to finalize rules restoring the correct interpretation of "sex discrimination" under Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4

(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
Years later, the situation has not much improved. The Department's [bold/underlined: 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 [bold/underlined: wide variety of contexts,] including physical and mental health care services. In a [bold/underlined: study published in [italics: Health Affairs,]] researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access. They concluded that discrimination, as well as insensitivity or disrespect on the part of health care providers, were key barriers to health care access. And a recent [bold/underlined: systematic literature review] conducted by Cornell University "found robust evidence that discrimination on the basis of sexual orientation or gender identity is associated with harms to the health of LGBT people."

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:
As health care providers we have witnessed first-hand the harm discrimination 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.apa.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-death-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 all Black people reporting this happens often or very often [embedded hyperlink text (https://patientengagementhit.com/news/one-quarter-of-adults-report-racial-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 [embedded hyperlink text (https://www.nationalpartnership.org/our-work/health/reports/black-womens-maternal-health.html)]to die from a pregnancy related cause than white women. For LGBTQ+ people, pervasive discrimination also discourages a significant number of patients from seeking health care. According to data from the Center for American Progress [embedded hyperlink text (https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/)], 8 percent of all LGBTQ+ people and 14 percent of those who had experienced discrimination on the basis of their sexual orientation or gender identity in the past year – avoided or postponed needed medical care. Among transgender people 22 percent reported such avoidance. The pervasive discrimination in our health care systems must be addressed through robust implementation and enforcement of Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: Colors+

Excerpt Text:
These problems persist in 2022. Data in a 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" [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 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 risk for anxiety, depression, suicidality, obesity, isolation, and bullying/assault because of how society, individuals, and organizations respond to them. This rule would be vital in not only allowing our LGBTQ+ youth to survive, but thrive as young people and adults. We want to support our youth in becoming healthy individuals and community members with this rule, we can make a big step toward doing that.

Comment Number: HHS-OS-2022-0012-DRAFT-43609-0002
All Sections: 4.3.1.2.5

(b)(5)

Organization: Endocrine Society

Excerpt Text:
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 transgender woman) due to insurance coverage limits. In our 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
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 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-lgbtqi-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.

Comment Number: HHS-OS-2022-0012-DRAFT-39726-0002
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3

(b)(5)

Organization: Family Equality

Excerpt Text:
LGBTQI+ Families and Children

LGBTQI+ people face discrimination and barriers to health care which can directly lead to disparities in health outcomes. A recently published report by the Center for American Progress highlighted 2022 data revealing the continued extent of discrimination and disparities faced by LGBTQI+ people when seeking health care.

- Fifteen 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.

- 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 refusal by a health care provider in the past year.

- 55 percent of intersex respondents reported that a health care provider refused to see them because of their sex characteristics or intersex variation, with over half of those cases being due to the religious beliefs or tenants of the hospital or health care facility.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0021
All Sections: 4.3.1.2.7, 4.3.1.2.5, 4.3.1.2.1, 4.3.1.2.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:
Discrimination in health care remains a widespread problem for LGBTQI+ people, especially for LGBTQI+ people of color, transgender people, and people with intersex traits [Footnote 31: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/ ; Shabab Ahmed Mirza and Caitlin Rooney, "Discrimination Prevents LGBTQ People from Accessing Health Care," (Washington: Center for American Progres, 2018), available at https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/]. LGBTQI+ individuals may experience discrimination when a health care provider refuses to provide them with care due to their sexual orientation, gender identity, or variations in sex characteristics. New data from CAP's nationally representative survey emphasize that discrimination in the form of denial of care by a health care provider is a significant concern among LGBTQI+ people. For example, in the past year [Footnote 32: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/]:

? 17 percent of LGBQ respondents reported having concerns that if they disclosed their sexual orientation to a health care provider, they could be denied good medical care.

? 49 percent of transgender or nonbinary respondents reported having concerns that if they disclosed their gender identity to a health care provider, they could be denied good medical care.

? 61 percent of intersex respondents reported having concerns that if they disclosed their intersex status to a health care provider, they could be denied good medical care.

CAP's 2022 survey also examined instances when doctors or other health care providers refused to provide care to LGBTQI+ respondents in the year prior. According to the data, overall [Footnote 33: Ibid]:

? 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 past year.

? 32 percent of transgender or nonbinary respondents, including 46 percent of transgender or nonbinary respondents of color, reported that, in the past year, they experienced at least one kind of care refusal by a health care provider.

? 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.

Not only does health care discrimination directly negatively affect the mental and physical health of LGBTQI+ people, hut it also engenders avoidance behavior, delays, or denials of care that exacerbate health disparities among LGBTQI+ populations [Footnote 34: See National Academies of Sciences, Engineering, and Medicine, "Understanding the Well-Being of LGBTQI+ Populations" (Washington: 2020), available at https://www.nap.edu/read/25877/chapter/1]. For example, according to CAP's nationally representative survey data from 2022 [Footnote 35: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/]:

? 23 percent of LGBTQI+ people - including 27 percent of LGBTQI+ respondents of color, 32 percent of LGBTQI+ respondents with disabilities, 37 percent of transgender or nonbinary respondents, and 50 percent of intersex respondents - 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. By comparison, 7 percent of non-LGBTQI+ people reported the same.

? 21 percent of LGBTQI+ people - including 26 percent of LGBTQI+ respondents of color, 28 percent of LGBTQI+ respondents with disabilities, 41 percent of transgender or nonbinary respondents, and 42 percent of intersex respondents - reported that in the past year they postponed or avoided getting preventive screenings due to disrespect or discrimination from doctors or other health care providers. By comparison, 7 percent of non-LGBTQI+ people reported the same.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0003
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 4.3.1.1, 4.3.1.2.3
(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
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-lgbtqi-communities/)] by Center for American Progress. 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66854-0003
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)

Organization: Wisconsin Primary Health Care Association

Excerpt Text:

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.

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0003
All Sections: 4.3.1.2.5
(b)(5)

Organization: American Academy of Family Physicians

Excerpt Text:
The AAFP strongly opposed the 2020 rule that weakened protections for lesbian, 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-1557-080719.pdf] [Hyperlink: https://www.aafp.org/dam/AAFP/documents/advocacy/administration/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):120-198] [Footnote 2: American Medical Association. Issue brief: Health insurance coverage for gender-affirming care of transgender patients. 2019;04(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., Colón-Diaz, M., LeCroix, 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 this care [Hyperlink: https://www.aafp.org/about/policies/all/transgender-nonbinary.html].

Comment Number: HHS-OS-2022-0012-DRAFT-39726-0003
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3
(b)(5)

Organization: Family Equality

Excerpt Text:
The National Institute for Health has determined that LGBTQI+ individuals experience worse physical health compared to their heterosexual and cis-gender counterparts [Footnote 4: KFF (2018), Health and Access to Care and Coverage LGBT Individuals in the US – Health Challenges, https://www.kff.org/report-section/health-and-access-to-care-and-coverage-lgbt-individuals-in-the-us-health-challenges/]. While historically HIV/AIDS has been a devastating health issue for the LGBTQI+ community, the range of health issues which disproportionately affect the community are much more varied, including chronic conditions, early onset disabilities, cancer, and cardiovascular disease [Footnote 5: Id]

Comment Number: HHS-OS-2022-0012-DRAFT-68873-0003
All Sections: 4.3.1.2.5, 4.3.1.2.4
(b)(5)

Organization: Fenway Community Health Center

Excerpt Text:
It is also critically important that, consistent with the Bostock ruling and subsquent federal agency interpretations noted in the NPRM footnote 46, nondiscrimination language be restored that to federal regulation that explicitly prohibits discrimination based on both sexual orientation and gender identity. As we have noted, such discrimination negatively impacts the health and well- being of LGBTQIA+ people, and in particular BIPOC LGBTQIA+ people, and constitutes a barrier to accessing care.

Access to health care is important to all people, and we believe that health care is a right. LGBT people are more likely to have chronic conditions such as diabetes, asthma, obesity, hypertension, and cardiovascular disease [Footnote 11: Beach LB, Elasy TA, Gonzales G. Prevalence of Self-Reported Diabetes by Sexual Orientation: Results from the 2014 Behavioral Risk Factor Surveillance System. LGBT Health. 2018 Feb/Mar;5(2):121-130] [Footnote 12: Caceres BA, Jackman KB, Edmondson D, Bockting WO. Assessing gender identity differences in cardiovascular disease in US adults: an analysis of data from the 2014-2017 BRFSS. J Behav Med. 2020 Apr;43(2):329-338] [Footnote 13: Karen I. Fredriksen-Goldsen, Hyun-Jun Kim, Chengshi Shui, and Amanda E. B. Bryan, 2017: Chronic Health Conditions and Key Health Indicators Among Lesbian, Gay, and Bisexual Older US Adults, 2013–2014. American Journal of Public Health 107, 1332_1338] [Footnote 14: Laska MN, VanKim NA, Erickson DJ, Lust K, Eisenberg ME, Rosser BR. Disparities in Weight and Weight Behaviors by Sexual Orientation in College Students. Am J Public Health. 2015 Jan;105(1):111-121] [Footnote 15: Deputy NP, Boehmer U. Weight status and sexual orientation: differences by age and within racial and ethnic subgroups. Am J Public Health. 2014;104(1):103-109. doi:10.2105/AJPH.2013.301391] [Footnote 16: Azagba S, Shan L, Latham K. Overweight and Obesity among Sexual Minority Adults in the United States. Int J Environ Res Public Health. 2019 May 23;16(10):1828] [Footnote 17: Caceres BA, Brody AA, Halkitis PN, Dorsen C, Yu G, Chyun DA. Sexual Orientation Differences in Modifiable Risk Factors for Cardiovascular Disease and Cardiovascular Disease Diagnoses in Men. LGBT Health. 2018;5(5):284-294] [Footnote 18:

Jackson CL, Agénor M, Johnson DA, Austin SB, Kawachi I. Sexual orientation identity disparities in health behaviors, outcomes, and services use among men and women in the United States: a cross-sectional study. BMC Public Health. 2016;16(1):807] [Footnote 19: Fredriksen-Goldsen KI, Kim H-J, Emlet CA, et al. The Aging and Health Report: Disparities and Resilience Among Lesbian, Gay, Bisexual, and Transgender Older Adults. Seattle: University of Washington; 2011] [Footnote 20: Caceres BA, Makarem N, Hickey KT, Hughes TL. Cardiovascular Disease Disparities in Sexual Minority Adults: An Examination of the Behavioral Risk Factor Surveillance System (2014-2016). Am J Health Promot. 2019 May;33(4):576-585] [Footnote 21: Caceres BA, Jackman KB, Edmondson D, Bockting WO. Assessing gender identity differences in cardiovascular disease in US adults: an analysis of data from the 2014-2017 BRFSS. J Behav Med. 2020 Apr;43(2):329-338] [Footnote 22: Nokoff NJ, Scarbro S, Juarez-Colunga E, Moreau KL, Kempe A. Health and Cardiometabolic Disease in Transgender Adults in the United States: Behavioral Risk Factor Surveillance System 2015. J Endocr Soc. 2018 Mar 5;2(4):349-360]. LGBT people experience higher rates of cancer, and gay and bisexual men and transgender women experience disproportionate burden of HIV and other STIs [Footnote 23: Cahill SR. Legal and Policy Issues for LGBT Patients with Cancer or at Elevated Risk of Cancer. Semin Oncol Nurs. 2018 Feb;34(1):90- 98] [Footnote 24: Centers for Disease Control and Prevention. HIV and Gay and Bisexual Men. Fact Sheet. Updated September 2021. https://www.cdc.gov/hiv/pdf/group/msm/cdc-hiv-msm.pdf] [Footnote 25: Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the Prevalence of HIV and Sexual Behaviors Among the US Transgender Population: A Systematic Review and Meta-Analysis, 2006-2017. Am J Public Health. 2019 Jan;109(1):e1-e8]. Because of these disparities, LGBTQIA+ people are in need of the critical health and social support services that HHS grantee organizations provide.

The efficacy of the Ending the HIV Epidemic initiative will be heavily influenced by this nondiscrimination rule. In this country, 69% of people living with HIV and newly diagnosed with HIV each year are gay and bisexual men [Footnote 26: Centers for Disease Control and Prevention. HIV and Gay and Bisexual Men. Fact Sheet. Updated September 2021. https://www.cdc.gov/hiv/pdf/group/msm/cdc-hiv-msm.pdf]. Transgender women are also disproportionately burdened by HIV [Footnote 27: Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the Prevalence of HIV and Sexual Behaviors Among the US Transgender Population: A Systematic Review and Meta-Analysis, 2006-2017. Am J Public Health. 2019 Jan;109(1):e1-e8]. Black and Latino gay and bisexual men and Black transgender women experience the most striking disparities in the domestic HIV epidemic [Footnote 28: CDC (2018), HIV among African American Gay and Bisexual Men. https://www.cdc.gov/hiv/group/msm/bmsm.html. Accessed January 22, 2018] [Footnote 29: Becasen et al., 2019]. Access to critical services provided by HHS grantees—including housing support, mental health and substance use treatment, and nutritional support—that help people living with HIV stay healthy and adhere to treatment hang in the balance. Treatment adherence is of critical importance in the Ending the HIV Epidemic initiative.

Homeless services, funding by HHS, are especially important to LGBT people, and especially for LGBT people of color. LGBT youth represent as much as 20-40% of homeless youth in some cities [Footnote 30: Ray, N. (2007). Lesbian, Gay, Bisexual and Transgender Youth: An Epidemic of Homelessness. National Gay and Lesbian Task Force Policy Institute, National

Coalition for the Homeless. https://www.thetaskforce.org/lgbt-youth-an-epidemic-of-homelessness/]. Data from the 2015 National Transgender Discrimination Survey show that 30% of transgender Americans have experienced homeless at some point in their lives, and 12% in the past year [Footnote 31: James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). The Report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality].

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0030
All Sections: 6.2.1, 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:
The 2022 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. Proscribing discrimination on these bases will improve health care access for LGBTQI+ people of color, in particular. Further, transgender people of color face significant barriers to health care access. As noted in a 2021 CAP report, transgender people of color more frequently experience denial of care and medical abuse than white transgender people [Footnote 71: Caroline Medina and others, "Protecting and Advancing Health Care for Transgender Adult Communities" (Washington: Center for American Progress, 2021), available at https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/]. That report further notes that transphobia is often inseparable from racism and sexism in the medical system.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0034
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.3

(b)(5)

Organization: Justice in Aging

Excerpt Text:
[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. 47,824, 47,916 (§ 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 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 LGBTQI+ 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 I. 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/#S1title.]

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0035
All Sections: 4.3.1.2.5, 4.3.1.2.6
(b)(5)

Organization: Justice in Aging

Excerpt Text:
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 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."

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0036
All Sections: 4.3.1.2.5, 7.7.4
(b)(5)

Organization: Center for American Progress

Excerpt Text:

XII. Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage (§ 92.207)

a. Access to Coverage for Gender-Affirming Care and Other Health Care Services

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 Section 1557 do apply to insurance. We support the Proposed Rule's prohibition of nondiscrimination in the coverage of gender-affirming and transition-related care, which aims to protect individuals from discriminatory benefit design and other practices by insurers which are contrary to well-established standards of care. This section is particularly important to help address the many challenges that transgender and nonbinary people encounter when seeking access to insurance coverage.

Although transgender people benefited from the adoption of the ACA, disparities persist in the uninsured rate for transgender people compared with cisgender people and transgender people who have insurance continue to be denied coverage for medically necessary services, including gender-affirming care [Footnote 80: Wyatt Koma and others, "Demographics, Insurance Coverage, and Access to Care Among Transgender Adults" (San Francisco: Kaiser Family Foundation, 2020), available at https://www.kff.org/health-reform/issue-brief/demographics-insurance-coverage-and-access-to-care-among-transgender-adults/] [Footnote 81: Matthew Bakko and Shanna K. Kattari. "Transgender-Related Insurance Denials as Barriers to Transgender Healthcare: Differences in Experience by Insurance Type," Journal of General Internal Medicine 35 (6) (2020): 1693–1700, available at https://pubmed.ncbi.nlm.nih.gov/32128693/]. For example, issuers continue to maintain internal coverage guidelines that exclude an array of medically necessary gender-affirming surgeries by designating these procedures as "cosmetic" or "not medically necessary" despite strong clinical evidence and standards of care that find these procedures medically necessary to provide gender-affirming care, including by treating gender dysphoria, improving mental health, and improving quality of life [Footnote 82: Connecticut Commission on Human Rights and Opportunities, "Declaratory Ruling on Petition Regarding Health Insurers' Categorization of Certain Gender-Confirming Procedures as Cosmetic" (Hartford, CT: 2020), pp. 10–12, available at https://www.glad.org/wp-content/uploads/2020/04/Dec-Rule_04152020.pdf].

New data from CAP's nationally representative survey emphasize the need to address discriminatory health insurance policies and to improve access to coverage for transgender and nonbinary people. Overall, 30 percent of transgender or nonbinary people, including 47 percent of transgender or nonbinary people of color, reported experiencing one form of denial by a health insurance company in the past year. These kinds of refusals can include a range of experiences when respondents reported barriers to access care both related to and unrelated to gender affirmation. For example, 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.

? 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.

? 15 percent of transgender or nonbinary respondents, including 33 percent of transgender or nonbinary respondents of color, reported that a health insurance company denied them coverage for gender-specific preventive care.

? 10 percent of transgender or nonbinary respondents, including 22 percent of transgender or nonbinary respondents of color, reported that a health insurance company denied them coverage for preventive care or screenings.

We strongly support this section and encourage the Department to adopt the following recommendations to strengthen this section. Consistent with our recommendations above, we suggest adding "transgender status" to § 92.207(b)(3). We also recommend a slight modification to § 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 proscribe exclusions of "any" such services. Thus, we propose deleting the word "all" from 2.207(b)(4):

"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 [strikethrough: all] health services related to gender transition or other gender-affirming care:"

As explained in more detail in the next section, we also believe that the terms "termination of pregnancy, contraception, fertility care, miscarriage management, pregnancy loss, maternity care, other reproductive and sexual health services, or any health services," should be added to § 92.207(b)(5).

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0037
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.6
(b)(5)
Organization: Justice in Aging

Excerpt Text:
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: Ivette 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 re-closet themselves to get the care they need or delay or forgo services altogether.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0038
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.6
(b)(5)
Organization: Justice in Aging

Excerpt Text:
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 where 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.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0004
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 4.3.1.2.3
(b)(5)
Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-39726-0004
All Sections: 4.3.1.2.5, 4.3.1.2.4

(b)(5)

Organization: Family Equality

Excerpt Text:
HHS has acknowledged many of these issues in its preamble to its Notice of Proposed Rulemaking as well as the pressing necessity to ensure that as many Americans as possible have access to health care services in the wake of the COIVD-19 pandemic. Family Equality also would like to highlight a crucial segment of the population that is often overlooked: the children and families of LGBTQI+ individuals. Nearly 3.7 million children in the US have LGBTQ+ parents, and 77% of LGBTQ+ millennials either are already parents or are considering expanding their families in the years ahead [Footnote 6: Family Equality (2019) LGBTQ Family Building Survey. https://www.familyequality.org/fbs]. It is estimated that around 3 million LGBTQ+ are the primary caregiver for someone over the age of 50 [Footnote 7: SAGE, Caregiving in the LGBT Community,

https://www.lgbtagingcenter.org/resources/pdfs/SAGE%20Caregiver%20Guide%20Final%20Interactive.pdf]. LGBTQI+ people don't just face the prospect of a doctor refusing to treat them, they must grapple with the reality that the people that they love and care for might also be refused treatment, even in emergency situations.

For example, in 2014 a Detroit pediatrician refused to provide pediatric care to a six-day old baby, because the parents were a lesbian couple [Footnote 8: Pediatrician refuses to treat baby with lesbian parents and there's nothing illegal about it - The Washington Post]. The doctor met with the mothers during their pregnancy and agreed to take the baby as a new patient upon birth, and yet turned the family away unexpectedly and at the most vulnerable moment. This decision not only flew in the face of professional guidance and ethics, but also could have endangered the health of the child. At best, it caused extreme emotional harm and distress to new parents, left to find a new doctor for their newborn.

Similarly, the young child of a lesbian couple in Texas, experienced a delay in care due to discrimination because she had two moms. When their two-year-old daughter fell and knocked out her front tooth, one of the mothers rushed the crying, bleeding child to a pediatric dentist only to be told that "a child cannot have two mothers" and that they would not treat her child until the "real" mother (aka the mother who gave birth to the child) arrived with a birth certificate. This mother later stated that:

Although my wife and I ... expected we might face discrimination at some point in our lives ..., we never expected to face discrimination from a medical provider—especially from someone taking care of our child. I don't think anything could have prepared us for this [Footnote 9: Brief Of Amici Curiae Lambda Legal Defense And Education Fund, Inc., Family Equality Council, Et Al., In Support Of Respondents, Masterpiece Cakeshop v. Colorado Civil Rights Commission, 584 U.S. (2018), https://www.familyequality.org/wp-content/uploads/2018/07/20171030-LambdaLegal-FamEq-Amicus-Brief- Masterpiece.pdf].

Children and family members of LGBTQI+ individuals should never have their health endangered due to their association with LGBTQI+ people, nor should LGBTQI+ parents and caregivers have to live in a state of fear that their loved ones will not be able to receive necessary health treatment. The finalized Section 1557 rules must reflect that goal.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0047
All Sections: 4.3.1.2.5, 4.3.1.2.4, 8.4, 4.3.1.2.3
(b)(5)
Organization: Center for American Progress

Excerpt Text:
XVIII. Notification of Views Regarding Application of Federal Conscience and Religious Freedom Laws (§ 92.302)

The federal government has a compelling interest in preventing discrimination in health care. The very purpose of Section 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.

It is crucial that the Department's Final Rule includes the Proposed Rule's revised approach to religious exemptions. Expansion of religious exemptions in health care settings disproportionately harms vulnerable populations including women - especially women of color - and LGBTQI+ individuals who are seeking a wide range of care, including gender-affirming and reproductive care [Footnote 101: Emily London and Maggie Siddiqi, "Religious Liberty Should Do No Harm," (Washington: Center for American Progress, 2019) available at https://www.americanprogress.org/article/religious-liberty-no-harm/].

Data from CAP's 2022 nationally representative survey shed light on occurrences when doctors and other health care providers refuse to provide care for religious reasons. For example [Footnote 102: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/]:

? 8 percent of LGBQ respondents (including 14 percent of LGBQ respondents of color), 12 percent of transgender or nonbinary respondents (including 20 percent of transgender or nonbinary respondents of color), and 53 percent of intersex respondents reported that, in the past year, a health care provider refused to see them due to the provider's religious beliefs or the stated religious tenets of the hospital or health care facility.

Denial of medical care for religious purposes negatively affects patients who require the denied care, not only by creating delays that may result in harm but also because the stress of being denied care and fear of encountering similar denials is detrimental and can engender avoidance behavior [Footnote 103: National Academies of Sciences, Engineering, and Medicine, "Understanding the Well-Being of LGBTQI+ Populations" (Washington: 2020), available at https://www.nap.edu/read/25877/chapter/1]. The 2020 version of Section 1557 disregarded those harms by implementing regulations that improperly incorporated a religious exemption that violated the plain language of the statute and is contrary to the express purpose of Section 1557. We strongly support the Proposed Rule's case-by-case process, which 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0049
All Sections: 4.3.1.2.2, 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 5.11, 4.3.1.2.3

(b)(5)

(b)(5)

Organization: Center for American Progress

Excerpt Text:

b. Data Collection

We appreciate that the Department recognizes the importance of demographic data collection to understand program populations and advance health equity and that the Proposed Rule acknowledges that demographic data collection and civil rights enforcement are inextricably linked [Footnote 104: HHS has incorporated demographic data collection into its 2022 Equity Action Plan, U.S. Dep't of Health & Hum. Svcs., Equity Action Plan (Apr. 2022), available at https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf, and demographic data collection has long been a stated priority for its subagencies; see, e.g., Ctrs. for Medicare & Medicaid Svcs., The CMS Equity Plan for Improving Quality in Medicare (Sept. 2015), available at https://www.cms.gov/about-cms/agency-information/omh/omh_dwnld-cms_equityplanformedicare_090615.pdf; Ctrs. for Medicare & Medicaid Svcs., CMS Framework for Health Equity 2022-2032 (Apr. 2022); available at https://www.cms.gov/files/document/cms-framework-health-equity.pdf; Ctrs. for Medicare & Medicaid Svcs., CMS Strategic Plan, Pillar: Health Equity (Aug. 2022), available at https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf].

While the Department considered a demographic data collection requirement outside of Section 1557 regulations, we encourage the Department to adopt a basic demographic data requirement in the Final Rule. Establishing a clear requirement will improve demographic data collection across the agency, enhance civil rights enforcement, and further the Department's goal of advancing health equity.

Investing in demographic data collection across programs and activities used by the public will better equip the Department to equitably serve all people, especially members of historically underserved populations. Establishing demographic data as a function of civil rights monitoring across the agency will also help to ensure and demonstrate compliance with the civil rights requirements of Section 1557.

Currently, health data stratified by key demographic variables such as race, ethnicity, disability, sexual orientation, gender identity, and variations in sex characteristics remains incomplete or inadequate [Footnote 105: For example, see Nat'l Acad. of Sciences, Engineering & Medicine, Understanding the Well-Being of LGBTQI+ Populations 75-81 (White, J., Sepulveda M.J., & Patterson C.J., eds., 2020), available at https://www.ncbi.nlm.nih.gov/books/NBK563325/pdf/Bookshelf_NBK563325.pdf and Bonnelin Swenor, A Need for Disability Data Justice, Health Affairs (Aug. 22, 2022), available at https://www.healthaffairs.org/content/forefront/need-disability-data-justice]. Studies have overwhelmingly shown high acceptability among patients and enrollees in self-reporting race and ethnicity, sexual orientation and gender identity, and other demographic information, given that appropriate steps are taken to support data collection activities [Footnote 106: David Baker et al., Patients' attitudes toward health care providers collecting information about their race and

ethnicity, 20 J. Gen. Intern. Med. 895-900 (2005), available at https://pubmed.ncbi.nlm.nih.gov/16191134/; David W. Baker, Romana Hasnain-Wynia, Namratha R. Kandula, Jason A. Thompson, and E. Richard Brown, Attitudes Toward Health Care Providers, Collecting Information About Patients' Race, Ethnicity, and Language, 45 Med. Care 1034 (Nov. 2007)] [Footnote 107: Sean Cahill et al., Do Ask Do Tell: High Levels of Acceptability by Patients of Routine Collection of Sexual Orientation and Gender Identity Data in Four Diverse American Community Health Centers, PLoS One (2014), available at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0107104] [Footnote 108: See, e.g., Chris Grasso et al., Planning and implementing sexual orientation and gender identity data collection in electronic health records, 26 J. Am. Med. Inform. Assoc. 66-70 (2019), available at https://pubmed.ncbi.nlm.nih.gov/30445621/; Pittman et al., Who, When, and How: The Current State of Race, Ethnicity, and Primary Language Data Collection in Hospitals, The Commonwealth Fund (2004), available at https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2004_may_who__when__and_how__the_current_state_of_race__ethnicity__and_primary_language_data_collection_in_ho_hasnain_wynia_whowhenhow_726_pdf.pdf]. Information gathered through these data collections have shaped policy interventions to address disparities and improve access to health care for underserved communities [Footnote 109: See, e.g., U.S. Dep't of Health & Hum. Svcs., HHS Initiatives to Address the Disparate Impact of COVID-19 on African Americans and Other Racial and Ethnic Minorities (2020), available at https://www.hhs.gov/sites/default/files/hhs-fact-sheet-addressing-disparities-in-covid-19-impact-on-minorities.pdf].

We recognize the Department's concern about dynamic and responsive data collection methods and standards given the fluctuating nature of populations and that understandings of identity continue to evolve. However, the Department's proposal to adopt an approach modeled after the U.S. Department of Education (ED), may not be the most effective means of collecting these data. While we agree that HHS has the authority to require data collection and reporting for compliance reporting under Section 1557 as well as other civil rights statutes, a sub-regulatory approach has thus far not yielded sufficient progress toward standardized demographic data collection within HHS [Footnote 110: See Charly Gilfoil, Nat'l Health L. Prog., Demographic Data Collection in Medicaid & CHIP: CMS Authority to Collect Race & Ethnicity Data (Sept. 7, 2022), available at https://healthlaw.org/resource/demographic-data-collection-in-medicaid-chip-cms-authority-to-collect-race-ethnicity-data/]. Additionally, ED's civil rights data collection program is not an ideal proxy for how the Department could collect demographic data since the Department's scope of demographic data to collect will be larger, it will need to collect these data from more entities, and each entity engages with patients, enrollees, and grantees using different methods and at different frequencies. These differences may pose significant challenges for the Department to standardize and coordinate demographic data collection and report across the agency's many programs and activities.

For these reasons, we believe that a better approach would be for the Department to set a baseline demographic data collection requirement within the 2022 Final Rule and direct each sub-agency or program to set its own requirements and methods for data collection with a specific timeline for implementation. Notably, 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. HHS has already established or acknowledged recommended practices for engaging in demographic data collection in each of these demographic categories. HHS should adopt those existing data collection practices and engage in additional research where necessary.

Whether the Department includes a demographic data collection requirement in the 2022 Final Rule, engages in further rulemaking, or issues sub-regulatory guidance, we offer the following recommendations for principles to guide demographic data collection. Specifically, the Department should develop resources and toolkits for collecting demographic data; provide appropriate training and technical assistance to programs and grantees; adopt clear privacy and nondiscrimination protections; ensure that data collected is maintained safely and securely by the appropriate entities; ensure requests for data are required but that providing demographic data is voluntary and self-reported; set, review, and update minimum standard variables for each demographic category; support analyses based on multiple demographic variables; conduct regular review and meaningfully engage in community feedback; ensure public reporting of data and analysis. It is also essential that strict standards are adopted to make clear that data cannot be used for negative actions such as immigration or law enforcement, redlining or targeting of specific groups.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0005
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1
(b)(5)
Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
[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 [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.

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0005
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1, 4.3.1.2.3
(b)(5)
Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
As a result of discriminatory government policies and bias in the health care 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 THURGOOD MARSHALL INST. & INST. ON ASSETS AND SOC. POL'Y AT BRANDEIS UNIV. THE BLACK-WHITE RACIAL WEALTH GAP (2019), https://tminstituteldf.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. 10, 2022), https://www.npr.org/2022/03/10/1085882933/redlining-pollution-racism; Daniel Cusick, 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, MILBANK Q., Jun. 2005, at 247, 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 C. Arcaya & Alina Schnake-Mahl, Health in the Segregated City, NYU FURMAN CTR. (Oct. 2017), https://furmancenter.org/research/iri/essay/health-in-the-segregated-city] Black households also struggle to access healthy food: One out of every five Black households is situated in a food desert, [Footnote 15 Michael Chui, et al., A $300 billion opportunity: Serving the emerging Black consumer, MCKINSEY Q. (Aug. 6, 2021), https://www.mckinsey.com/featured-insights/diversity-and-inclusion/a-300-billion-dollar-opportunity- serving-the-emerging-black-american-consumer.] and communities of color have fewer large supermarkets than predominantly white neighborhoods, even when controlling for income. [Footnote 16 Kelly Brooky, Research Shows Food Deserts More Abundant in Minority Neighborhoods, JOHNS HOPKINS UNIV. MAG. (Spring 2014), https://hub.jhu.edu/magazine/2014/spring/racial-food-deserts/.]

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0005
All Sections: 4.3.1.2.5

(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
Youth who identify as transgender and gender diverse face unique health disparities. [Footnote

iv: 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. [Footnotes v and vi: Tishelman AC, Kaufman 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):37–45pmid:26807001; 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):957–974pmid: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 2015 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 their abilities 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0005
All Sections: 4.3.1.2.5, 7.7.2, 7.7.4, 4.3.1.2.3

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
The Department's proposal to once again recognize Section 1557's application to private insurance continues this 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-lgbtqi-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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0050
All Sections: 4.3.1.2.5

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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: Id.] The final phrase of that definition ("regardless of whether those individuals explicitly use the term transgender to describe themselves") highlights the Rule's arbitrary and unfair constructions, which appear to privilege anyone who asserts a claim of discrimination on the basis of "gender identity."

"Gender-non-conforming," 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 asserted "need" for "gender-affirming" medical or surgical interventions, the Proposed Rule lists a "gender non-conforming" identity as one which might require receipt of "gender affirming … hormone therapy, [or] surgery." [Footnote 127: 87 Fed. Reg. 47834.] This 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0051
All Sections: 4.3.1.2.5

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
HHS justifies its broad inclusion of a range of self-described identities by claiming it "review of

the literature" showed "continued discrimination experienced by transgender and gender non-conforming individuals." [Footnote 129: 87 Fed. Reg. 47833.] 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]

Comment Number: HHS-OS-2022-0012-DRAFT-43609-0006
All Sections: 4.3.1.2.5

(b)(5)

Organization: Endocrine Society

Excerpt Text:
Discrimination is one of the largest barriers that transgender individuals face when accessing health care. Studies indicate that 70% of transgender individuals have experienced maltreatment by medical providers, including harassment and violence, and 28% of transgender individuals have postponed necessary medical care 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 Program and Practicing Clinicians. J Clin Endocrinol Metab. (2017) 102(4):1286-1290] [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 report when they have been a victim of discrimination.

Comment Number: HHS-OS-2022-0012-DRAFT-68873-0007
All Sections: 4.3.1.2.5, 4.3.1.2.4

(b)(5)

Organization: Fenway Community Health Center

Excerpt Text:
As noted in the preamble to the NPRM, LGBTQI+ people face both health disparities and barriers to healthcare. More than one in three LGBTQ Americans, and more than three in five transgender people, experienced discrimination in the past year. Fifteen percent of LGBTQ Americans report postponing or avoiding medical treatment due to discrimination; nearly three in

ten transgender individuals do so [Footnote 36: Gruberg S, Mahowald L, Halpin J. The state of the LGBTQ community in 2020. A national public opinion study. Washington, DC: Center for American Progress. 2020, October 6. https://www.americanprogress.org/issues/lgbtq-rights/reports/2020/10/06/491052/state-lgbtq-community-2020/]. Some 69% of those who reported discrimination said it affected their psychological well-being; 44% said it affected their physical well- being.

The 2016 final rule implementing Section 1557 of the ACA explicitly prohibits discrimination based on gender identity and sex stereotyping, which includes sexual orientation discrimination, across federally-funded health care programs. This rule was implemented to address anti-LGBT discrimination in healthcare. This discrimination, as well as the fear of experiencing it, is a barrier to seeking routine, preventive care as well as emergency care. It also negatively affects people's mental and physical health, and sense of safety and belonging in society. We thank you for restoring the original intent of Section 1557 of the ACA—to expand access to health care without fear of discrimination.

Section 4.3.1.2.6 - Age

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0015
All Sections: 4.3.1.2.5, 4.3.1.2.6, 2
(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[Bold: a. Impacts on Transgender Youth]

LGBTQ youth are especially vulnerable. 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/PMC5478215.] 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/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 M. 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 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: Ximena 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 social support and gender-affirming healthcare experience mental health outcomes equivalent to their cisgender peers. [Footnote 29: Dominic J. Gibson et al., Evaluation of Anxiety and Depression in a Community Sample of Transgender Youth, 4(4) J. Am. Med. Ass'n Open 1, 1–2 (Apr. 7, 2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2778206 (finding no significant group differences in self and parent reported depressive and anxiety symptoms among "socially transitioned transgender youth, their siblings, and age- and gender-matched control participants"); Lily Durwood et al., Social Support and Internalizing Psychopathology in Transgender Youth, 50 J. of Youth and Adolescence 841 (2021), https://link.springer.com/article/10.1007%2Fs10964-020-01391-y ("Parents who reported higher levels of family, peer, and school support for their child's gender identity also reported fewer internalizing symptoms."); Kristina R Olson et al., Mental Health of Transgender Children Who Are Supported in Their Identities, 137(3) Pediatrics 1, 1 (2016), https://pubmed.ncbi.nlm.nih.gov/26921285 (similar); Anna I. R. van der Miesen et al., Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender General Population Peers, 66 J. Adolescent Health 699, 703 (2020), https://pubmed.ncbi.nlm.nih.gov/32273193 (similar); see also Jack L. Turban et al., Access To Gender- Affirming Hormones During Adolescence and Mental Health Outcomes Among Transgender Adults 17 PLOS One 1, 8 (2022), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0261039 (access to gender-affirming hormones during adolescence was associated with lower rates of past-month severe psychological distress, past-year suicidal ideation, past month binge drinking, and lifetime illicit drug use when compared to access to gender-affirming hormones during adulthood).] And for teens under the age of eighteen, use of gender-affirming hormone therapy was associated with 39% lower odds of recent depression and 38% lower odds of attempting suicide compared to adolescents who wanted, but did not receive, such therapy. [Footnote 30: Amy E. Green et al., Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth, 70 J. Adolescent Health 643, 647–48 (2022), https://doi.org/10.1016/j.jadohealth.2021.10.036; see also Diana M. Tordoff, et al., Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care, 5 J. Am. Med. Ass'n Network Open 1, 1 (2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789423 (access to gender affirming care associated with improved mental health outcomes in youths).] Adolescents who begin gender-affirming treatment at later stages of puberty are over five times more likely to have been diagnosed with depression and over four times more likely to have anxiety disorders than adolescents who seek treatment in early puberty. [Footnote 31: Julia C. Sorbara et al., Mental Health and Timing of Gender-Affirming Care, 146 Pediatrics 1, 5 (2020),

https://publications.aap.org/pediatrics/article/146/4/e20193600/79683/Mental-Health-and-Timing- of-Gender-Affirming-Care.]

In addition to improved mental health outcomes, access to gender-affirming treatment improves overall well-being in transgender teenagers and young adults. A longitudinal study that followed transgender adolescents from their intake at a gender clinic into young adulthood found that gender-affirming treatment resulted in significant improvement in global functioning and psychological wellbeing. [Footnote 32: Annelou L.C. de Vries et al., Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment, 134 Pediatrics 696, 702 (2014), https://doi.org/10.1542/peds.2013-2958.] The study reported that post-treatment, participants had "rates of clinical problems that are indistinguishable from general population samples," and that their life satisfaction, quality of life, and subjective happiness were comparable to their same-age cisgender peers. [Footnote 33: Id.] Another study found significant improvement in teens' self-worth and perceived physical appearance after starting hormone replacement therapy. [Footnote 34: Marijn Arnoldussen et al., Self-Perception of Transgender Adolescents After Gender-Affirming Treatment: A Follow-Up Study Into Young Adulthood, 9 LGBT Health 238 (2022), https://www.liebertpub.com/doi/epdf/10.1089/lgbt.2020.0494; see also Mona Ascha et al., Top Surgery and Chest Dysphoria Among Transmasculine and Nonbinary Adolescents and Young Adults, JAMA Pediatr. (forthcoming 2022), doi:10.1001/jamapediatrics.2022.3424 (reconstructive chest surgery associated with statistically significant improvement in chest dysphoria, gender congruence, and body image at three months follow-up).]

[Bold: b. Impacts on Transgender Elders]

LGBTQ elders are also particularly vulnerable to discrimination. In a survey of 2,560 LGBTQ older adults in the United States, nearly half of respondents were living at or below 200 percent of the federal poverty line. [Footnote 35: Karen I. Fredriksen-Goldsen et al., The Aging and Health Report: Disparities and Resilience Among Lesbian, Gay, Bisexual, and Transgender Older Adults Institute for Multigenerational Health 4 (2011), https://www.lgbtagingcenter.org/resources/pdfs/LGBT%20Aging%20and%20Health%20Report_final.pdf; see also Karen I. Fredriksen-Goldsen et al., Iridescent Life Course: LGBTQ Aging Research and Blueprint for the Future: A Systematic Review 65 Gerontology 253 (2019), https://pubmed.ncbi.nlm.nih.gov/30826811 (discussing state of literature).] More than one in ten LGBTQ older adults (13%) who participated in the project have been denied healthcare or provided with inferior care. [Footnote 36: Fredriksen-Goldsen et al. (2011), supra note 35, at 4.] Fifteen percent of LGBTQ older adults fear accessing healthcare outside the LGBTQ community, and 8% fear accessing healthcare inside the community. [Footnote 37: Id.] More than 21% of LGBTQ older adults have not revealed their sexual orientation or gender identity to their primary physician, and bisexual older women and men are less likely to disclose than lesbian and gay older adults. [Footnote 38: Id. at 4–5.]

Nationally, 40% of transgender seniors reported being denied healthcare or facing discrimination by healthcare providers. [Footnote 39: Id. at 31; see also Annie Snow et al., Barriers to Mental Health Care for Transgender and Gender-Nonconforming Adults: A Systematic Literature Review 44 Health & Social Work 149–55 (2019), https://pubmed.ncbi.nlm.nih.gov/31359065.] Transgender older adults are at significantly higher risk of poor physical health, disability,

depressive symptomatology, and perceived stress, and suffer from fear of accessing health services, lack of physical activity, internalized stigma, victimization, and lack of social support. [Footnote 40: Karen I. Fredriksen-Goldsen et al., The Physical and Mental Health of Transgender Older Adults: An At-Risk and Underserved Population 54 The Gerontologist 488 (2014), https://pubmed.ncbi.nlm.nih.gov/23535500; see also Vanessa D. Fabbre & Eleni Gaveras, The Manifestation of Multilevel Stigma in the Lived Experiences of Transgender and Gender Nonconforming Older Adults 90 Am. J. of Orthopsychiatry 350 (2020), https://pubmed.ncbi.nlm.nih.gov/31971406; Kristen E. Porter et al., Providing Competent and Affirming Services for Transgender and Gender Nonconforming Older Adults 39 Clinical Gerontologist 366 (2016), https://pubmed.ncbi.nlm.nih.gov/29471769 Charles P. Hoy-Ellis & Karen I. Fredriksen-Goldsen, Depression Among Transgender Older Adults: General and Minority Stress 59 Am. J. of Cmty. Psychology 295 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5474152.] Discrimination in a long-term care setting and the related anxiety anticipating it are associated with negative health outcomes. [Footnote 41: Jaclyn White Hughto & Sari Reisner, Social Context of Depressive Distress in Aging Transgender Adults 37 J. of Applied Gerontology 1517 (2018), https://pubmed.ncbi.nlm.nih.gov/28380703; see also Dagfinn Nåden et al., Aspects of Indignity in Nursing Home Residences as Experienced by Family Caregivers 20 Nursing Ethics 748 (2013), https://pubmed.ncbi.nlm.nih.gov/23462504.] At least one recent study has shown that LGBTQ older adults reported a higher likelihood of moving to a long-term care facility, as compared to heterosexual older adults. [Footnote 42: Mekiayla Singleton et al., Anticipated Need for Future Nursing Home Placement by Sexual Orientation: Early Findings from the Health and Retirement Study 19 Sexuality Research & Soc. Policy 656 (2022), https://doi.org/10.1007/s13178-021-00581-y.] A survey of LGBTQ elders and their families by Justice in Aging also found that 89% of respondents predicted that staff would discriminate against an openly LGBTQ elder. [Footnote 43: Justice in Aging, Stories from the Field: LGBT Older Adults in Long-Term Care Facilities 8 (2d. ed. 2015), https://www.justiceinaging.org/wp-content/uploads/2015/06/Stories-from-the-Field.pdf.] A majority also thought that other residents would discriminate (81%) and, more specifically, that other residents would isolate an LGBTQ resident (77%). [Footnote 44: Id.] More than half also predicted that staff would abuse or neglect the person (53%). [Footnote 45: Id.]

These facts demonstrate the need for robust LGBTQ protections under Section 1557 and the harm caused by the 2020 Rule's departure from proper statutory interpretation. "[T]he unmistakable basis for HHS's action was a rejection of the position taken in the 2016 Rules that sex discrimination includes discrimination based on gender identity and sex stereotyping." [Italics: Walker], 480 F. Supp. 3d at 430. "[W]hether by design or bureaucratic inertia, the fact remains that HHS finalized the 2020 Rules without addressing the impact of the Supreme Court's decision in [Italics: Bostock]." Id. Instead, the 2020 Rule drew "from the Government's losing litigating position in [Italics: Bostock]" to justify stripping away needed protections. [Italics: Whitman-Walker Clinic], 485 F. Supp. 3d at 41 (citing 85 Fed. Reg. at 37,178-79). Abundant evidence of harm, discrimination, and health disparities experienced by LGBTQ people demands reversal. It is critical for HHS to finalize rules restoring the correct interpretation of "sex discrimination" under Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0031
All Sections: 4.3.1.2.6

(b)(5)

Organization: Justice in Aging

Excerpt Text:
[Italics: Age Discrimination]

We appreciate HHS's discussion in the preamble to this 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, in 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/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 under age 65. [Footnote 14: Draft Recommendation Statement: Screening for Anxiety in Adults (Sep. 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 no 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 ensure older adults are screened and treated for anxiety, their symptoms are dismissed as a "normal" part of aging.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0035
All Sections: 4.3.1.2.5, 4.3.1.2.6

(b)(5)

Organization: Justice in Aging

Excerpt Text:
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 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."

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0036
All Sections: 4.3.1.2.4, 4.3.1.2.6
(b)(5)

Organization: Justice in Aging

Excerpt Text:
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'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. 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365932/#S1title.] 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0037
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.6
(b)(5)

Organization: Justice in Aging

Excerpt Text:
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: Ivette 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 re-closet themselves to get the care they need or delay or forgo services altogether.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0038
All Sections: 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.6

(b)(5)

Organization: Justice in Aging

Excerpt Text:
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 where 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0041
All Sections: 4.3.1.2.1, 4.3.1.2.6

(b)(5)

Organization: Justice in Aging

Excerpt Text:
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: Ana Sandoiu, '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.]

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0042
All Sections: 4.3.1.2.1, 4.3.1.2.6

(b)(5)

Organization: Justice in Aging

Excerpt Text:
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 Holgash & 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/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.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0008
All Sections: 4.3.1.2.7, 4.3.1.2.1, 4.3.1.2.6

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
Improving health care access for 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 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.

Section 4.3.1.2.7 - Disability

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0001
All Sections: 4.3.1.2.2, 4.3.1.2.7, 4.3.1.2.5

(b)(5)

Organization: Health Care For All

Excerpt Text:
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 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69700-0001
All Sections: 4.3.1.2.7, 3.1.4

(b)(5)

Organization: Senator Kirsten Gillibrand

Excerpt Text:
We write to you today in response to the Department of Health and Human Services (HHS) proposed rule to Strengthen Nondiscrimination in Health Care and to express our support for continued action from HHS to clarify specific guidelines on 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 their 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=3d44507be9-Daily_Recap&utm_medium=email&utm_term=0_8cab1d7961-3d44507be9-148644513> [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. Post-Roe, many autoimmune patients lose access to 'gold standard' drug. [online] Los Angeles Times. Available at: <https://www.latimes.com/california/story/2022- 07-11/post-roe-many-autoimmune-patients-lose-access-to-gold-standard-drug> [Accessed 19 July 2022]]. There are confirmed reports of methotrexate being denied to women of childbearing age, which is the main medication that provides relief to many people with severe arthritis pain [Footnote 5: Rath, L., 2022. New Barrier to Methotrexate for Arthritis Patients. [online] Arthritis.org. Available at: <https://www.arthritis.org/about-us/news-and-updates/new-barrier-to-methotrexate- for-arthritis-patients> [Accessed 14 July 2022]]. Physicians and disability advocates have been clear that continued access to this and similar medications is needed to treat these conditions [Footnote 6: Arthritis.org. 2022. Arthritis Foundation Statement on Methotrexate Access. [online] Available at: <https://www.arthritis.org/about-us/news-and-updates/statement-on-methotrexate- access>

[Accessed 19 July 2022]. Cantrell, J. and Saag, MD, MSc, K., 2022. The ACR Responds to Impact of the Dobbs v. Jackson Decision on Rheumatology Patients and Providers - The Rheumatologist. [online] The Rheumatologist. Available at: <https://www.the-rheumatologist.org/article/the-acr-responds-to- impact-of-the-dobbs-v-jackson-decision/> [Accessed 19 July 2022]].

While people with disabilities already face barriers to abortion access, the Dobbs decision has exposed numerous chilling incidents of systemic discrimination against people with disabilities with respect to medical decision-making, medical privacy, and access to treatment [Footnote 7: Ducharme, J., 2022. Abortion Restrictions May Be Making Methotrexate Harder to Access. [online] Time. Available at: <https://time.com/6194179/abortion-restrictions- methotrexate-cancer-arthritis/> [Accessed 14 July 2022]]. It has been reported that people with disabilities are less likely to receive access to critical medications, are more likely to experience high-risk and life- threatening pregnancies, are highly likely to visit doctors or other health care providers who refuse or feel ill-equipped to serve their needs, and are more likely to face barriers to obtaining care even when they have insurance [Footnote 8: Krahn, G. L., Walker, D. K., & Correa-De-Araujo, R. (2015). Persons With Disabilities as an Unrecognized Health Disparity Population. American Journal of Public Health, 105(S2), S198– S206. https://doi.org/10.2105/AJPH.2014.302182] [Footnote 9: National Institute of Health. 2021. NIH study suggests women with disabilities have higher risk of birth complications and death. [online] Available at: https://www.nih.gov/news- events/news-releases/nih-study-suggests-women-disabilities-have-higher-risk-birth- complications-death [Accessed 19 July 2022] Sarkar, D. (2012). Recurrent pregnancy loss in patients with thyroid dysfunction. Indian Journal of Endocrinology and Metabolism, 16(Suppl 2), S350–S351. https://doi.org/10.4103/2230-8210.104088] [Footnote 10: Iezzoni, L. I., Rao, S. R., Ressalam, J., Bolcic-Jankovic, D., Agaronnik, N. D., Donelan, K., Lagu, T., & Campbell, E. G. (2021). Physicians' Perceptions Of People With Disability And Their Health Care. Health Affairs, 40(2), 297–306. https://doi.org/10.1377/hlthaff.2020.01452] [Footnote 11: Kennedy, J., Wood, E. G., & Frieden, L. (2017). Disparities in Insurance Coverage, Health Services Use, and Access Following Implementation of the Affordable Care Act: A Comparison of Disabled and Nondisabled Working-Age Adults. Inquiry : a journal of medical care organization, provision and financing, 54, 46958017734031. https://doi.org/10.1177/0046958017734031 Lezzoni, L. I., Frakt, A. B., & Pizer, S. D. (2011). Uninsured persons with disability confront substantial barriers to health care services. Disability and Health Journal, 4(4), 238–244. https://doi.org/10.1016/j.dhjo.2011.06.001]. Additionally, a June 2022 memorandum was developed to document the broader legal implications of disability discrimination that could occur in anticipation of the Dobbs decision [Footnote 12: Autisticadvocacy.org. 2022. Memorandum: Dobbs v. Jackson Women's Health Organization and Its Implications for Reproductive, Civil, and Disability Rights. [online] Available at: <https://autisticadvocacy.org/wp-content/uploads/2022/06/Dobbs-memo.pdf> [Accessed 14 July 2022]].

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0001
All Sections: 4.3.1.2.2, 4.3.1.2.7, 4.3.1.2.1, 4.3.1.2.3
(b)(5)

(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66192-0001
All Sections: 4.3.1.2.7

(b)(5)

Organization: Kidney Care Partners

Excerpt Text:
We are pleased that OCR/HHS once again is proposing policies to support individuals with disabilities in the Proposed Rule. Given our members' experience during the pandemic, as well as the historic discriminatory actions undertaken by some private insurers even prior to the pandemic, KCP asks that the final rule expressly describe the protections that apply to individuals with kidney failure.
First, we recommend that OCR reaffirm that individuals with kidney failure (also known as End Stage Renal Disease (ESRD)) who require dialysis are classified as disabled, consistent with other federal laws. As such, the protections that OCR provides to those individuals who are disabled also apply to those individuals with kidney failure. These protections include prohibitions against discriminating against these individuals directly or indirectly. This clarification is important because dialysis patients have had an extremely difficult time obtaining relief when health plans discriminate against them. Given the Administration's commitment to address racial and ethnic disparities in the delivery of health care, the applicability of the Section 1557 protections to this group of people becomes even more important.

Comment Number: HHS-OS-2022-0012-DRAFT-67996-0001
All Sections: 4.3.1.2.7

(b)(5)

Organization: The Alabama Disabilities Advocacy Program

Excerpt Text:
As the P&A, ADAP has significant experience advocating for Alabamians who have faced discrimination in health care settings- both on the basis of disability and due to intersecting identities. The primary issue area where Alabamians encounter this most is when interacting with the non-expanded state Medicaid Agency. Additionally, it is extremely difficult for Alabamians with disabilities to access beneficial Medicaid programs, such as home- and community-based services (HCBS) waiver programs, managed care benefits, and other programs such as money follows the person (MFP). Individuals who are dually eligible for Medicaid and Medicare also face their own set of challenges when dealing with the state's arcane system.

Lastly, in the private realm, individuals with disabilities and specifically another intersecting identity face discrimination in private health care coverage. They further face discrimination from health care providers, who often do not follow the provisions set forth in the Affordable Care and Patient Protection Act (ACA) Sec. 1557. Given the unique position of Alabamians with disabilities, ADAP feels it appropriate to offer comment giving some insight into the lives of those Alabamians, and it hopes to shed some light on how the proposed changes to 1557 will positively affect folks on the ground.

ADAP would like to note that we are unable to offer comment on many of the § 1557 provisions because our clients' access to care is so limited that their access issues are often far more rudimentary and base-level than the issues highlighted in these provisions.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0016
All Sections: 4.3.1.2.7, 4.3.1.2.1, 4.3.1.2.3

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[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 47,832. 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65692-0020
All Sections: 4.3.1.2.7

(b)(5)

Organization: Disability Rights Maine

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0021
All Sections: 4.3.1.2.7, 4.3.1.2.5, 4.3.1.2.1, 4.3.1.2.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:
Discrimination in health care remains a widespread problem for LGBTQI+ people, especially for LGBTQI+ people of color, transgender people, and people with intersex traits [Footnote 31: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/ ; Shabab Ahmed Mirza and Caitlin Rooney, "Discrimination Prevents LGBTQ People from Accessing Health Care," (Washington: Center for American Progres, 2018), available at https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/]. LGBTQI+ individuals may experience discrimination when a health care provider refuses to provide them with care due to their sexual orientation, gender identity, or variations in sex characteristics. New data from CAP's nationally representative survey emphasize that discrimination in the form of denial of care by a health care provider is a significant concern among LGBTQI+ people. For example, in the past year [Footnote 32: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/]:

? 17 percent of LGBQ respondents reported having concerns that if they disclosed their sexual orientation to a health care provider, they could be denied good medical care.

? 49 percent of transgender or nonbinary respondents reported having concerns that if they disclosed their gender identity to a health care provider, they could be denied good medical care.

? 61 percent of intersex respondents reported having concerns that if they disclosed their intersex status to a health care provider, they could be denied good medical care.

CAP's 2022 survey also examined instances when doctors or other health care providers refused to provide care to LGBTQI+ respondents in the year prior. According to the data, overall [Footnote 33: Ibid]:

? 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 past year.

? 32 percent of transgender or nonbinary respondents, including 46 percent of transgender or nonbinary respondents of color, reported that, in the past year, they experienced at least one kind of care refusal by a health care provider.

? 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.

Not only does health care discrimination directly negatively affect the mental and physical health of LGBTQI+ people, but it also engenders avoidance behavior, delays, or denials of care that exacerbate health disparities among LGBTQI+ populations [Footnote 34: See National Academies of Sciences, Engineering, and Medicine, "Understanding the Well-Being of LGBTQI+ Populations" (Washington: 2020), available at https://www.nap.edu/read/25877/chapter/1]. For example, according to CAP's nationally representative survey data from 2022 [Footnote 35: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/]:

? 23 percent of LGBTQI+ people - including 27 percent of LGBTQI+ respondents of color, 32 percent of LGBTQI+ respondents with disabilities, 37 percent of transgender or nonbinary respondents, and 50 percent of intersex respondents - 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. By comparison, 7 percent of non-LGBTQI+ people reported the same.

? 21 percent of LGBTQI+ people - including 26 percent of LGBTQI+ respondents of color, 28 percent of LGBTQI+ respondents with disabilities, 41 percent of transgender or nonbinary respondents, and 42 percent of intersex respondents - reported that in the past year they

postponed or avoided getting preventive screenings due to disrespect or discrimination from doctors or other health care providers. By comparison, 7 percent of non-LGBTQI+ people reported the same.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0028
All Sections: 4.3.1.2.2, 4.3.1.2.7, 4.3.1.2.1, 5.11, 4.3.1.2.3
(b)(5)
Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
[Bold: B. The final rule must require disaggregated data collection]

The availability 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: 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 & Mark V. Johnston, Relationships between level of disability and receipt of preventive health services, Archives of Physical Medicine and Rehabilitation, 749 (2004).] Racial and ethnic minorities with disabilities experience greater disparities in diagnoses and utilization of assistive

technology. [Footnote 22: D.S. Mandell et al., Racial/ethnic disparities in the identification of children with autism spectrum disorders, Am. J. Public Health 493 (2009); H.S. Kaye, P. Yeager & M. Reed, Disparities in usage of assistive technology among people with disabilities, 20 Assist. Technol. 194 (2008).]

While investigations of alleged discrimination sometimes focus on variations based on a single demographic variable, in our increasingly multicultural society, it is imperative that HHS's civil rights enforcement should support these types of analyses. This requires standardized categories and definitions for all these demographic variables and relevant combinations. The department must act decisively and require covered entities to collect demographic data, as existing data collection efforts are insufficient.

Additionally, the department must ensure that data collected is maintained safely and securely by the appropriate entities. Strict standards must be adopted to make clear that data cannot be used for negative actions such as immigration or law enforcement, redlining, or targeting of specific groups. While requests for data should be required, individuals' responses must be voluntary and should be self-reported to ensure accuracy. It is critical to train relevant staff on the collection of demographic data, including how to explain why data is being collected. These policies will help to ensure that data collected can be best utilized to prevent discrimination and disparities in health care access and outcomes.

Comment Number: HHS-OS-2022-0012-DRAFT-65692-0003
All Sections: 4.3.1.2.7, 3.1.4
(b)(5)

Organization: Disability Rights Maine

Excerpt Text:
The "no visitation" policies adopted almost universally among in-patient facilities during 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 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 wellbeing. 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 law 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 award 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 refuse to accommodate Deaf individuals by modifying policies or practices such as having an in-person interpreter when discussing important and vial healthcare information. DRM has had Deaf clients go to hospitals where the video remote interpreting system did not work or it froze, in violation of federal regulations. DRM has had Deaf clients who are in hospitals or nursing homes and do understand the treatment instructions because they are Deaf and the facilities do not accommodate the clients. Deaf clients were administered medications in a nursing home using only notes. The client did not understand what the medications, were, or what the risks were.

Violations of disability civil rights laws occur not only due to intentional ill will. They can happen because of ignorance, neglect, and administrative indifference, as noted in the findings of the ADA. In the arena of health care, covered entities tend to prioritize the establishment of policies, procedures, and a "chain of command" for meeting medical regulations, viewing civil rights regulations as an inconvenient add-on obligation; sometimes even a nuisance. Fortunately, there is a growing awareness across all segments of the healthcare system, from providers to insurers to public health, that technical adherence to medical regulations does not automatically achieve equitable health care and more needs to be done to eliminate embedded systemic and implicit bias.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0008
All Sections: 4.3.1.2.7, 4.3.1.2.1, 4.3.1.2.6
(b)(5)
Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
Improving health care access for 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 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.

Section 4.3.1.2.7.1 - Effective communication barriers

Comment Number: HHS-OS-2022-0012-DRAFT-65692-0016
All Sections: 4.3.1.2.7.1
(b)(5)

Organization: Disability Rights Maine

Excerpt Text:
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 their 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 vison loss and cannot see a screen. The primary consideration language seems to be telling providers to do more than that, but it's vague, and often a battle. We've seen it in dialysis centers, hospital emergency rooms, longer-term hospital stays, specialist offices (DRM had two cases involving the same GI specialist).

Recently a local hospital would not accommodate two individuals 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.

Comment Number: HHS-OS-2022-0012-DRAFT-39872-0009
All Sections: 4.3.1.2.7.1
(b)(5)

Organization: Tennessee Disability Coalition

Excerpt Text:
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 provide 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.

Section 4.3.1.2.7.2 - Physical accessibility barriers

No comments are associated with this issue

Section 4.3.1.2.7.3 - Accessible medical equipment

Comment Number: HHS-OS-2022-0012-DRAFT-39872-0010
All Sections: 13.5, 4.3.1.2.7.3
(b)(5)
Organization: Tennessee Disability Coalition

Excerpt Text:
[Bold: VII. Accessible Medical and Diagnostic Equipment]

The Tennessee Disability 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/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.] 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 disability rights or already uncomfortable with English are less likely to press for a full exam or insist on getting accurate current weight before medication strengths are prescribed or surgery with full anesthesia is scheduled. And many times people with disabilities who have already had encounters with providers who lack accessible equipment will simply avoid making health care appointments.

We cannot emphasize enough that the ability to receive effective healthcare in one's own community, with one's freely chosen provider, in a manner that is as timely and appropriate as the care received by persons without disabilities, should not depend on whether one uses a wheelchair or has certain chronic conditions or is aging. Again, without enforceable medical diagnostic equipment standards, this discrimination based on disability is the reality for thousands of people with disabilities.

There are offices that to this day – 32 years after the ADA came into effect –that are physically inaccessible. One person who called out office said they were told to go around back to the loading dock area to get into the building and called the media who did a story about it. Enforcement is a key provision that must be included in any rule.

Another person who is a wheelchair user who contacted our office had been denied a full medical examination because the person could not independently get up on the exam table. This person is employed by a local government as their ADA Coordinator.

Comment Number: HHS-OS-2022-0012-DRAFT-65692-0018
All Sections: 13.6, 4.3.1.2.7.3

(b)(5)

Organization: Disability Rights Maine

Excerpt Text:
[Bold: 2017 Medical Diagnostic Equipment Accessibility Standards]

DRM believes 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 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 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, 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 rights or already uncomfortable with English are less likely to press for a full exam or insist on getting accurate current weight before medication strengths are prescribed or surgery with full anesthesia is scheduled. And those people with disabilities who have already had bad encounters with providers who lack accessible equipment and fail to take responsibility for that fact or the need for transfer assistance will simply avoid making healthcare appointments if they can't bring assistants with them, whether they know their rights or not.

The ability to receive effective healthcare in one's own community, with one's freely chosen provider, in a manner that is as timely and appropriate as the care received by persons without disabilities, should not depend on whether one uses a wheelchair or has certain chronic conditions or is aging, but without enforceable medical diagnostic equipment standards this is the reality for thousands of people with disabilities. This is inherently discrimination based on disability and is why an enforceable requirement for accessible medical diagnostic equipment, along with scoping rules that establish how much equipment is needed by different sizes and types of facilities and a clear timeline, should be incorporated within the proposed rule. The request for comment asks whether accessible equipment is a matter of network adequacy or benefit design? It should be a matter for both. Network adequacy is a particular concern for

managed care entities and health insurers who would have to monitor the availability of provider types with accessible equipment to ensure that an adequate range of primary care and specialist providers with accessible equipment were available so that any given network was not a matter of paper only for disabled members. Network adequacy will allow equipment accessibility to be considered in conjunction with other important components of adequacy such as time and distance standards or providers per member. Benefit design requirements embed accessible equipment considerations and require health insurers to proactively consider accessibility as an integral component of what constitutes a healthcare benefit. Network adequacy has existing state enforcement mechanisms that can be used by people with disabilities and disability advocates to ensure not only that equipment is available, but that policies and procedures are in place to ensure that disabled persons receive coordination around making appointments and having those appointments in rooms with working accessible equipment. Ultimately, both network adequacy and benefit design should incorporate medical diagnostic equipment accessibility requirements as important steps to involve all health care stakeholders in resolving this intractable problem.

DRM is aware of woman with a brain injury who had difficulty getting a mammogram because she used a wheelchair and the x-ray does not go that low. Finally, she was able to get a mammogram but the technicians told her that she should not get mammograms any more.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0050
All Sections: 4.3.1.2.7.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:
Over 20 million adults in the U.S. have a physical disability that impacts mobility, and many cannot access standard MDE [Footnote 113: Ibid]. The lack of accessible MDE can lead to exacerbation of one's disability, in addition to delayed or incorrect examinations. As a result, women with disabilities frequently report receiving Pap tests and mammograms at lower rates than non-disabled women [Footnote 114: Megan Buckles and Mia Ives-Rublee, "Improving Health Outcomes for Black Women and Girls with Disabilities," Center for American Progress, February 15, 2022, available at https://www.americanprogress.org/article/improving-health-outcomes-for-black-women-and-girls-with-disabilities/]. A 2017 study of wheelchair users found that nearly 74 percent of individuals surveyed encountered physical barriers when accessing primary care services [Footnote 115: National Council on Disability, "Enforceable Accessible Medical Equipment Standards: A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities," (Washington: 2021), available at https://ncd.gov/sites/default/files/Documents/NCD_Medical_Equipment_Report_508.pdf]. Without enforceable standards, common practices including "ad hoc accommodations" and other forms of discrimination against people with physical disabilities will continue, resulting in deteriorating health and mortality [Footnote 116: Ellen P. McCarthy and others, "Disparities in breast cancer treatment and survival for women with disabilities," Annals of Internal Medicine 145 (9) (2006): 637–645, available at

https://www.researchgate.net/publication/6707840_Disparities_in_Breast_Cancer_Treatment_and_Survival_for_Women_with_Disabilities].

Section 6.2 - Discrimination Prohibited on the Basis of Sex (§ 92.101(a)(2))

No comments are associated with this issue

Section 6.2.1 - Generally

Comment Number: HHS-OS-2022-0012-1003-0001
All Sections: 1.1, 6.2.1
(b)(5)

Organization: URAC

Excerpt Text:
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, and gender identity.

Comment Number: HHS-OS-2022-0012-DRAFT-64284-0001
All Sections: 6.2.1, 5.2.2, 5.2.3, 5.10.2, 5.7.1, 7.10.1, 5.8.1, 10.1, 7.11.1, 8.1
(b)(5)

Organization: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-55761-0001
All Sections: 6.2.1, 6.1
(b)(5)

Organization: Cincinnati Children's Hospital Medical Center

Excerpt Text:
Championing diversity, equity and inclusion (DEI) and living it 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's critical that you move forward with these protections to secure access to care, free from any discrimination or prejudice.

Comment Number: HHS-OS-2022-0012-DRAFT-46426-0013
All Sections: 6.2.1, 6.1
(b)(5)

Organization: Genesee County Legal Aid Society dba Center for Civil Justice

Excerpt Text:
Discrimination Prohibited

CCJ supports the intersectional nature of Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0015
All Sections: 6.2.1, 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-66437-0016
All Sections: 6.2.1

(b)(5)

Organization: Center for Elder Law & Justice

Excerpt Text:
Bold: Strong Prohibitions on Sex Discrimination are Necessary to Address Health Disparities for LGBTQ+ Older Adults]

We strongly support the proposed broad regulatory language to prohibit discrimination on the basis of sex that specifically includes discrimination on the basis of sex stereotypes, sex characteristics, including intersex traits, sexual orientation, and gender identity (Sec. 92.101). LGBTQ+ 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 discrimination. 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 disability. [Footnote 8: LGBT Health, Racial Disparities and Aging by the Numbers, SAGE https://issuu.com/lgbtagingcenter/docs/sage_equity_infographic (2013).]

There is significant evidence that discrimination in health care contributes to these disparities: LGBTQ+ older adults may be denied care or provided inadequate care, or they may be afraid to seek necessary care for fear of mistreatment. For example, many LGBTQ+ elders and their loved one's experience discrimination in long-term care facilities ranging from verbal and physical harassment, to being denied basic care such as a shower, to visiting 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 lifesaving tests and treatments associated with one gender. Transgender people of color face significant 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/ (2021).] Few physicians have the requisite knowledge and comfort level to provide transgender treatment because it is not taught in conventional medical curricula. [Footnote 10: Barriers to Health Care for Transgender Individuals, National Library of Medicine https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4802845/ (2017).] The lack of education inhibits many transgender patient's access to medical interventions such as hormone therapy or surgery. [Footnote 11: Id.]

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0018
All Sections: 6.2.1, 7.7.3, 7.7.2, 7.7.1, 6.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:
VII. Discrimination Prohibited (§ 92.101)

In the preamble of the Proposed Rule, the Department rightly notes that people may experience intersectional discrimination in health care when they are discriminated against because of the combination of two or more protected bases. This can include individuals who experience heath care discrimination stemming from 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), ableism, or ageism. For instance, women with physical disabilities often report a range of barriers to accessing maternity and reproductive care like a lack of provider training – and this can be heightened for disabled women of color [Footnote 26: Mariëlle Heideveld-Gerritsen and others, "Maternity care experiences of women with physical disabilities: A systematic review," Midwifery 96 (2021), available at https://www.sciencedirect.com/science/article/pii/S0266613821000176].

We believe that the proposed rule would be strengthened by including more explicit references to intersectional discrimination within the regulatory text. As such, we propose the following change to § 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, [strikethrough, bold: 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 §§ 92.207(a), (b)(1), and (b)(2).

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0019
All Sections: 6.2.1, 7.6.3, 7.6.7, 7.7.4, 7.6.4

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: C. The proposed rule should include transgender status as a protected 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 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).] 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; [Underline: 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 §156.1230 by the 2020 rule. However, because the proposed language of these protections differs from the language proposed under §92, we urge the Department to here, too, adopt language in the final rule consistent with the language in §92.101 to avoid confusion and ensure consistency of implementation.

Comment Number: HHS-OS-2022-0012-DRAFT-67813-0002
All Sections: 6.2.1, 6.2.6, 6.2.5

(b)(5)

Organization: Pennsylvania Health Insurance Exchange Authority d/b/a Pennie

Excerpt Text:
Pennie supports extending the nondiscrimination provisions to include the prohibition of discrimination based on gender, gender identity, sexual orientation, relationship, association, and/or family status. These protections align with federal court rulings that consider the protection against LGBTQI+ discrimination to be part of the sex nondiscrimination protections. Pennie concurs with HHS' assessment that members of the LGBTQI+ population face barriers to appropriate health care and insurance access for needed coverage. Pennie believes that extending nondiscrimination provisions to expressly include sexual orientation and gender identity is a necessary step to ensure all Pennsylvanians have equitable access to the health coverage and health care services they need.

Comment Number: HHS-OS-2022-0012-DRAFT-66244-0002
All Sections: 6.2.1

(b)(5)

Organization: Association of American Medical Colleges (AAMC)

Excerpt Text:
[Bold: The AAMC appreciates and strongly supports HHS' proposed clarification that "on the basis of sex" includes discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions, sexual orientation, and gender identity.] We believe this is a critical step to affirm health care access for pregnant people and LGBTQI+ people, especially for transgender, nonbinary, and intersex people. [Footnotes 3 and 4: See AAMC Comments to the 2015 Proposed Rule (October 2015), urging HHS to expressly extend protections against discrimination to lesbian, gay and bisexual populations; See AAMC Comments to the 2019 Proposed Rule (August 2019), reiterating the AAMC's encouragement that HHS explicitly include lesbian, gay and bisexual individuals in the definition of "sex" for Section 1557 nondiscrimination protection and urging HHS withdraw the 2019 proposed changes.] As HHS notes, health inequity tied to discrimination related to sex is well-documented. [Footnote 5: 87 Fed. Reg. 47824, at 47833-35.] The AAMC Center for Health Justice conducted a poll earlier this year to better understand birthing people's experiences and found that people who are Black, Hispanic, younger, with lower income, or LGBTQ+ were more likely to feel that their care was affected by experiences of bias or discrimination. [Footnote 6: Logan Burdette et. al., AAMC Center for Health Justice, From Pregnancy to Policy (May 2022)] Going further, a large share of LGBTQ+ birthing people reported experiencing complications following childbirth. [Footnote 7: Carla S. Alvarado, PhD, MPH et al., AAMC Center for Health Justice, Polling Spotlight: Understanding the Experiences of LGBTQ+ Birthing People (June 2022).] Furthermore, LGBTQI+ people in particular face widespread discrimination in health care settings, and this discrimination acts as a barrier to seeking and accessing basic and life-saving health care services, including preventive care, check-ups, and emergency care. [Footnote 8: See

Center for American Progress, The State of the LGBTQ Community in 2020: A National Public Opinion Study (October 2020), finding that 15% of LGBTQ respondents overall, and 28% of transgender respondents, reported postponing or avoiding need medical treatment due to discrimination.]

Comment Number: HHS-OS-2022-0012-DRAFT-44581-0002
All Sections: 6.2.1

(b)(5)

Organization: Academy of Managed Care Pharmacy (AMCP)

Excerpt Text:
AMCP's strategic priorities include a commitment to optimizing patients' health outcomes, addressing barriers to access to care, and addressing health disparities [Footnote 6: https://www.amcp.org/about/about-amcp/amcp-strategic-priorities]. For this reason, AMCP strongly supports the proposed rule's specificity regarding the definition of discrimination on the basis of sex, which would explicitly prohibit discrimination on the basis of sex stereotypes, sex characteristics including intersex traits, pregnancy or related conditions, sexual orientation, and gender identity, consistent with Bostock and related case law [Footnote 7: Bostock v. Clayton County, 140 S. Ct. 1731 (2020)]. The LGBTQ+ population has a higher prevalence of physical and mental health problems, such as HIV and depression as well as lower self-reported health-related quality of life [Footnote 8: National Academies of Sciences, Engineering, and Medicine 2022. Measuring Sex, Gender Identity, and Sexual Orientation. Washington, DC: The National Academies Press. https://doi.org/10.17226/26424]. Despite this, the 2020 Final Rule removed protections for LGBTQ+ individuals. Reinstating these protections is vital to ensure access to needed health care for all and is an important first step in reducing health disparities. AMCP encourages HHS to finalize these provisions as proposed.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0023
All Sections: 6.2.1, 2

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: C. The proposed regulation should be considered an important tool to 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 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. 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, 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, including on issues such as immigration and discrimination protections, which Section 1557 is also designed to protect.

The implications of the recent [Italics: Dobbs] decision have drawn concern from the international human rights community. Victor Madrigal-Borloz, the UN Independent Expert on Sexual Orientation and Gender Identity who visited the United States in August 2022, called the decision "a devastating action for the human rights of lesbian and bisexual women, as well as trans men and other gender diverse persons with gestational faculties." [Footnote 113: Victor Madrigal-Borloz, Mandate of the United Nations Independent Expert on Protection from Violence and Discrimination based on Sexual Orientation and Gender Identity 2 (2016).] Madrigal-Borloz further noted that such bans have or will lead "to the closure of clinics that are critical sources of sexual and reproductive health care for LGBT persons: contraception and abortion services, wellness services, examinations, STI testing and treatment, hormone replacement therapy and insemination services." [Footnote 114: Id. at 3.] At the conclusion of its 2022 review of the United States, the Committee on the Elimination of Racial Discrimination (CERD Committee) noted deep concerns with the decision in Dobbs and recommended that the United States address the disparate impact that it will have on racial and ethnic minorities, Indigenous women, and those with low incomes. [Footnote 115: U.N. CERD, International Convention on the Elimination of All Forms of Racial Discrimination: Concluding observations on the combined tenth to twelfth reports of the United States of America, CERD/C/USA/CO/10-12, para 35 (Sept. 21, 2022).]

The proposed rule's renewed emphasis on protections against discrimination on the basis of sex are an important tool in holding strong against a retrogression of rights. This is critical to reenforcing core international human rights principles.

Comment Number: HHS-OS-2022-0012-DRAFT-43847-0003
All Sections: 6.2.1

(b)(5)

Organization: Boston Children's Hospital

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-46192-0003
All Sections: 7.8.1, 6.2.1

(b)(5)

Organization: American Nurses Association

Excerpt Text:
3) HHS should work closely with nurses while implementing Section 1557 provisions relating to discrimination on the basis of sex.

HHS is proposing to ensure equal access to health care programs on 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. 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/~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 unique barriers to care, including LGQTQ+ 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 communicates 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 LGBTQ+ patients based on sex-stereotyping.

This crucial work complements ANA's focus on educating nurses on their biases and prejudices for indications of discriminatory actions. ANA stands ready to work with HHS to build on this work to ensure that covered entities have the right resources and support to educate staff on combatting sex discrimination in the provision of health care services. [Bold: As such, ANA urges HHS to work closely with nurses to support covered entities coming into compliance with Section 1557 sex discrimination provisions].

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0030
All Sections: 6.2.1, 6.1, 2
(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0030
All Sections: 6.2.1, 4.3.1.2.5, 4.3.1.2.4, 4.3.1.2.1
(b)(5)

Organization: Center for American Progress

Excerpt Text:
The 2022 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. Proscribing discrimination on these bases will improve health care access for LGBTQI+ people of color, in particular. Further, transgender people of color face significant barriers to health care access. As noted in a 2021 CAP report, transgender people of color more frequently experience denial of

care and medical abuse than white transgender people [Footnote 71: Caroline Medina and others, "Protecting and Advancing Health Care for Transgender Adult Communities" (Washington: Center for American Progress, 2021), available at https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/]. That report further notes that transphobia is often inseparable from racism and sexism in the medical system.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0032
All Sections: 6.2.1, 4.3.1.2.1, 6.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:
X. The Proposed Rule Addresses Discriminatory Conduct that Disproportionately Impacts Communities of Color

While the Proposed Rule does not have specific provisions related 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. Given the deep legacy of racism and other forms of discrimination in health systems and health policy, Section 1557 of the ACA is a significant step towards rectifying centuries of policies and practices that have created worse health outcomes for underserved groups.

This 2022 Proposed Rule not only clarifies the broad civil rights protections extended in Section 1557, but provides concrete tools to combat racism and other forms of discrimination in health care. First, the 2022 Proposed Rule addresses various forms of discrimination that disproportionately affect communities of color, including on the basis of disability status, age, national origin, and sex. Second, the 2022 Proposed Rule addresses systemic discrimination, including policies and practices that harm people of color. Ultimately, we support this Proposed Rule as an important regulatory effort to address discrimination and racism in health care.

Comment Number: HHS-OS-2022-0012-DRAFT-67830-0004
All Sections: 6.2.1

(b)(5)

Organization: U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Excerpt Text:

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 and 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? (2019) (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).

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0006
All Sections: 6.2.1
(b)(5)
Organization: Physicians for Reproductive Health

Excerpt Text:
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' discussion of 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 this 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.

Comment Number: HHS-OS-2022-0012-DRAFT-43142-0006
All Sections: 6.2.1
(b)(5)
Organization: American Psychological Association

Excerpt Text:
Accordingly, APA recommends that HHS add abortion to the definition of prohibited sex discrimination at § 92.101(a)(2) as follows:

o "discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; [italic, bold: pregnancy or related conditions, including termination of pregnancy and transgender status]."

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0007
All Sections: 6.2.1
(b)(5)
Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: D. The final rule should affirm that denial of contraceptive care is 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 frequent form of sex discrimination, and the [Italics: 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 13, 2022, the Department issued guidance to retail pharmacies about Section 1557 protections in response to violations that occurred after [Italics: Dobbs]. [Footnote 48: U.S. DEPT. OF HEALTH AND HUMAN SERVS., HHS ISSUES GUIDANCE TO THE NATION'S RETAIL PHARMACIES CLARIFYING THEIR OBLIGATIONS TO ENSURE ACCESS TO COMPREHENSIVE REPRODUCTIVE HEALTH CARE SERVICES, (Jul. 13, 2022), https://www.hhs.gov/about/news/2022/07/13/hhs-issues-guidance-nations-retail-pharmacies-clarifying-their-obligations-ensure-access-comprehensive-reproductive-health-care-services.html.] The guidance addressed certain types of discrimination that are specific to contraceptive access in the retail pharmacy setting, for example, denial of hormonal contraception to an individual when the pharmacy otherwise provides contraceptives. We urge the Department to include these examples in the final rule.

We also recommend that the final rule expressly list other forms of discrimination related to contraceptive access. For example, the rule should include references to prohibited discrimination such as:

- state programs that discriminate by providing coverage of contraceptives, but excluding a specific contraceptive because of an assertion that the contraception causes an abortion;
- provider networks that only include facilities that refuse to perform "female" sterilization;
- limiting access to and coverage of reproductive health services such as contraceptive services and prenatal, birthing and postpartum care to "female" beneficiaries.

The Department should also specify that items or services related to contraception are also protected. Additional medications or services are often needed to facilitate contraceptive use, such as anesthetics for insertion of long-acting reversible contraceptives, or misoprostol – a medication also used as part of the medication abortion protocol – which is used to make IUD insertion easier.

[Bold: E. The final rule should affirm that discrimination on the basis of sex in fertility care is prohibited under Section 1557.]

We urge the Department to explicitly clarify that Section 1557's protections against discrimination on the basis of sex include discrimination against people seeking or accessing fertility care.

While the 2020 rule sowed confusion regarding whether Section 1557 prohibits discrimination against individuals who are seeking or who have obtained fertility care, Title VII prohibits such discrimination that occurs in the context of employment. [Footnote 49: See, e.g., Hall v. Nalco Co., 534 F.3d 644 (7th Cir. 2008), Ciocca v. Heidrick & Struggles, Inc., No. CV 17-5222, 2018 WL 2298498 (E.D. Pa. May 21, 2018).] Section 1557's protections against discrimination on the basis of sex include robust protections against discrimination for people who are seeking fertility

care. Respectful and nondiscriminatory access to fertility care is key to fulfilling every person's right to make decisions about their reproductive life and choose if, when, and how to become a parent.

Despite Section 1557's clear prohibition of sex discrimination in health care, discrimination persists in the context of accessing infertility diagnosis, fertility treatment, and fertility services including assisted reproductive technology like in vitro fertilization (IVF). It is thus essential that the final rule explicitly name it as prohibited conduct under this provision.

Sex discrimination in the context of fertility care can take many forms. Some insurance companies refuse to cover certain types of care that are traditionally used by women (e.g., IVF). [Footnote 50: Gabriela Weigel et al., Coverage and Use of Fertility Services in the U.S., WOMEN'S HEALTH POLICY (September 15, 2020), https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/.] Even in those states that do require insurance providers to cover IVF, some insurance providers require that patients use their "spouse's sperm" to fertilize their eggs to be eligible for IVF insurance coverage, discriminating against patients based on their sex with respect to marital status, sexual orientation, and gender identity. [Footnote 51: E.g., Haw. Rev. Stat. § 431:10A-116.5 (1987); Ark. Code R. 054.00.1–5(B) (1991). Furthermore, Texas, which only requires insurance providers to offer IVF insurance, also includes this same eligibility requirement. See Tex. Ins. Code Ann. § 1366.005.] In a recent example of discrimination on the basis of sex, sexual orientation and, marital status, OSF HealthCare, a self-insured Catholic hospital system with facilities in Illinois and Michigan, recently adopted an insurance policy for its employees that limits IVF coverage to "married couple[s] of opposite sex spouses." [Footnote 52: Shira Stein, Hospital Chain Blocks Fertility Coverage for Its LGBTQ Employees, BLOOMBERG LAW (July 18, 2022), https://news.bloomberglaw.com/daily-labor-report/hospital-chain-blocks-fertility-coverage-for-its-lgbt- employees.]

Additionally, public and private insurers often discriminate against patients based on sex by requiring that they meet outdated and heteronormative definitions of infertility before providing IVF coverage. For example, relying on a 2013 definition that has since been rescinded by the American Society for Reproductive Medicine, [Footnote 53: Compare Practice Committee of the American Society for Reproductive Medicine, Definitions of Infertility and Recurrent Pregnancy Loss: A Committee Opinion, 99 FERTILITY & STERILITY 63, 63 (2013) (defining infertility as "a disease defined by failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination," with Practice Committee of the American Society for Reproductive Medicine, Definitions of Infertility and Recurrent Pregnancy Loss: A Committee Opinion, 113 FERTILITY & STERILITY 533, 533 (2020) (defining infertility as "a disease historically defined by the failure to achieve a successful pregnancy after 12 months or more of regular, unprotected sexual intercourse or due to an impairment of a person's capacity to reproduce either as an individual or with her/his partner.").] many insurers maintain a double standard: They require that patients in different-sex relationships simply attest that they have unsuccessfully tried to become pregnant by having unprotected sex for six months or a year, depending on their age, but require same-sex couples and single individuals to undergo six to twelve unsuccessful cycles of intrauterine insemination at their own expense before deeming them eligible for IVF coverage. These patients are thereby

forced to absorb exorbitant costs out of pocket and are delayed or denied access to their IVF coverage benefits solely due to their sexual orientation.

Health care providers have also refused to provide fertility care for discriminatory reasons. For example, Guadalupe Benitez underwent a year of invasive, costly treatment by the sole in-network fertility care provider on her insurance plan only to then be denied the fertility treatment she needed based on the provider's religious objections to performing the procedure because Benitez identified as a lesbian. Benitez was forced to pay for her fertility care out-of-pocket at another clinic. [Footnote 54: Benitez v. North Coast Women's Care Medical Group, Inc., 106 Cal.App.4th 978 (Cal.App. 4 Dist., 2003).]

We urge the Department to clarify that such discrimination in health care, including in the context of seeking or accessing fertility care, is impermissible discrimination on the basis of sex under Section 1557, and to include examples of a broad range of impermissible sex discrimination in the context of seeking or accessing fertility care in the final rule.

Section 6.2.2 - Recent Developments in Sex Discrimination Law (preamble II.B)

Comment Number: HHS-OS-2022-0012-DRAFT-66316-0001
All Sections: 6.2.2

(b)(5)

Organization: American Association of Christian Schools

Excerpt Text:
[Italics: Redefinition of sex:]

The Department of Health and Human Services proposes in this rule to expand the definition of sex by incorporating the new definition in the Department of Education's proposed Title IX rules. 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 (47858). 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 (47911).

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 their 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 decision 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 religious liberty?

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0002
All Sections: 6.2.2, 2

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Italics: The Bostock Supreme Court Case Ruling]

The Department's proposal to 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 in regulation 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: Morrison, "HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate in Health Care." https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-in-health-care-1]

The Supreme Court explicitly stated that Bostock v. Clayton County cannot be used to apply to matters beyond employment nondiscrimination under Title VII. As Justice Gorsuch wrote:

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; we have not had the benefit of adversarial testing about the meaning of their terms, and we do not prejudge any such question today.

Under Title VII, too, we do not purport to address bathrooms, locker rooms, or anything else of the kind. The only question before us is whether 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.'

This is not simply lip-service. The court's logic applies to matters of employment under Title VII in ways that it does not apply to matters covered by Title IX. Jobs may be performed equally well by qualified individuals regardless of sex. However, unlike matters of employment sexual differences are extremely relevant when it comes to things like health care, housing and bathroom facilities, and athletics.

The Department's attempt to apply [Italics: Bostock] to Section 1557 relies on poor legal reasoning and should not be finalized.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0022
All Sections: 6.2.2
(b)(5)
Organization: Ethics & Public Policy Center

Excerpt Text:
[Bold: 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. 47827-47828.] 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0024
All Sections: 6.2.2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
But [Italics: Bostock] was not a Title IX nor a Section 1557 case. Rather, in [Italics: 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, 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. 41530.] 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 spectrum, fluidity, or subjective self-definition (which is promoted in the Proposed Rule).

As a federal district court judge just explained, HHS "misread Bostock by melding 'status' and 'conduct' into one catchall 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 Opportunity Comm'n, No. 2:21-cv-194, at *6 (N.D. Tex. Oct. 1, 2022).] For example, the court rejects HHS' conclusion that [Italics: Bostock] supports the claim that "'denial of … care

solely on the basis of [a patient's] sex assigned at birth or gender identity likely violates Section 1557.'" [Footnote 69: Id. at *18.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0025
All Sections: 6.2.2
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
Further, [Italics: Bostock] was a limited holding. The Supreme Court specifically cabined its decision to the hiring and firing context under Title VII, stating it 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 th[o]se other laws [we]re 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 [Italics: 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).]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0026
All Sections: 6.2.2, 15.2
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 "starkly 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 this 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66191-0003
All Sections: 6.2.2

(b)(5)

Organization: Dignity, Inc dba DignityUSA

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0004
All Sections: 6.2.2

(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0004
All Sections: 6.2.2, 6.2.6

(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:
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 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 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), (b)(2) and (b)(4), and in §92.207(b)(3).

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.

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0005
All Sections: 6.2.2, 6.2.6, 6.2.5

(b)(5)

Organization: The Century Foundation

Excerpt Text:
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 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, September 8, 2022, https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi- communities/].

Comment Number: HHS-OS-2022-0012-DRAFT-44558-0009
All Sections: 6.2.2, 6.2.3
(b)(5)

Organization: Equitas Health

Excerpt Text:
We applaud HHS for articulating a clear and expansive explanation of 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 their 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 point and the associated case law mentioned above, we advise HHS to incorporate the following key suggestions:

1) It is essential that this 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/benefits for LGBTQI+ persons are clearly and unequivocally communicated.

2) We also strongly support the clear and explicit inclusion of non-discrimination provisions based on sex characteristics, [italic: including] intersex traits [i.e. internal, external, hormonal/secondary, and chromosomal/genetic characteristics). As an agency, we firmly find that this is an important and necessary addition to the proposed rule, as such discrimination inherently and unabashedly relies upon sex.

3) We also strongly 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 documented instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between the two concepts [Footnote 2: 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)]. Therefore, it is preferable to enumerate both terms in the regulatory text, which further ensures statutory protections for transgender, non-binary, and gender expansive people.

Section 6.2.3 - Sex characteristics, intersex

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0001
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:
[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 762,000 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 (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.

Comment Number: HHS-OS-2022-0012-DRAFT-39933-0001
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: Minnesota Association of Community Health Centers

Excerpt Text:
[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 762,000 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 (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.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0001
All Sections: 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
We strongly support the explicit clarification that Section 1557 unequivocally prohibits discrimination on the basis of sexual orientation, gender identity, and sex characteristics, including intersex traits. These forms of discrimination have run rampant 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 built 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66854-0001
All Sections: 6.2.3, 7.7.4, 7.1.3
(b)(5)

Organization: Wisconsin Primary Health Care Association

Excerpt Text:
WPHCA 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. WPHCA recommends also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0010
All Sections: 6.2.3

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:
[Bold: D. Proposed § 92.101 should be supplemented with specific examples of 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 corresponding dearth of prior case law, guidance, or enforcement examples, covered entities may struggle to concretely understand their responsibilities with regard to preventing or addressing discrimination against people with variations in their sex characteristics. Likewise, intersex patients 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 or 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. This may constitute sex-based discrimination.

[Underline: Example 5:] A hospital's general informed consent policies and procedures require that patients and/or families to be provided with clear and accurate information on the risks, benefits, irreversibility, and alternatives to sterilizing treatment. If the hospital follows this practice for other patients, but does not follow this practice when performing a non-emergency gonadectomy because of an infant or child's intersex traits, thereby causing harm to the child, it may engage in sex-based discrimination.

[Underline: Example 6:] A hospital's policies and procedures generally limit the performance of sterilizing procedures on minors (such as by imposing special requirements for independent medical or judicial review below a certain patient age). If the hospital follows this policy or practice for children with developmental disabilities, but does not follow it with respect to performing a non-emergency gonadectomy because of an infant or child's intersex traits, thereby causing harm to the child, it may engage in sex-based discrimination.

[Underline: Example 7:] A hospital's policies or procedures generally prohibit performing major surgeries to alter the genitals of infants or young children based on social reasons, parental concern or distress, or future risks that are small or speculative, or otherwise absent a present or near-term physical or mental health risk to the patient. (The hospital may refer to such practices, in non-intersex patients, as "genital cutting" or "genital mutilation.") If the hospital follows this practice for other patients, but does not follow it with respect to performing non-emergency, genital surgery on an infant or child because of their intersex traits, thereby causing harm to the child, it may engage in sex-based discrimination.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0011
All Sections: 6.2.3, 6.2.10
(b)(5)
Organization: Colors+

Excerpt Text:
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 discrimination is inherently sex-based.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0011
All Sections: 6.2.6, 6.2.3, 6.2.10, 6.2.5

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[Bold: B. Protecting LGBTQ 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 47,858. [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.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0011
All Sections: 6.2.3

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
4. [Bold: Providing 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 their intersex traits, a provider refusing 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 genitalia for infants but not following this policy for intersex infants.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0012
All Sections: 6.2.3

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0014
All Sections: 3.1.1, 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
[Bold: 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 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 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 within comprehensive sex education, factoring for intersection 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-poc-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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0015
All Sections: 6.2.1, 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0015
All Sections: 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: II. 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 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 accessing care. In a 2016 study, one in five LGBTQ people, including 31 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 (2016), CTR FOR AMER. PROGRESS https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/ 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0016
All Sections: 6.2.3

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
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. 31,375, 31,389 (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/resource20180731hospital-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.]

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0018
All Sections: 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: B. The proposed rule's protections against LGBTQI+ discrimination is 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 robust 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(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 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. 9, 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. 20; 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 (1980) (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 (Nov. 17, 2011).] This principle has been affirmed by human rights bodies, including with respect to sexual and reproductive health. Countries have an obligation to ensure that their legal frameworks do not discriminate based on sexual orientation and gender identity and to protect against discrimination by third parties. [Footnote 75: 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. 41, U.N. Doc. E/C.12/GC/22 (2016) (stating that the "obligation to respect also requires States to repeal, and refrain from enacting, laws and policies that create barriers to access to sexual and reproductive health services. This includes third-party authorization requirements, such as parental, spousal and judicial authorization requirements for access to sexual and reproductive health services and information, including for abortion and contraception.").] See Section IV. below for a more detailed discussion of human rights in the context of sexual and reproductive health.

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0002
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: National Health Council

Excerpt Text:
In addition, the provisions clarifying antidiscrimination provisions for specific populations are necessary and welcome including provisions to:

- Affirm gender-based and disability and accessibility antidiscrimination 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."

Comment Number: HHS-OS-2022-0012-DRAFT-40175-0002
All Sections: 6.2.4, 6.2.6, 6.2.3, 7.9, 6.2.5
(b)(5)
Organization: California Department of Health Care Services

Excerpt Text:
[Bold/italics: Support for NPRM's Reinstatement of Provisions from the 2016 Final Rule]

Given this 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0020
All Sections: 6.2.6, 6.2.3, 6.2.10, 6.2.5
(b)(5)
Organization: Center for American Progress

Excerpt Text:
X. The Proposed Rule Correctly Strengthens the Definition of Sex Discrimination

a. Sex Discrimination Based on Sexual orientation, Gender Identity, and Sex Characteristics

We commend the Department for articulating a clear and expansive explanation of discrimination on the basis of sex. The Proposed Rule correctly clarifies that Section 1557's prohibition of discrimination on the basis of sex includes discrimination based on sex stereotypes, sexual orientation, gender identity, and sex characteristics, including intersex traits. We strongly support the explicit inclusion of discrimination based on these grounds. Supreme Court case law, including Price Waterhouse v. Hopkins and Bostock v. Clayton County, make clear that federal sex discrimination law includes sex stereotypes, sexual orientation, and gender

identity, including transgender status [Footnote 29: Price Waterhouse v. Hopkins, 490 U.S. 228 (May 1, 1989), available at https://supreme.justia.com/cases/federal/us/490/228/] [Footnote 30: Bostock v. Clayton County, 590 U.S. ___ (June 15, 2020), p. 1, available at https://www.supremecourt.gov/opinions/19pdf/17-1618_hfci.pdf]. We also support the explicit inclusion of discrimination based on sex characteristics, including intersex traits, because discrimination based on an individual's sex characteristics is inherently sex-based.

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0004
All Sections: 7.6.2, 6.2.4, 6.2.6, 6.2.3, 6.2.5
(b)(5)
Organization: Covered California

Excerpt Text:
- 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, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65871-0005
All Sections: 6.2.4, 6.2.3, 6.2.5
(b)(5)
Organization: AARP

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-69031-0006
All Sections: 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: Howard Brown Health

Excerpt Text:
[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].

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0008
All Sections: 6.2.3

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:
[Bold: 2. Proposed § 92.101's express codification that the ACA prohibits discrimination on the basis of sex characteristics, including intersex traits, is especially important.]

We especially applaud the Department's specification 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 or

physiological sex characteristics (such as genitals, gonads, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0008
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-44558-0009
All Sections: 6.2.2, 6.2.3

(b)(5)

Organization: Equitas Health

Excerpt Text:
We applaud HHS for articulating a clear and expansive explanation of 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 their 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 point and the associated case law mentioned above, we advise HHS to incorporate the following key suggestions:

1) It is essential that this 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/benefits for LGBTQI+ persons are clearly and unequivocally communicated.

2) We also strongly support the clear and explicit inclusion of non-discrimination provisions based on sex characteristics, [italic: including] intersex traits [i.e. internal, external, hormonal/secondary, and chromosomal/genetic characteristics). As an agency, we firmly find that this is an important and necessary addition to the proposed rule, as such discrimination inherently and unabashedly relies upon sex.

3) We also strongly 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 documented instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between the two concepts [Footnote 2: 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)]. Therefore, it is preferable to enumerate both terms in the regulatory text, which further ensures statutory protections for transgender, non-binary, and gender expansive people.

Comment Number: HHS-OS-2022-0012-DRAFT-72212-0009
All Sections: 6.2.6, 6.2.3, 7.9, 6.2.5

(b)(5)

Organization: Senate Democrats

Excerpt Text:
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 characteristic 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 LGBTQIA+ couples who may be turned away from care [Footnote 23: Id. at 47918 (Proposed § 92.209)].

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0009
All Sections: 6.2.3, 6.2.7, 6.2.5
(b)(5)
Organization: Alliance of Multicultural Physicians

Excerpt Text:
LGBTQI+ people

Transgender 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 provision 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.

Section 6.2.4 - Pregnancy or related conditions

Comment Number: HHS-OS-2022-0012-DRAFT-9845-0001
All Sections: 6.2.4, 6.2.6

(b)(5)

Organization:

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-9613-0001
All Sections: 6.2.4

(b)(5)

Organization:

Excerpt Text:
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 a covered benefit 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 which are also unwanted and cause psychological, physical, spiritual, and emotional distress?

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0001
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:
[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 762,000 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 (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.

Comment Number: HHS-OS-2022-0012-DRAFT-39933-0001
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: Minnesota Association of Community Health Centers

Excerpt Text:
[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 762,000 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 (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.

Comment Number: HHS-OS-2022-0012-DRAFT-75461-0001
All Sections: 6.2.4
(b)(5)

Organization: Charlotte Lozier Institute

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0010
All Sections: 6.2.4
(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
[Bold: Reproductive Health]

Access to comprehensive reproductive health care, 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 is 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 xxii and xxiii:
https://publications.aap.org/pediatrics/article/150/3/e2022058781/188340/Options-Counseling-for-the-Pregnant-Adolescent;
https://publications.aap.org/pediatrics/article/150/3/e2022058780/188339/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 withheld. In circumstances like these, abortion is not just medically indicated but indeed necessary to fulfill physicians' ethical obligations to their patients.
Policies that ban or otherwise restrict access to abortion care have a disproportionate impact on adolescents, who are less likely to have the resources necessary to travel out of state to receive care and have the effect of exacerbating health disparities for marginalized communities, including people of color and LGBTQ youth. Abortion restrictions that restrict access to care for adolescents who have been the victims of rape or incest also compound the trauma experienced and will exacerbate mental health issues.

When the Supreme Court overturned the constitutional right to abortion in Dobbs, it provoked covered entities to begin discriminatorily denying or erecting barriers to medications and treatments that can prevent, complicate, or end pregnancies. As of September 2022, 13 states have banned or severely restricted access to abortion services, while the legal status of abortion remains unclear in a handful of others. [Footnote xxiv: Kaiser Family Foundation, Abortion in the U.S. Dashboard. https://www.kff.org/womens-health- policy/dashboard/abortion-in-the-u-s-dashboard/. Accessed Sept. 23, 2022.] This reality leaves large swaths of the population of people capable of pregnancy without access to safe, legal abortion services. The impacts of Dobbs are compounding preexisting barriers to abortions, contraception, miscarriage management, fertility care, and other sexual and reproductive health care, particularly for communities of color, people with disabilities, the LGBTQ community (especially transgender people), and more. Children with juvenile arthritis (JA) have been denied access to or experienced delays receiving methotrexate, commonly prescribed for the treatment of JA, since the Dobbs ruling because the drug is also used in the treatment of early pregnancy loss. [Footnote xxv: Sonja Sharp, "Post-Roe, many autoimmune patients lose access to 'gold standard' drug," Los Angeles Times. https://www.latimes.com/california/story/2022-07-11/post-roe-many-autoimmune-patients-lose-access-to-gold- standard-drug, July 11, 2022.] Severe restrictions on or outright bans of abortion care also create an environment of fear for patients that they may face the risk of civil or criminal liability for or experience discrimination on the basis of their pregnancy decisions and outcomes. This fear can cause patients to delay or deter individuals from seeking needed health care.

In the wake of Dobbs, it is critical that abortion care is clearly and consistently included with "pregnancy or related conditions" throughout the final rule. Given the pervasive nature of discrimination related to termination of pregnancy, particularly post-[Italics: Dobbs], we urge HHS to specifically include termination of pregnancy in the definition of sex discrimination in the proposed rule. Further, the final rule must make clear that Section 1557's protection against sex discrimination includes protections against discrimination related to all reproductive health decisions, such as discrimination against those seeking contraception or specific types of contraception. Finally, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0010
All Sections: 6.2.4

(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
Pregnant people

People 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 the 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0011
All Sections: 6.2.4, 7.8.2

(b)(5)

Organization: The Century Foundation

Excerpt Text:
This explicit protection should be present in at least two areas of the finalized 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."

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0012
All Sections: 6.2.4, 6.2.6

(b)(5)

Organization: Colors+

Excerpt Text:
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."

Comment Number: HHS-OS-2022-0012-DRAFT-72212-0013
All Sections: 6.2.4, 5.5.2
(b)(5)

Organization: Senate Democrats

Excerpt Text:
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, 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 47879 (Proposed § 92.208)].

Comment Number: HHS-OS-2022-0012-DRAFT-69166-0014
All Sections: 6.2.4
(b)(5)

Organization: UnidosUS

Excerpt Text:
[Bold: Prohibit discrimination based on pregnancy-related conditions, including termination of pregnancy (§ 92.101(a)(2))]

In response to the Department's request for comment, [Footnote ii: 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" at § 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 iii: José Pares-Avila, Mary Sobralske, and Janet Kats, "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 iv: Lisa 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 v: 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 through IPUMS USA, University of Minnesota, www.ipums.org (IPUMS). In 2020, 10.0% of Latinas reported delaying medical care because of cost, compared to 7.1% of non-Hispanic White women, 7.5% of non-Hispanic Black women, 9.2% of Native American women, 2.8% of Asian American and Pacific Islander women, and 2.8% of other women. UnidosUS analysis of National Health Interview Survey (NHIS) data for 2020, accessed through IPUMS. According to that same data source, 9.2% of Latina women reported having no usual source of health care, compared to 5.3% of non-Hispanic White women, 6.5% of non-Hispanic Black women, 6.6% of non-Hispanic Native American women, 7.1% of Asian American and Pacific Islander women, and 3.3% of other women.] The additional barrier of legal restrictions to abortion access, post-Dobbs, further exacerbates preexisting disparities based on national origin in many states.

Today, Latinas make up 18% of the total number of women in the U.S., a percentage that is projected to rise to 27% by 2060. Examining the population of three states, we can see how the growing number of Latinas can be disproportionately affected by abortion restrictions. [Footnote vi: UnidosUS analysis of 2019 ACS data, accessed through IPUMS.]

- In Arizona, Latinas comprise 37.4% of all women and girls of reproductive age (15–49), compared to 31.4% of women and girls of all ages.

- In Florida, Latinas make up 30.5% of women and girls ages 15–49, compared to 26.1% of women and girls of all ages.

- In Texas, 42.2% of women and girls ages 15–49 are Latina, compared to 39.2% of women and girls of all ages.

The proposed rule notes that Title IX regulations classify discrimination based on pregnancy-related conditions as sex-based discrimination. We respectfully submit that incorporating Title IX standards via cross-reference places Latinas at heightened risk. If those Title IX regulations are successfully challenged, such a challenge could implicate Section 1557 as well. Moreover, many other provisions of the proposed rule explicitly restate provisions that are already found in other regulations, including those implementing Title IX. Singling out this particular policy for incorporation by reference, rather than restatement, is an invitation to mischief. A court or later administration could infer from this difference in regulatory treatment an intent to apply less stringent prohibitions—or indeed, no prohibitions at all—compared to other prohibitions that 1557 regulations explicitly state.

Without clear and explicit protection in the final rule, state restrictions on abortion will add a chilling effect that deters Latinas and other women from accessing necessary reproductive health services for fear that pregnancy and potential complications could lead to discrimination while seeking health care. Patients seeking life-threatening emergency care for pregnancy or related conditions may find themselves subject to criminal prosecution or be turned away by providers refusing to provide care. The final rule must make it explicitly clear, wherever sex- based discrimination is discussed, that such discrimination includes discrimination based on "pregnancy or related conditions," which includes termination of pregnancy.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0017
All Sections: 6.2.4

(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt 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, [underlined/bold: including termination of pregnancy]; sexual orientation; [bold/underlined: transgender status;] and gender identity."

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0019
All Sections: 6.2.4
(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
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 included 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.

Comment Number: HHS-OS-2022-0012-DRAFT-20039-0002
All Sections: 6.2.4, 6.2.6, 6.2.5
(b)(5)

Organization: The Colorado Health Foundation

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0002
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: National Health Council

Excerpt Text:
In addition, the provisions clarifying antidiscrimination provisions for specific populations are necessary and welcome including provisions to:

- Affirm gender-based and disability and accessibility antidiscrimination 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."

Comment Number: HHS-OS-2022-0012-DRAFT-40175-0002
All Sections: 6.2.4, 6.2.6, 6.2.3, 7.9, 6.2.5
(b)(5)

Organization: California Department of Health Care Services

Excerpt Text:
[Bold/italics: Support for NPRM's Reinstatement of Provisions from the 2016 Final Rule]

Given this 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.

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0002
All Sections: 6.2.4

(b)(5)

Organization: American Academy of Family Physicians

Excerpt Text:
The AAFP also requests that HHS specify that "pregnancy-related conditions" includes termination of a pregnancy.

Comment Number: HHS-OS-2022-0012-DRAFT-66750-0002
All Sections: 6.2.4, 7.8.2

(b)(5)

Organization: Jacobs Institute of Women's Health

Excerpt Text:
To improve equity in care for those who are or could become pregnant, the Jacobs Institute of Women's Health recommends the following revisions to the rule:

- Explicitly name "termination of pregnancy" in any text where "pregnancy or related conditions" is defined as part of sex discrimination.

Comment Number: HHS-OS-2022-0012-DRAFT-39789-0002
All Sections: 6.2.4, 6.2.6, 6.2.5

(b)(5)

Organization: American Federation of State, County and Municipal Employees

Excerpt Text:
Discrimination on the Basis of Sex

Consistent with recent judicial decisions, the proposed rule extends protections against discrimination on the basis of sex to include discrimination based on sexual orientation and gender identity [Footnote 1: E.g., Bostock v. Clayton County, 590 U.S. (2020)]. Additionally, we agree that protections against discrimination on the basis of sex should include pregnancy and related conditions. We believe that these provisions are critically important to ensure that all individuals receive appropriate care in a timely manner. Especially in the wake of Dobbs v. Jackson Women's Health Organization, it is paramount that women and other pregnant individuals do not face subsequent discrimination for reproductive health choices made in consultation with their families and doctors [Footnote 2: 597 U.S. (2022)].

Comment Number: HHS-OS-2022-0012-DRAFT-65682-0002
All Sections: 6.2.4, 4.3.1.2.3

(b)(5)

Organization: Primary Care Development Corporation

Excerpt Text:

II. Inclusion of Pregnancy, Including Pregnancy Termination, Under the Definition of Sex Discrimination

High-quality, comprehensive primary care includes the full suite of physical and behavioral health services people need to live healthy, productive lives. Sexual and reproductive (SRH) health care, including birth control, preconception care, counseling, and abortion services, is an essential component of primary care, and it is critical that primary care providers both directly provide and refer for the full range of SRH services. The proposed rule's reinstatement of anti-discrimination protections for SRH care, and specifically for pregnancy termination services, is a needed change at a time when many who need these services are being denied care and when our country continues to face unacceptably high levels of maternal mortality and morbidity.

For many years, the United States has had by far the highest rates of maternal mortality compared to other developed nations, with over 23 deaths per 100,000 live births in 2020. [Footnote 9: Centers for Disease Control and Prevention, Maternal Mortality Rates in the United States, 2020, Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality- rates-2020.htm (last visited September 21, 2022).] In addition, recent research has found that more than eighty percent of those deaths are preventable, if only the pregnant individuals had received appropriate health care. [Footnote 10: Susanna Trost, MPH et al., Pregnancy-Related Deaths: Data from Maternal Mortality Review Committees in 36 US States, 2017–2019, Report, Centers for Disease Control and Prevention, https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc.html (last visited September 21, 2022).] Moreover, this serious failure of our health care system is not felt equally among communities – as with many health care outcomes, Black women and other women of color are more likely to suffer, with Black women "three times more likely to die from a pregnancy- related cause than White women" [Footnote 11: Center for Disease Control and Prevention, Health Equity: Working Together to Reduce Black Maternal Mortality, https://www.cdc.gov/healthequity/features/maternal-mortality/index.html (last visited May 31, 2022).] and 93% of maternal deaths among American Indian and Alaska Native women were found to be preventable. [Footnote 12: Susanna Trost, MPH et. al, Pregnancy-Related Deaths Among American Indian or Alaska Native Persons: Data from Maternal Mortality Review Committees in 36 US States, 2017–2019, Report, Centers for Disease Control and Prevention, https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc-aian.html (last visited September 21, 2022) (finding that 93% of maternal deaths for American Indian and Alaska Natives were preventable).] It is clear that this disparity stems largely from lack of access to high quality preventative and prenatal care, including high quality primary care, for many women, especially those in low-income, underserved, and disinvested communities, as well as communities of color. [Footnote 13

Munira Z. Gunja et al., Health and Health Care for Women of Reproductive Age: How the United States Compares with Other High-Income Countries, Issue Brief, Commonwealth Fund, April 5, 2022, https://www.commonwealthfund.org/publications/issue-briefs/2022/apr/health-and-health-care-women- reproductive-age (last visited September 21, 2022).]

While these groups already face worse and often tragic outcomes as a result of lack of access to care, the Supreme Court's recent decision in [italics: Dobbs v. Jackson] will almost certainly make these disparities even worse. After the Court overturned [italics: Roe v. Wade] and enabled states to restrict or ban access to abortion, many states have indeed begun imposing severe limitations on access to abortion care, impacting health care providers' ability to care for their patients, both those seeking abortions and those needing other pregnancy-related care. [Footnote 14 New York Times. Tracking the States Where Abortion Is Now Banned. https://www.nytimes.com/interactive/2022/us/abortion-laws-roe-v-wade.html (last visited September 21, 2022)] In some states, the laws have even interfered in health care providers' ability to care for their patients where the patient's health or life is in danger. [Footnote 15: See, e.g., Harris Meyer, Patients and Doctors Navigate Conflicting Abortion and Emergency Care Laws, Scientific American, August 9, 2022, https://www.scientificamerican.com/article/patients-and-doctors-navigate-conflicting-abortion-and-emergency-care-laws/ (last visited September 21, 2022).]

PCDC strongly supports the inclusion of pregnancy, including pregnancy termination, under the definition of sex discrimination, to help prevent discrimination against patients seeking sexual and reproductive health care and providers hoping to provide it. The [italics: Dobbs] decision has already resulted in increased barriers for pregnant individuals seeking the care they need, and has threatened access to contraception, counseling, and miscarriage care and other important care as well – only worsening an already dire situation for many women and others who can become pregnant in the United States. We appreciate the steps taken in this proposed rule to ensure that the prohibition against sex-discrimination adequately addresses pregnancy and pregnancy termination and believe this will advance health equity.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0023
All Sections: 6.2.4

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Italics: Lack of sufficient need; insufficient explanations]

The department offers 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.

Third, the proposed rule changes the language from "pregnancy and..." to "pregnancy or related conditions" and fails to explain the why. The department does not provide an explanation for the use of "or" in the place of "and" in the proposed regulation. The department must do so.

Fourth, the department breaks with the tradition of Title VII and Title X which explicitly refer to abortion provisions as that, abortion. Title VII allows for limited provisions related to medical insurance surrounding abortion while Title X prohibits the use of its funding "in programs where abortion is a method of family planning." Instead, Title IX refers to abortion as a "termination of pregnancy." The department fails to provide an explanation for what "termination of pregnancy" entails. Does it refer to abortion, as Title VII and Title X do? Does the broad shift in language include similar but distinct means of terminating a pregnancy? Regardless, the department is unclear in both their reasoning and definitions.

The proposed rule marks a notable departure from previously held definitions of pregnancy. Beyond the departments "tentative view," they do not provide adequate documentation to support the claim that the current rule is unclear; nor does the department sufficiently explain the impact of this change. The department fails to account for the significant impact this change will have on how the federal government and its subsidiary education centers understand, educate, and apply Title IX as it relates to pregnancy and abortion.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0023
All Sections: 6.2.4

(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt 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: including termination of pregnancy] ; sexual orientation;
[Bold: transgender status]; and gender identity."

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0024
All Sections: 6.2.8, 6.2.4

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Italics: The department fails to discuss the redefinition's impact]

Beyond explaining 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 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 own commitment to success. Thus, the proposal would hurt the very people it claims to help.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0024
All Sections: 6.2.4, 7.7.1, 7.6.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:

ii. The Final Rule must explicitly name discrimination on the basis of termination of pregnancy as part of sex discrimination.

While the Department acknowledges that discrimination based on "pregnancy or related conditions" includes protections against discrimination based on termination of pregnancy, the Department does not make that explicit in the regulatory text. Just as the Department should standardize its definition of "pregnancy or related conditions" throughout the regulatory text, it must also make clear that "termination of pregnancy" is specifically named in that definition. There are several places where the Department should clarify and further amend the Proposed Rule to make clear these and other reproductive and sexual health-related protections, including § 92.101(a)(2), and § 92.206 and § 92.207, and in a separate stand-alone provision on pregnancy or related conditions.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0026
All Sections: 6.2.4, 5.9.1, 5.7.2

(b)(5)

Organization: Center for American Progress

Excerpt Text:
Patients need to know that they cannot be discriminated against based on termination of pregnancy, and we urge the Department to make this clear in its Final Rule. This is particularly urgent in light of the public health crisis unfolding across the country as large swaths no longer have access to legal abortion care. Accordingly, in the regulatory text, the Department should explicitly name "termination of pregnancy" in any text where "pregnancy or related conditions" is defined as part of sex discrimination.

For example, in § 92.101(a)(2), where the Proposed Rule defines protections against discrimination on the basis of sex to include discrimination based on "pregnancy or related conditions," we urge the Department to incorporate "including termination of pregnancy" after "pregnancy or related conditions." Accordingly, that specific regulatory text at § 92.101(a)(2) should 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: including termination of pregnancy]; sexual orientation; [bold: transgender status]; and gender identity.

The Department should include this same text in the other places where pregnancy or related conditions is named, including § 92.8(b) and § 92.10(i).

Comment Number: HHS-OS-2022-0012-DRAFT-43142-0003
All Sections: 6.2.4, 7.8.2
(b)(5)
Organization: American Psychological Association

Excerpt Text:
2) Reproductive Healthcare. The NPRM clarifies the scope of Section 1557's 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, including 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, Chibber KS, Gould H, Rocca CH, Foster DG. Risk of violence from the man involved in the pregnancy after receiving or being denied an abortion. September 2014. BMC Medicine, 12:144].

The ability to control childbearing and to take advantage of educational and employment opportunities are often inextricably linked. Therefore, discrimination in access to all forms of reproductive health care can have devastating consequences across the lifespan, including worsening and/or leading to disparities in behavioral health outcomes. Restricting access to reproductive health care undermines the ability of women to attain the related rights of health, equality, and nondiscrimination in other sectors.

Comment Number: HHS-OS-2022-0012-DRAFT-75461-0003
All Sections: 6.2.4

(b)(5)

Organization: Charlotte Lozier Institute

Excerpt Text:

I.) A Final Rule Must Clarify Intended Department Interpretation, Application, 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/2022/07/13/2022-15138/protecting-access-to-reproductive-healthcare-services.)

We are concerned about this redefinition for multiple reasons. CLI seeks Department clarity 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; and,

2.) 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; and,

3.) 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); and,

4.) 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 (4) is supported by its reference to Dobbs and E.O. 14076; however, including abortion in "pregnancy-related conditions" is very troublesome, as induced abortion is not health care. (See CNS News, 9/29/2022, "OB-GYN: 'Abortion Neither Prevents, Treats or Palliates Any Disease … It Is Therefore Not Health Care for the Mother or Her Fetus,'" available at https://cnsnews.com/article/washington/melanie-arter/ob-gyn-abortion-neither-prevents-treats-or-palliates-any-disease.)

In addition, it is the standard of care for any physician to intervene in a life-threatening pregnancy, and the medical indication for separating a mother from her unborn child should not be confused with an induced abortion. (See "Fact Sheet: Medical Indications for Separating a Mother and Her Unborn Child," available at https://lozierinstitute.org/fact-sheet-medical-indications-for-separating-a-mother-and-her-unborn-child/.) Life-saving care for pregnancy complications is already protected under every state pro-life law. (See also Skop, I. (2022). "Pro-Life Laws Protect Mom and Baby: Pregnant Women's Lives are Protected in All States," available at https://lozierinstitute.org/pro-life-laws-protect-mom-and-baby-pregnant-womens-lives-are-protected-in-all-states/.) The Department should clarify its intended interpretation and application of this vague, ambiguous, arbitrary, and capricious terminology in order to communicate exactly what the NPRM suggests constitutes discrimination "on the basis of sex."

CLI is concerned because the context of the NPRM suggests that the proposed rule is not intended merely to protect women who are experiencing miscarriage or ectopic pregnancies, but instead is intended to require expanded access to abortion services. This goal is evident in both the text of the President's recent E.O. and the text of the NPRM. President Biden signed E.O. 14076 in the wake of Dobbs, after which he signed an additional Executive Order, E.O. 14079, stating that "the continued advancement of restrictive abortion laws in States across the country has created legal uncertainty and disparate access to reproductive healthcare services depending on where a person lives, putting patients, providers, and third parties at risk and fueling confusion for hospitals and healthcare providers, including pharmacies" (See "Securing Access to Reproductive and Other Healthcare Services," available at https://www.federalregister.gov/documents/2022/08/11/2022-17420/securing-access-to-reproductive-and-other-healthcare-services.) Moreover, the NPRM states that this proposed

definition is to ensure "nondiscriminatory access to care," which includes access to abortion services. (See NPRM at p. 47879.)

Such an interpretation of Section 1557's definition of discrimination "on the basis of sex" to include nondiscrimination in access to abortion services is ultra vires, going far beyond the statutory authority provided to the Secretary by Congressional charter. The antidiscrimination policies embodied in Title IX and Section 1557 are not mechanisms for providing a right to abortion disguised as "healthcare access." Indeed, in light of the Supreme Court's recent decision in Dobbs v. Jackson Women's Health Org. which held that the Constitution does not contain a "right to abortion," such an executive agency requirement is at odds with that decision's return of abortion law and policy to the people and their elected representatives. If Congress intends to force health care providers to provide abortion, it should make clear its intent by specifically amending the Affordable Care Act or Title IX itself.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0003
All Sections: 6.2.4

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Italics: 2. The final rule's regulatory text should clearly state that sex discrimination on the basis of pregnancy and pregnancy-related conditions includes abortion care.]

The [Italics: Dobbs] decision has unleashed chaos in our medical system. In the post-[Italics: 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/2022/02/28/1083536401/texas-abortion-law-6-months; Kate Zernike, Medical Impact of Roe Reversal 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 INITIATIVE 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 imperative 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, thus, 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 their trust in the health care system and their health care providers. For example, when patients experience abortion stigma while accessing reproductive health care, it "diminishes the trust that is essential to the patient-provider relationship and undermines women's ability to make informed medical decisions." [Footnote 24: NAT'L P'SHIP FOR WOMEN & FAMS., BAD MEDICINE: HOW POLITICAL AGENDA IS UNDERMINING ABORTION CARE AND ACCESS IN OKLAHOMA (2019), https://www.nationalpartnership.org/our-work/health/repro/reports/bad- medicine-oklahoma.html.]

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0004
All Sections: 7.6.2, 6.2.4, 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: Covered California

Excerpt Text:

- 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, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0004
All Sections: 6.2.4

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
The Department should also affirm in the final rule that discrimination on the basis of past medical history (including seeking, accessing, or having sought abortion, contraception or other reproductive health care) is prohibited conduct under Section 1557. Such discrimination happens when a health care provider refuses to appropriately treat a patient because the provider objects to a patient's medical history for including, among other things, abortion. Critically, the provider might object only to the patient's medical history, not object to the medical care they are currently choosing to deny. Objections to a patient's medical history are never an appropriate basis for refusing medically indicated care, and this should be expressly prohibited by the final rule where the past care objected to is care protected by Section 1557. To that end, we also recommend that the Department include examples in the final rule or preamble to clarify the discriminatory nature of refusing to provide health care based on a patient's actual or perceived medical history.

Finally, we note that clarifying in the final rule that termination of pregnancy is covered by 1557, and providing examples of prohibited conduct, would ensure that the rule aligns with international human rights standards. Discrimination against individuals seeking abortion services is a concern shared by the international human rights community, including the Committee on the Elimination of Discrimination Against Women (CEDAW Committee) [Footnote 33: CEDAW Committee, Concluding observations on the eighth periodic report of Australia, para. 49(a), U.N. Doc. CEDAW/C/AUS/CO/8 (2018); CEDAW Committee, Inquiry concerning the United Kingdom of Great Britain and Northern Ireland under article 8 of the Optional Protocol to the Convention on the Elimination of All Forms of Discrimination against Women, Report of the Committee, para. 65, U.N. Doc. CEDAW/C/OP.8/GBR/1 (March 6, 2018) (finding that abortion restrictions in Northern Ireland constituted discrimination because they affected only women, "preventing them from exercising reproductive choice.").] and the Special Rapporteur on the Right to Health. [Footnote 34: Anand Grover, Special Rapporteur of the Human Rights Council on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, para. 34, U.N. Doc. A/66/254 (2011).] Multiple treaty monitoring bodies and human rights experts have also noted the disproportionate effect of intersectional discrimination on certain communities, including people of color, people with disabilities, the LGBTQI+ community, and low-income women, in the context of sexual and reproductive health. [Footnote 35: Committee on Economic, Social and Cultural Rights, General Comment No. 22, para. 30; See also, e.g., Committee on the Rights of the Child, General Comment No. 15 (2013) on the rights of the child to the enjoyment of the highest attainable standard of health (art. 24), paras. 8-11, U.N. Doc. CRC/C/GC/15 (Apr. 17, 2013); Committee on the Rights of People with Disabilities, General Comment No. 3 (2016) on women and girls with disabilities, para. 2, U.N. Doc. CRPD/C/GC/3 (Nov. 25, 2016); Human Rights Council, General Comment No. 28: Article 3 (The equality of rights between men and women), para. 30, U.N. Doc. CCPR/C/21/Rev.1/Add.10 (Mar. 29, 2000); CEDAW Committee, General Recommendation No. 34 (2016) on the rights of rural women, para. 38, U.N. Doc, CEDAW/C/GC/34 (Mar. 7, 2016); Human Rights Council, Report of the Special Rapporteur on Extreme Poverty and Human Rights on his mission to the United States of America, para. 56, U.N. Doc. A/HRC/38/33/Add.1 (May 4, 2018) (noting that "low-income women['s] lack of

access to abortion services traps [them] in cycles of poverty.").] See Section IV. below for a detailed discussion of human rights in the context of sexual and reproductive health.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0004
All Sections: 6.2.4, 8.2

(b)(5)

Organization: Health Care For All

Excerpt Text:
Pregnancy Status and Reproductive Rights

Abortion is a critical part of the 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 with "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 incorporate 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 and cause life-threatening situations for individuals based upon their pregnancy related condition.

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0005
All Sections: 6.2.4

(b)(5)

(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:

b. [Bold: Discrimination related to pregnancy or related conditions]

Abortion is health care. The American College of Obstetricians and Gynecologists (ACOG) [embedded hyperlink text (https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/12/increasing-access-to-abortion)], along with many other medical societies, identifies abortion as an essential health care service that requires timely access to care. Many of these same medical societies also recognize the importance of addressing racism, bias, and discrimination in health care in order to ensure patients are able to get the comprehensive care they need, including abortion. As outlined above, given the moment we are in and the continued fallout from the Supreme Court's decision, it is essential for HHS to strengthen its approach to defining sex discrimination related to pregnancy or related conditions throughout the regulatory text. In the preamble, HHS notes that although it does not propose restoring the 2016 language that the 2020 rule eliminated, 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.

RECOMMENDATION: HHS must add abortion 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 on the basis of sex stereotypes; sex characteristics, including intersex traits; [Italics: pregnancy or related conditions, including termination of pregnancy]; sexual orientation; [Bold: transgender status], and gender identity.

In addition, HHS should ensure that sex discrimination is defined consistently throughout final regulations and includes "pregnancy or related conditions, including termination of pregnancy." Consistency is of particular importance given that HHS does not currently include a definition of sex discrimination.

Comment Number: HHS-OS-2022-0012-DRAFT-65871-0005
All Sections: 6.2.4, 6.2.3, 6.2.5

(b)(5)

Organization: AARP

Excerpt Text:

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.

Comment Number: HHS-OS-2022-0012-DRAFT-43142-0005
All Sections: 6.2.4, 5.9.1, 7.8.3

(b)(5)

Organization: American Psychological Association

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66235-0006
All Sections: 6.2.4, 7.8.5

(b)(5)

Organization: National Association of Health Underwriters

Excerpt Text:
[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 it 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0006
All Sections: 6.2.4, 6.2.6

(b)(5)

Organization: The Century Foundation

Excerpt Text:
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 this number was much higher for transgender and nonbinary patients of color.

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0007
All Sections: 6.2.4, 6.2.6, 6.1

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:
[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."
-- Add the phrase "transgender status" after "sexual orientation."

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0008
All Sections: 6.2.4, 7.8.3, 7.8.5

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[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 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 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]

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0008
All Sections: 6.2.4

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: F. The final rule should affirm that discrimination in pregnancy-related care 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: ABORTION 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 revealed 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/polling/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 explicitly clear the role that discrimination and mistreatment play in the high rates of severe maternal mortality and morbidity among these most impacted communities. [Footnote 58: NY TIMES MAGAZINE, WHY AMERICA'S BLACK MOTHERS AND BABIES ARE IN A LIFE-OR-DEATH CRISIS (2018), https://www.nytimes.com/2018/04/11/magazine/black-mothers-babies-death-maternal-mortality.html; CTR FOR AM. PROGRESS, AM. INDIAN AND ALASKAN NATIVE MATERNAL AND INFANT MORTALITY: CHALLENGES AND OPPORTUNITIES (2018), https://www.americanprogress.org/article/american-indian-alaska-native-maternal-infant- mortality-challenges-opportunities/; ABORTION CARE NETWORK ET AL., SYSTEMIC RACISM AND REPRODUCTIVE INJUSTICE IN THE US: 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; NAT'L P'SHIP FOR WOMEN & FAMS., Listening to Latina Mothers in California, (2018), https://www.nationalpartnership.org/our-work/resources/health-care/maternity/listening-to-latina-mothers-in- california.pdf; Elizabeth Chuck and Haimy Assefa, She Hoped to Shed a Light on Maternal Mortality Among Native Americans. Instead, She Became a Statistic of It, NBC NEWS (Feb. 8, 2020), https://www.nbcnews.com/news/us- news/she-hoped-shine-light-maternal-mortality-among-native-americans-instead-n1131951.] In August of 2022, the UN Committee on the Elimination of Racial Discrimination (CERD), in reviewing the United States' progress on eliminating racial discrimination, expressed concern that "systemic racism along with intersecting factors such as gender, race, ethnicity and migration status have a profound impact on the ability of women and girls to access the full range of sexual and reproductive health services…without discrimination." [Footnote 59: U.N. CERD, International Convention on the Elimination of All Forms of Racial Discrimination: Concluding observations on the combined tenth to twelfth reports of the United States of America, CERD/C/USA/CO/10-12, para 35 (Sept. 21, 2022).] The Committee was also concerned about the "limited availability of culturally sensitive and respectful maternal health care, including midwifery care for low-income, rural and people of African descent and Indigenous communities." [Footnote 60: Id.] It further noted that "racial and ethnic minorities are disproportionally impacted by higher rates of maternal mortality and morbidity; higher risk of unwanted pregnancies and lack of means to overcome socioeconomic and other barriers to access safe abortion." [Footnote 61: Id.] We commend the Department on the actions it has taken thus far to address and eliminate these disparities in maternal and reproductive health care and urge the Department to issue a final rule that expressly affirms that discrimination in the provision of care throughout pregnancy and in the postpartum period is prohibited under Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0008
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5

(b)(5)

(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
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.

Section 6.2.5 - Sexual orientation

Comment Number: HHS-OS-2022-0012-DRAFT-9871-0001
All Sections: 6.2.5

(b)(5)

Organization:

Excerpt Text:
I support the proposed rule adding sexual orientation to Section 1557 of the Affordable Care Act. This will give LGBTQ+, and particularly LGBTQ+ elders, 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, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-9870-0001
All Sections: 6.2.6, 6.2.5

(b)(5)

Organization:

Excerpt Text:
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's nothing new--LGBTQ adults and children are being denied vital healthcare across the country. This not just cruel and immoral, it's 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.

Comment Number: HHS-OS-2022-0012-11936-0001
All Sections: 6.2.6, 3.1.3, 6.2.5

(b)(5)

Organization: John Clarke Senior Living

Excerpt Text:
We strongly support Proposed Rule Section 1557 of the Affordable Care Act.

John Clarke increasingly cares for residents of the LGBTQI 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-35534-0001
All Sections: 6.2.6, 6.2.5

(b)(5)

Organization: Temple University Health System

Excerpt Text:
On behalf of Temple University Health System, our patients and the vulnerable comm unities we serve, thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services proposed rule on Section 1557 of the [italics: 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66191-0001
All Sections: 6.2.6, 6.2.5
(b)(5)
Organization: Dignity, Inc dba DignityUSA

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0001
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5
(b)(5)
Organization: Tennessee Primary Care Association

Excerpt Text:
[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 762,000 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 (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.

Comment Number: HHS-OS-2022-0012-DRAFT-39933-0001
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5
(b)(5)
Organization: Minnesota Association of Community Health Centers

Excerpt Text:
[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 762,000 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 (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.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0001
All Sections: 6.2.6, 6.2.3, 6.2.5
(b)(5)
Organization: 38 Members of Congress

Excerpt Text:
We strongly support the explicit clarification that Section 1557 unequivocally prohibits discrimination on the basis of sexual orientation, gender identity, and sex characteristics, including intersex traits. These forms of discrimination have run rampant 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 built 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0011
All Sections: 6.2.6, 6.2.3, 6.2.10, 6.2.5
(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[Bold: B. Protecting LGBTQ 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 47,858. [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.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0014
All Sections: 3.1.1, 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
[Bold: 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 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 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 within comprehensive sex education, factoring for intersection 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-poc-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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0015
All Sections: 6.2.1, 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0015
All Sections: 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:

[Bold: II. 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 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 accessing care. In a 2016 study, one in five LGBTQ people, including 31 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 (2016), CTR FOR AMER. PROGRESS https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/ 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0018
All Sections: 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: B. The proposed rule's protections against LGBTQI+ discrimination is 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 robust 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(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 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. 9, 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. 20; 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 (1980) (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 (Nov. 17, 2011).] This principle has been affirmed by human rights bodies, including with respect to sexual and reproductive health. Countries have an obligation to ensure that their legal frameworks do not discriminate based on sexual orientation and gender identity and to protect against discrimination by third parties. [Footnote 75: 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. 41, U.N. Doc. E/C.12/GC/22 (2016) (stating that the "obligation to respect also requires States to repeal, and refrain from enacting, laws and policies that create barriers to access to sexual and reproductive health services. This includes third-party authorization requirements, such as parental, spousal and judicial authorization requirements for access to sexual and reproductive health services and information, including for abortion and contraception.").] See Section IV. below for a more detailed discussion of human rights in the context of sexual and reproductive health.

Comment Number: HHS-OS-2022-0012-DRAFT-67813-0002
All Sections: 6.2.1, 6.2.6, 6.2.5

(b)(5)

Organization: Pennsylvania Health Insurance Exchange Authority d/b/a Pennie

Excerpt Text:
Pennie supports extending the nondiscrimination provisions to include the prohibition of discrimination based on gender, gender identity, sexual orientation, relationship, association, and/or family status. These protections align with federal court rulings that consider the protection against LGBTQI+ discrimination to be part of the sex nondiscrimination protections. Pennie concurs with HHS' assessment that members of the LGBTQI+ population face barriers to appropriate health care and insurance access for needed coverage. Pennie believes that extending nondiscrimination provisions to expressly include sexual orientation and gender identity is a necessary step to ensure all Pennsylvanians have equitable access to the health coverage and health care services they need.

Comment Number: HHS-OS-2022-0012-DRAFT-20039-0002
All Sections: 6.2.4, 6.2.6, 6.2.5

(b)(5)

Organization: The Colorado Health Foundation

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0002
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: National Health Council

Excerpt Text:
In addition, the provisions clarifying antidiscrimination provisions for specific populations are necessary and welcome including provisions to:

- Affirm gender-based and disability and accessibility antidiscrimination 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."

Comment Number: HHS-OS-2022-0012-DRAFT-40175-0002
All Sections: 6.2.4, 6.2.6, 6.2.3, 7.9, 6.2.5

(b)(5)

Organization: California Department of Health Care Services

Excerpt Text:
[Bold/italics: Support for NPRM's Reinstatement of Provisions from the 2016 Final Rule]

Given this 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0002
All Sections: 6.2.6, 6.1, 6.2.5

(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
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 in health care. Section 1557 therefore fills in a critical gap by extending antidiscrimination protections to patients at the intersection of multiple identities. The Proposed Rule proscribes many forms of discrimination that amplify the impacts of racism and subject people to dual 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-39789-0002
All Sections: 6.2.4, 6.2.6, 6.2.5

(b)(5)

Organization: American Federation of State, County and Municipal Employees

Excerpt Text:
Discrimination on the Basis of Sex

Consistent with recent judicial decisions, the proposed rule extends protections against discrimination on the basis of sex to include discrimination based on sexual orientation and gender identity [Footnote 1: E.g., Bostock v. Clayton County, 590 U.S. (2020)]. Additionally, we agree that protections against discrimination on the basis of sex should include pregnancy and related conditions. We believe that these provisions are critically important to ensure that all individuals receive appropriate care in a timely manner. Especially in the wake of Dobbs v. Jackson Women's Health Organization, it is paramount that women and other pregnant individuals do not face subsequent discrimination for reproductive health choices made in consultation with their families and doctors [Footnote 2: 597 U.S. (2022)].

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0020
All Sections: 6.2.6, 6.2.3, 6.2.10, 6.2.5

(b)(5)

Organization: Center for American Progress

Excerpt Text:

X. The Proposed Rule Correctly Strengthens the Definition of Sex Discrimination

a. Sex Discrimination Based on Sexual orientation, Gender Identity, and Sex Characteristics

We commend the Department for articulating a clear and expansive explanation of discrimination on the basis of sex. The Proposed Rule correctly clarifies that Section 1557's prohibition of discrimination on the basis of sex includes discrimination based on sex stereotypes, sexual orientation, gender identity, and sex characteristics, including intersex traits. We strongly support the explicit inclusion of discrimination based on these grounds. Supreme Court case law, including Price Waterhouse v. Hopkins and Bostock v. Clayton County, make clear that federal sex discrimination law includes sex stereotypes, sexual orientation, and gender identity, including transgender status [Footnote 29: Price Waterhouse v. Hopkins, 490 U.S. 228 (May 1, 1989), available at https://supreme.justia.com/cases/federal/us/490/228/] [Footnote 30: Bostock v. Clayton County, 590 U.S. ___ (June 15, 2020), p. 1, available at https://www.supremecourt.gov/opinions/19pdf/17-1618_hfci.pdf]. We also support the explicit inclusion of discrimination based on sex characteristics, including intersex traits, because discrimination based on an individual's sex characteristics is inherently sex-based.

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0003
All Sections: 6.2.6, 6.2.5

(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:

[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 ii and iii: 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): 506–10. doi:10.1016/j.jadohealth.2013.01.015 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/e20182162] Despite some advances in public awareness and legal protections, youth who identify as LGBTQ continue to face disparities that stem from multiple sources, including inequitable 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, gender identity and sex characteristics, including intersex traits.

Comment Number: HHS-OS-2022-0012-DRAFT-65871-0003
All Sections: 7.11.2, 10.1, 6.2.5

(b)(5)

Organization: AARP

Excerpt Text:
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 the federal civil rights statutes the HHS Department enforces.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0003
All Sections: 6.2.6, 7.6.3, 7.6.7, 7.7.4, 7.6.4, 6.2.5

(b)(5)

Organization: Health Care For All

Excerpt Text:
Protections against Discrimination on Basis of Sex

Sex discrimination disproportionately impacts women of color, LGBTQI+ 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 improper 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 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 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 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, therefore, recommend also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0003
All Sections: 6.2.6, 6.2.5

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
[Bold/Underline: I. The Proposed Rule Correctly Provides Protections Under All Health-Related Programs and Activities From Discrimination Based on Sexual Orientation and Gender Identity]

We strongly support the Department's decision to clearly add sexual orientation and restore gender identity into the rule and ensure that all health-related programs and activities are covered by Section 1557. Across the nation, many individuals are at risk of discrimination in health-related programs due to the Current Rule which unjustifiably limits the definition of discrimination based on sex. [Footnote 1: Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2022).] The New

Rule would prevent such discrimination from happening and provide recourse when discrimination does occur ensuring that individuals receive needed healthcare.

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0004
All Sections: 6.2.6, 6.2.5
(b)(5)

Organization: The Century Foundation

Excerpt Text:
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"].

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0004
All Sections: 7.6.2, 6.2.4, 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: Covered California

Excerpt Text:
- 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, 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.

Comment Number: HHS-OS-2022-0012-1003-0005
All Sections: 6.2.5

(b)(5)

Organization: URAC

Excerpt Text:
Additionally, URAC 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. 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72795-0005
All Sections: 6.2.6, 6.2.5

(b)(5)

Organization: Tribal Technical Advisory Group to CMS (TTAG)

Excerpt Text:
[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).]

Comment Number: HHS-OS-2022-0012-DRAFT-66191-0005
All Sections: 6.2.6, 6.2.5

(b)(5)

Organization: Dignity, Inc dba DignityUSA

Excerpt Text:
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 nonbinary individuals' access care that addresses gender dysphoria.

Comment Number: HHS-OS-2022-0012-DRAFT-65871-0005
All Sections: 6.2.4, 6.2.3, 6.2.5
(b)(5)

Organization: AARP

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0005
All Sections: 6.2.2, 6.2.6, 6.2.5
(b)(5)

Organization: The Century Foundation

Excerpt Text:
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 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, September 8, 2022, https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi- communities/].

Comment Number: HHS-OS-2022-0012-DRAFT-69031-0006
All Sections: 6.2.6, 6.2.3, 6.2.5
(b)(5)

(b)(5)

Organization: Howard Brown Health

Excerpt Text:
[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].

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0006
All Sections: 6.2.6, 6.2.5, 2

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
[Bold/Underline: II. The New Rule Correctly Adopts Widely Held Interpretations of Sex Discrimination, But It Could More Explicitly Define It To Prevent Confusion]

The reinclusion of sexual orientation and gender identity into the protected characteristics under Section 1557 is consistent with applicable case law and the law's stated purpose. Moreover, it affirms what has already been recognized across the federal government and by many federal courts, including the Supreme Court of the United States: that discrimination based on sexual orientation, gender identity, gender transition, transgender status, or sex-based stereotypes are forms of sex discrimination. The proposed rule will also foster consistency between Federal agencies, regulations, and case law. [Footnote 2: See, e.g., Department of Labor, Job Corps Program Instruction Notice No. 14-31, Ensuring Equal Access for Transgender Applicants and Students to the Job Corps Program (May 1, 2015); Bostock v. Clayton County, No. 17–1618, 723 Fed. Appx. 964; No. 17–1623, 883 F. 3d 100, No. 18–107, 884 F. 3d 560.] All taken

together, the proposed rule's creation of more inclusive definitions of sex discrimination acknowledges the necessity of recognizing non-binary identities in the provision of health care and health-related programs, as it has been widely accepted among medical organizations. [Footnote 3: Am. Psychological Ass'n, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People 6 (2015); World Prof. Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender and Gender-Nonconforming People 171, 175 (2012) (requiring physicians to provide affirming care for both binary and non-binary transgender and gender non-conforming patients); Am. College of Obstetricians and Gynecologists, Committee Opinion No. 512: healthcare for Transgender Individuals, Obstetrics & Gynecology 118(6): 1454 (2011) (same); see also Am. Psychiatric Ass'n, Diagnostic and Statistical Manual of Mental Disorders, Version 5 451-53 (2013) (defining gender identity to include identities other than male or female, and specifying diagnostic criteria for gender dysphoria to include such identities); Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding, 25-26 (2011) (same).]

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0008
All Sections: 6.2.6, 6.2.5

(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:
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 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 condition s may be.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0008
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0008
All Sections: 6.2.6, 6.2.5
(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
Returning to the original scope of Section 1557 by expressly including discrimination based on sexual orientation and gender identity, the proposed rule ensures that those engaged in and those providing health and health-related programs have sufficient clarity on what sex discrimination means. This will serve to help health care and health-related program providers understand their obligations to comply with the law thereby achieving Section 1557's core purpose of eradicating discrimination. For similar reasons, the Department of Education issued a notice of proposed rulemaking to amend the language of the Title IX regulations to include sexual orientation and gender identity in the definition of sex discrimination. [Footnote 8: The U.S. Department of Education Releases Proposed Changes to Title IX Regulations, Invites Public Comment, U.S. Departent of Education (June 23, 2022), https://www.ed.gov/news/press-releases/us-department-education-releases-proposed-changes-title-ix-regulations-inv ites-public-comment.] By amending the current rule, the Department makes the rule consistent with the current legal doctrine and the statute's purpose.

Comment Number: HHS-OS-2022-0012-DRAFT-72212-0009
All Sections: 6.2.6, 6.2.3, 7.9, 6.2.5
(b)(5)

Organization: Senate Democrats

Excerpt Text:
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 characteristic 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 LGBTQIA+ couples who may be turned away from care [Footnote 23: Id. at 47918 (Proposed § 92.209)].

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0009
All Sections: 6.2.3, 6.2.7, 6.2.5
(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
LGBTQI+ people

Transgender 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 provision 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.

Section 6.2.6 - Gender identity, transgender

Comment Number: HHS-OS-2022-0012-DRAFT-9870-0001
All Sections: 6.2.6, 6.2.5

(b)(5)

Organization:

Excerpt Text:
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's nothing new--LGBTQ adults and children are being denied vital healthcare across the country. This not just cruel and immoral, it's 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.

Comment Number: HHS-OS-2022-0012-DRAFT-9845-0001
All Sections: 6.2.4, 6.2.6

(b)(5)

Organization:

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-11936-0001
All Sections: 6.2.6, 3.1.3, 6.2.5
(b)(5)
Organization: John Clarke Senior Living

Excerpt Text:
We strongly support Proposed Rule Section 1557 of the Affordable Care Act.

John Clarke increasingly cares for residents of the LGBTQI 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-35534-0001
All Sections: 6.2.6, 6.2.5
(b)(5)
Organization: Temple University Health System

Excerpt Text:
On behalf of Temple University Health System, our patients and the vulnerable comm unities we serve, thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services proposed rule on Section 1557 of the [italics: 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66191-0001
All Sections: 6.2.6, 6.2.5
(b)(5)
Organization: Dignity, Inc dba DignityUSA

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0001
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:
[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 762,000 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 (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.

Comment Number: HHS-OS-2022-0012-DRAFT-39933-0001
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: Minnesota Association of Community Health Centers

Excerpt Text:
[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 762,000 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 (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.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0001
All Sections: 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
We strongly support the explicit clarification that Section 1557 unequivocally prohibits discrimination on the basis of sexual orientation, gender identity, and sex characteristics, including intersex traits. These forms of discrimination have run rampant 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 built 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0011
All Sections: 6.2.6, 6.2.3, 6.2.10, 6.2.5

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other

States

Excerpt Text:
[Bold: B. Protecting LGBTQ 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 47,858. [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.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0012
All Sections: 6.2.4, 6.2.6

(b)(5)

Organization: Colors+

Excerpt Text:
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."

Comment Number: HHS-OS-2022-0012-DRAFT-72212-0012
All Sections: 6.2.6

(b)(5)

Organization: Senate Democrats

Excerpt Text:
Considering the onslaught of discriminatory attacks on transgender and nonbinary people, we recommend the proposed rule add 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 in vitro fertilization or limit coverage of in vitro fertilization to cisgender heterosexual couples and exclude LGBTQIA+ couples [Footnote 28: Shira Stein, "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].

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0013
All Sections: 6.2.8, 6.2.6

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
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 Cty. 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 ban 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).

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0014
All Sections: 6.2.6

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0014
All Sections: 3.1.1, 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
[Bold: 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 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 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 within comprehensive sex education, factoring for intersection 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-poc-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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0014
All Sections: 6.2.6

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
3. In section 92.101(a)(2) we recommend the text 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 15: 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).] Enumerating both terms in the regulatory text will discourage efforts to draw distinctions between the two and clarify that transgender and nonbinary people are fully covered by the final rule. It is also important to make clear in the final rule that "pregnancy or related conditions" includes the termination of pregnancy. To address these issues, we recommend the following change: "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, [Underline: including termination of pregnancy;] sexual orientation; t[Underline: ransgender status;] and gender identity."

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0015
All Sections: 6.2.1, 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0015
All Sections: 6.2.6

(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0015
All Sections: 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: II. 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 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 accessing care. In a 2016 study, one in five LGBTQ people, including 31 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 (2016), CTR FOR AMER. PROGRESS https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/ 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0016
All Sections: 6.2.6

(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-66437-0017
All Sections: 6.2.6
(b)(5)

Organization: Center for Elder Law & Justice

Excerpt Text:
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. 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, we recommend that HHS enumerate both in the regulatory text and amend Sec. 92.101(a)(2) to explicitly include transgender status.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0018
All Sections: 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: B. The proposed rule's protections against LGBTQI+ discrimination is 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 robust 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(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 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. 9, 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. 20; 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 (1980) (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 (Nov. 17, 2011).] This principle has been affirmed by human rights bodies, including with respect to sexual and reproductive health. Countries have an obligation to ensure that their legal frameworks do not discriminate based on sexual orientation and gender identity and to protect against discrimination by third parties. [Footnote 75: 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. 41, U.N. Doc. E/C.12/GC/22 (2016) (stating that the "obligation to respect also requires States to repeal, and refrain from enacting, laws and policies that create barriers to access to sexual and reproductive health services. This includes third-party authorization requirements, such as parental, spousal and judicial authorization requirements for access to sexual and reproductive health services and information, including for abortion and contraception.").] See Section IV. below for a more detailed discussion of human rights in the context of sexual and reproductive health.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0019
All Sections: 6.2.6, 6.2.7

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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. 41531.] 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 proposal 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. Jun. 30, 2022).]

Comment Number: HHS-OS-2022-0012-DRAFT-67813-0002
All Sections: 6.2.1, 6.2.6, 6.2.5

(b)(5)

Organization: Pennsylvania Health Insurance Exchange Authority d/b/a Pennie

Excerpt Text:
Pennie supports extending the nondiscrimination provisions to include the prohibition of discrimination based on gender, gender identity, sexual orientation, relationship, association, and/or family status. These protections align with federal court rulings that consider the protection against LGBTQI+ discrimination to be part of the sex nondiscrimination protections. Pennie concurs with HHS' assessment that members of the LGBTQI+ population face barriers to appropriate health care and insurance access for needed coverage. Pennie believes that extending nondiscrimination provisions to expressly include sexual orientation and gender identity is a necessary step to ensure all Pennsylvanians have equitable access to the health coverage and health care services they need.

Comment Number: HHS-OS-2022-0012-DRAFT-20039-0002
All Sections: 6.2.4, 6.2.6, 6.2.5

(b)(5)

Organization: The Colorado Health Foundation

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0002
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5

(b)(5)

Organization: National Health Council

Excerpt Text:
In addition, the provisions clarifying antidiscrimination provisions for specific populations are necessary and welcome including provisions to:

- Affirm gender-based and disability and accessibility antidiscrimination 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."

Comment Number: HHS-OS-2022-0012-DRAFT-65934-0002
All Sections: 9.1, 6.2.6, 7.7.4

(b)(5)

Organization: Sam & Devorah Foundation for Transgender Youth

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-40175-0002
All Sections: 6.2.4, 6.2.6, 6.2.3, 7.9, 6.2.5

(b)(5)

Organization: California Department of Health Care Services

Excerpt Text:
[Bold/italics: Support for NPRM's Reinstatement of Provisions from the 2016 Final Rule]

Given this 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0002
All Sections: 6.2.6, 6.1, 6.2.5
(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
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 in health care. Section 1557 therefore fills in a critical gap by extending antidiscrimination protections to patients at the intersection of multiple identities. The Proposed Rule proscribes many forms of discrimination that amplify the impacts of racism and subject people to dual 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-39789-0002
All Sections: 6.2.4, 6.2.6, 6.2.5
(b)(5)

Organization: American Federation of State, County and Municipal Employees

Excerpt Text:
Discrimination on the Basis of Sex

Consistent with recent judicial decisions, the proposed rule extends protections against discrimination on the basis of sex to include discrimination based on sexual orientation and gender identity [Footnote 1: E.g., Bostock v. Clayton County, 590 U.S. (2020)]. Additionally, we agree that protections against discrimination on the basis of sex should include pregnancy and related conditions. We believe that these provisions are critically important to ensure that all individuals receive appropriate care in a timely manner. Especially in the wake of Dobbs v. Jackson Women's Health Organization, it is paramount that women and other pregnant individuals do not face subsequent discrimination for reproductive health choices made in consultation with their families and doctors [Footnote 2: 597 U.S. (2022)].

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0020
All Sections: 6.2.6, 6.2.3, 6.2.10, 6.2.5

(b)(5)

Organization: Center for American Progress

Excerpt Text:

X. The Proposed Rule Correctly Strengthens the Definition of Sex Discrimination

a. Sex Discrimination Based on Sexual orientation, Gender Identity, and Sex Characteristics

We commend the Department for articulating a clear and expansive explanation of discrimination on the basis of sex. The Proposed Rule correctly clarifies that Section 1557's prohibition of discrimination on the basis of sex includes discrimination based on sex stereotypes, sexual orientation, gender identity, and sex characteristics, including intersex traits. We strongly support the explicit inclusion of discrimination based on these grounds. Supreme Court case law, including Price Waterhouse v. Hopkins and Bostock v. Clayton County, make clear that federal sex discrimination law includes sex stereotypes, sexual orientation, and gender identity, including transgender status [Footnote 29: Price Waterhouse v. Hopkins, 490 U.S. 228 (May 1, 1989), available at https://supreme.justia.com/cases/federal/us/490/228/] [Footnote 30: Bostock v. Clayton County, 590 U.S. ___ (June 15, 2020), p. 1, available at https://www.supremecourt.gov/opinions/19pdf/17-1618_hfci.pdf]. We also support the explicit inclusion of discrimination based on sex characteristics, including intersex traits, because discrimination based on an individual's sex characteristics is inherently sex-based.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0022
All Sections: 6.2.6

(b)(5)

Organization: Center for American Progress

Excerpt Text:

Although the terms "gender identity" and "transgender status" are often used interchangeably, those seeking to permit discrimination against transgender people have sometimes justified it by pressing distinctions between the two concepts [Footnote 36: 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)]. For that reason, we urge the Department to enumerate both terms in the regulatory text and to amend the language in § 92.101(a)(2) to include the term "transgender status."

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0029
All Sections: 6.2.6, 6.2.7

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
In contrast, the case for "transitioning" as the medical solution to gender 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, adjusting 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 could be born in the bodily form of a female, invisible 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 organization 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: coherent concept] only 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 provides the only coherent way to classify the two sexes.

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0003
All Sections: 6.2.6, 6.2.5

(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
[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 ii and iii: 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): 506–10. doi:10.1016/j.jadohealth.2013.01.015 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/e20182162] Despite some advances in public awareness and legal protections, youth who identify as LGBTQ continue to face disparities that stem from multiple sources, including inequitable 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, gender identity and sex characteristics, including intersex traits.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0003
All Sections: 6.2.6

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 design 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.

Comment Number: HHS-OS-2022-0012-DRAFT-37768-0003
All Sections: 6.2.6

(b)(5)

Organization: Massachusetts Health Connector

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-67830-0003
All Sections: 6.2.6

(b)(5)

Organization: U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Excerpt Text:
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) (In a landmark 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.").]

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0003
All Sections: 6.2.6, 7.6.3, 7.6.7, 7.7.4, 7.6.4, 6.2.5
(b)(5)

Organization: Health Care For All

Excerpt Text:
Protections against Discrimination on Basis of Sex

Sex discrimination disproportionately impacts women of color, LGBTQI+ 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 improper 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 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 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 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, therefore, recommend also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0003
All Sections: 6.2.6, 6.2.5
(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
[Bold/Underline: I. The Proposed Rule Correctly Provides Protections Under All Health-

Related Programs and Activities From Discrimination Based on Sexual Orientation and Gender Identity]

We strongly support the Department's decision to clearly add sexual orientation and restore gender identity into the rule and ensure that all health-related programs and activities are covered by Section 1557. Across the nation, many individuals are at risk of discrimination in health-related programs due to the Current Rule which unjustifiably limits the definition of discrimination based on sex. [Footnote 1: Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2022).] The New Rule would prevent such discrimination from happening and provide recourse when discrimination does occur ensuring that individuals receive needed healthcare.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0036
All Sections: 6.2.6

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[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 its 80,000 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 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. But sex in medicine and research is to be replaced 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 it 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0037
All Sections: 6.2.6

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
The term "gender identity" was coined by psychoanalyst Robert J. Stoller, writing in Sex and Gender (1968), to express a person's psychological self-categorization, distinct from one's sex (male or female). [Footnote 90: R. Green, Robert Stoller's Sex and Gender: 40 Years On, 39 Arch Sex Behav, 1457 (2010), https://doi.org/10.1007/s10508-010-9665-5. (Dr. John Money previously used the term "gender roles.")] 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 even 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 "biological sex" and "gender identity." [Footnote 92: Am. Psychiatric Ass'n, Diagnostic And Statistical Manual Of Mental Disorders 532–33 (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 reproductive organs and external genitalia." Gender identity, in contrast, "refers to one's sense of oneself as male, female or something else (APA, 2011)." "Sex" is an objective fact; "gender identity" is a subjective perception.

The APA describes a person who identifies as "transgender" as one who has a "gender identity and biological sex [that] are not congruent." [Footnote 94: Gender And Sexual Orientation Diversity in Children And Adolescents in Schools, Am. Psychological Ass'n (last updated Sept. 2021), https://www.apa.org/Pi/Lgbt/Resources/Diversity-Schools.] According to the American Psychological Association, "transgender" is "an umbrella term ... wherein one's assigned biological sex doesn't match their felt identity." [Footnote 95: American Psychological Association & National Association of School Psychologists, Resolution on Gender and Sexual Orientation Diversity in Children and Adolescents in Schools (2015), https://www.apa.org/pi/lgbt/resources/diversity-schools?item=3.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0038
All Sections: 6.2.6
(b)(5)

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:

The Human Rights Campaign Foundation publication entitled [Italics: Coming Out: Living Authentically as Transgender or Non-binary] defines "gender identity" as a person's subjective self-perception, and a "transgender" gender identity as one that is "different from their sex assigned at birth." [Footnote 96: "Gender identity - 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 their 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-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, Welcoming Schools, the 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: Hurt] feelings? [Italics: Unwelcome] feelings? [Italics: Unpleasant] feelings?

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0039
All Sections: 6.2.6

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:

Medicine is a science, dependent on observable biological facts and scientific 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, evidence), 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). Given 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 ethical 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 suspect, liable to be labeled a "pretext" for unlawful discrimination. How do we know? Because the Proposed Rule tells us. [Footnote 99: 87 Fed. Reg. 47867, 47868, 47870, 47874.]

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0004
All Sections: 6.2.2, 6.2.6
(b)(5)
Organization: Physicians for Reproductive Health

Excerpt Text:
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 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 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), (b)(2) and (b)(4), and in §92.207(b)(3).

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.

Comment Number: HHS-OS-2022-0012-DRAFT-43609-0004
All Sections: 6.2.6

(b)(5)

Organization: Endocrine Society

Excerpt Text:
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 justified 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 codifying 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0004
All Sections: 6.2.6, 6.2.5

(b)(5)

Organization: The Century Foundation

Excerpt Text:
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"].

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0004
All Sections: 7.6.2, 6.2.4, 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: Covered California

Excerpt Text:

- 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, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0004
All Sections: 6.2.6
(b)(5)

Organization: The Heritage Foundation

Excerpt Text:

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 80 FR 54176–54177] But differential 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 unwarranted 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72795-0005
All Sections: 6.2.6, 6.2.5

(b)(5)

Organization: Tribal Technical Advisory Group to CMS (TTAG)

Excerpt Text:
[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).]

Comment Number: HHS-OS-2022-0012-DRAFT-66191-0005
All Sections: 6.2.6, 6.2.5

(b)(5)

Organization: Dignity, Inc dba DignityUSA

Excerpt Text:
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 nonbinary individuals' access care that addresses gender dysphoria.

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0005
All Sections: 6.2.2, 6.2.6, 6.2.5

(b)(5)

(b)(5)

Organization: The Century Foundation

Excerpt Text:
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 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, September 8, 2022, https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi- communities/].

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0006
All Sections: 6.2.6

(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
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 obtain clinically 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65871-0006
All Sections: 6.2.6

(b)(5)

Organization: AARP

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0006
All Sections: 6.2.4, 6.2.6
(b)(5)

Organization: The Century Foundation

Excerpt Text:
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 this number was much higher for transgender and nonbinary patients of color.

Comment Number: HHS-OS-2022-0012-DRAFT-69031-0006
All Sections: 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: Howard Brown Health

Excerpt Text:
[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].

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0006
All Sections: 6.2.6, 6.2.5, 2

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
[Bold/Underline: II. The New Rule Correctly Adopts Widely Held Interpretations of Sex Discrimination, But It Could More Explicitly Define It To Prevent Confusion]

The reinclusion of sexual orientation and gender identity into the protected characteristics under Section 1557 is consistent with applicable case law and the law's stated purpose. Moreover, it affirms what has already been recognized across the federal government and by many federal courts, including the Supreme Court of the United States: that discrimination based on sexual orientation, gender identity, gender transition, transgender status, or sex-based stereotypes are forms of sex discrimination. The proposed rule will also foster consistency between Federal agencies, regulations, and case law. [Footnote 2: See, e.g., Department of Labor, Job Corps Program Instruction Notice No. 14-31, Ensuring Equal Access for Transgender Applicants and Students to the Job Corps Program (May 1, 2015); Bostock v. Clayton County, No. 17–1618, 723 Fed. Appx. 964; No. 17–1623, 883 F. 3d 100, No. 18–107, 884 F. 3d 560.] All taken together, the proposed rule's creation of more inclusive definitions of sex discrimination acknowledges the necessity of recognizing non-binary identities in the provision of health care and health-related programs, as it has been widely accepted among medical organizations. [Footnote 3: Am. Psychological Ass'n, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People 6 (2015); World Prof. Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender and Gender-Nonconforming People 171, 175 (2012) (requiring physicians to provide affirming care for both binary and non-binary transgender and gender non-conforming patients); Am. College of Obstetricians and Gynecologists, Committee Opinion No. 512: healthcare for Transgender Individuals, Obstetrics & Gynecology 118(6): 1454 (2011) (same); see also Am. Psychiatric Ass'n, Diagnostic and Statistical Manual of Mental Disorders, Version 5 451-53 (2013) (defining gender identity to include identities other than male or female, and specifying diagnostic criteria for gender dysphoria to include such identities); Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding, 25-26 (2011) (same).]

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0007
All Sections: 6.2.4, 6.2.6, 6.1

(b)(5)

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:
[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."
-- Add the phrase "transgender status" after "sexual orientation."

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0008
All Sections: 6.2.6

(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
The proposed rule also aims to protect transgender and gender diverse individuals from discriminatory benefit design 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 ix: 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/2019-03/transgender-coverage-issue-brief.pdf] the American College of Obstetricians and Gynecologists; [Footnote xi: 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/2021/03/health-care-for-transgender-and-gender-diverse-individuals] the American College of Physicians; [Footnote xii: 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 xiii: 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 Nonconforming People. American Psychologist, December 2015. Vol. 70, No. 9, 832–864] the American Academy of Family Physicians; [Footnote xv: American Academy of Family Physicians. Care for the Transgender and Gender Nonbinary Patient. 2020. Accessed on June 23, 2022. https://www.aafp.org/about/policies/all/transgender-nonbinary.html] the American Academy of Child and Adolescent Psychiatry; [Footnote xvi: Adelson SL. Practice parameter on gay, lesbian, or bisexual sexual orientation, gender non-conformity, and gender discordance in children and adolescents. Jrnl of the American Academy of Child & Adolescent Psychiatry. 2020; 957-974] the Endocrine Society; [Footnote xvii: Hembree W, Cohen-Kettenis P, Gooren L, Hannema S, Meyer W, Murad M, Rosenthal S, Safer J, Tangpricha V, T'Sjoen T. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism. 2017; 102(11): 3869–3903] the Society for Adolescent Health and Medicine; [Footnote xviii: Barkley L, Kodjo C, West KJ, et al. Promoting Health Equality and Nondiscrimination for Transgender and Gender-Diverse Youth. Jrnl of Adolescent Health. 2020; 66 (6): 804-807] the Pediatric Endocrine Society; [Footnote xix: Lopez X, Marinkovic M, Rosenthal SM, et al. Statement on gender-affirmative approach to care from the pediatric endocrine society special interest group on transgender health. Current Opinion in Pediatric. 2017; 29(4). 475-480.] the World Professional Association for Transgender Health (WPATH); [Footnote xx: The World Professional Association for Transgender Health (WPATH). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. International Journal of Transgender Health. 2022; 23 (S1),S1-S258.] and many more members of the medical community. [Footnote xxi: Eknes-Tucker et al v Ivey et al. Brief amicus curiae American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations. 4 May 2022. https://downloads.aap.org/DOFA/%5b%5bAs-Filed%5d%5d2022.05.04EknesTuckerv.IveyMedicalOrgAmicusBrief.pdf]

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0008
All Sections: 6.2.6, 6.2.5

(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:
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 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 condition s may be.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0008
All Sections: 6.2.4, 6.2.6, 6.2.3, 6.2.5
(b)(5)
Organization: Alliance of Multicultural Physicians

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0008
All Sections: 6.2.6, 6.2.5
(b)(5)
Organization: Human Rights Campaign

Excerpt Text:

Returning to the original scope of Section 1557 by expressly including discrimination based on sexual orientation and gender identity, the proposed rule ensures that those engaged in and those providing health and health-related programs have sufficient clarity on what sex discrimination means. This will serve to help health care and health-related program providers understand their obligations to comply with the law thereby achieving Section 1557's core purpose of eradicating discrimination. For similar reasons, the Department of Education issued a notice of proposed rulemaking to amend the language of the Title IX regulations to include sexual orientation and gender identity in the definition of sex discrimination. [Footnote 8: The U.S. Department of Education Releases Proposed Changes to Title IX Regulations, Invites Public Comment, U.S. Departent of Education (June 23, 2022), https://www.ed.gov/news/press-releases/us-department-education-releases-proposed-changes-title-ix-regulations-inv ites-public-comment.] By amending the current rule, the Department makes the rule consistent with the current legal doctrine and the statute's purpose.

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0009
All Sections: 6.2.6

(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
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 pulled him out and 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 his provider. When the family took legal action, the patient prevailed in the case thanks to the strong protections provided by the 2016 rule on Section 1557. We are encouraged that these protections are included in the Biden Administration proposed rule.

Comment Number: HHS-OS-2022-0012-DRAFT-72212-0009
All Sections: 6.2.6, 6.2.3, 7.9, 6.2.5

(b)(5)

Organization: Senate Democrats

Excerpt Text:
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 characteristic 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 LGBTQIA+ couples who may be turned away from care [Footnote 23: Id. at 47918 (Proposed § 92.209)].

Section 6.2.7 - Sex as immutable (biologically male or female)

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0019
All Sections: 6.2.6, 6.2.7
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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. 41531.] 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 proposal 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. Jun. 30, 2022).]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0027
All Sections: 15.2, 6.2.7
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[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 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 what sex is in medicine, it must answer it correctly and in accordance with logic and science.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0028
All Sections: 6.2.7
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
A person's sex is defined as "male or female according to their reproductive organs and functions assigned by the chromosomal complement." [Footnote 81: Institute of Medicine 2001. Exploring the Biological Contributions 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 Contributions 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=oshnZrAKkiY&feature=youtu.be.] and, as of this writing, still requires its 80,000 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, in 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 & 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0029
All Sections: 6.2.6, 6.2.7
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
In contrast, the case for "transitioning" as the medical solution to gender 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, adjusting 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 could be born in the bodily form of a female, invisible 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 organization 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: coherent concept] only 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 provides the only coherent way to classify the two sexes.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0003
All Sections: 6.2.7
(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Italics: Reasonable judgments about biology are not "discriminatory"]

Many 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, many 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-threatenfreedom; 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/2015/03/14649/ (accessed October 27, 2015); John Finnis, "Law, Morality, and 'Sexual Orientation,'" in Human Rights and Common.] 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 "discriminatory" and seek to forbid them from being followed in the coverage or provision of health care services.

Gender identity and sexual orientation, unlike race or sex, can vary, are 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 with 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. 2857, November 1, 2013, http://www.heritage.org/research/reports/2013/11/enda-threatens-fundamental-civil-liberties; and Anderson, "Sexual Orientation and Gender Identity Are Not Like Race."]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0030
All Sections: 6.2.7

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
Lawrence Mayer and Paul McHugh highlighted the same truth in a recent review of the scientific literature on sexuality and gender identity:

The underlying basis of maleness 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 binary and stable, and allows us to distinguish males from females on the grounds of their reproductive systems, even when these 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 "binary 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 outdated view of biological sex" in her declaration to a federal court in North Carolina, Dr. Mayer responded in his rebuttal declaration: "This statement is stunning. I have searched dozens of references in biology, medicine and genetics—even Wiki!—and can find no alternative scientific definition. In fact the only references to a more fluid definition of biological sex are in the social policy literature." Just so, yet the proposed regulation adopts a wholly subjective and amorphous understanding of the person, based on gender identity, divorced from scientific realities.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0031
All Sections: 6.2.7

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
Here is how one scholar put it in [Italics: 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 tissue distribution. Adult males have greater arm muscle mass, larger and stronger bones, and reduced limb fat, but 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, which drive 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0032
All Sections: 6.2.7
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[Bold: E. Innate sex differences affect our health.

There are biological differences 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 included 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, in many cases, pathological functions—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." The 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 sexes." Written into our genetic code are differences that manifest themselves at the cellular level, in ways that can affect our health. Sexual differentiation begins at conception, progresses in the womb, and continues throughout life, notably at puberty but also, significantly at menopause in females. "Hormonal events occurring in puberty lay a framework for biological differences that persist through life and contribute to the variable onset and progression of disease in males and females."

"Basic genetic and physiological differences, in combination with environmental factors, result in behavioral and cognitive differences between males and females," says the Institute of Medicine. These biological differences seem to have consequences for mental health. An article in the Neuroscience and Biobehavioral Review points to well-known differences between men and women in susceptibility to mental disorders: "Examples of male-biased conditions include autism, attention deficit/hyperactivity disorder, conduct disorder, specific language impairment, Tourette syndrome, and dyslexia, and examples of female-biased conditions include depression, anxiety disorder, and anorexia nervosa." This is not to say that these are exclusively male or female conditions, but that one sex or another experiences them with greater frequency.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0033
All Sections: 6.2.7

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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." 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0034
All Sections: 6.2.7
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 on investigations of the brain."

Of course, male and female bodies are alike in many ways, but there are notable differences in average male and average female bodies beyond our different organizations for reproduction. In other words, there is a fundamental, essential difference, and there are subsidiary, average differences. There is also wide variation among males and 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's 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).]

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0004
All Sections: 6.2.7
(b)(5)

Organization: Concerned Women for America

Excerpt Text:
"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.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0009
All Sections: 6.2.3, 6.2.7, 6.2.5
(b)(5)
Organization: Alliance of Multicultural Physicians

Excerpt Text:
LGBTQI+ people

Transgender 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 provision 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.

Section 6.2.8 - Title IX

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0013
All Sections: 6.2.8, 6.2.6
(b)(5)
Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
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 Cty. 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 ban 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).

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0024
All Sections: 6.2.8, 6.2.4
(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Italics: The department fails to discuss the redefinition's impact]

Beyond explaining 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 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 own commitment to success. Thus, the proposal would hurt the very people it claims to help.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0025
All Sections: 6.2.8
(b)(5)
Organization: The Heritage Foundation

Excerpt Text:
[Italics: Well-intended but inadequate justification]

The proposed rule recognizes that this misconception often exists, and rightly seek to provide further clarification. It says, "this 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0026
All Sections: 6.2.8
(b)(5)
Organization: The Heritage Foundation

Excerpt Text:
[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 cites 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, particularly 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. Hous. 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 these mothers with this accommodation they need to pursue an education.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0027
All Sections: 6.2.8
(b)(5)
Organization: The Heritage Foundation

Excerpt Text:
[Bold: Proposed changes to Title IX and Post-Roe Abortion State Laws: Grey Zone]

Given the Supreme Court's decision in Dobbs, the American people through their elected representatives are empowered to pass abortion laws that reflect our 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 IXs' 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 clarifications about 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 in 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 V.A. facilities (a 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, it places women in danger of coercion, malpractice, or the responsibility of making an impossible decision: must they kill their preborn child to "fully" pursue their dreams? In the short term, the financial cost of an abortion is cheaper than the long-term costs associated with parenting, which could make it the preferred or suggested option under the abortion "grey zone."

Additionally, does the department believe that the proposed rule would affect pro-life speech, pro-life organizations, pro-life events, and pro-life speakers at educational institutions? Imagine a pro-life student group organizes a display of crosses commemorating the number of children aborted in a single year in a given state. Would a public display like this be considered harassment based on termination of pregnancy under the proposed rule? The department has failed to explain exactly what falls under the scope of discrimination related to abortion.

Title IX's normalization – and apparent promotion – of abortion under its proposed rule paired with the Dobbs decision could give schools greater incentives to "opt in" to providing abortion access for athletes and students. The department provides no explanation for this shift, following the overturning of Roe v. Wade. Additionally, the department provides no explanation for how it will protect students from coercion, malpractice, or uninformed consent regarding abortion access or referrals.

Given the administration's recent action related to the V.A., we are justifiably concerned that the department intends to once again use heavy-handed administrative action to do what cannot be accomplished through the democratic process.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0028
All Sections: 6.2.8, 7.8.5

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[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 comment humbly requests similar explanations and definitions from the department related to abortion and Title IX.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0030
All Sections: 6.2.8
(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Bold: Professional Athletes and Legal Scholars Wrongly Conflate Title IX and Roe v. 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, mode of enforcement, and reach. Nonetheless, many athletes and scholars have begun to equate 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 suhmitted 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 afforded under Roe v. Wade.

A few quotes from the Amicus Brief highlight the dangerous conflation internalized 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, in 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 their 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 a pregnancy imposes enormous changes on a woman's body."

The conclusion goes so far as to say that without a right to abortion afforded by Roe v. Wade Title IX is rendered incomplete and unable to achieve it's intended ends.

"Women's increased participation and success in sports has been propelled to remarkable heights by women's exercise of, and reliance on, constitutional guarantees of liberty and gender equality, including the right to reproductive autonomy. Continued access to, and reliance on, those rights will empower the next generation of girls and women to continue to excel in athletics and beyond, strengthening their communities and this nation. If women were to be deprived of these constitutional guarantees, the consequences for women's athletics—and for society as whole—would be devastating."

These quotes highlight the twisted relationship between Title IX and access to abortion. We hope that in the coming months and years female athletes will feel the freedom and support they need to pursue both their dreams and motherhood, should the opportunity arise.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0031
All Sections: 6.2.8, 2

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[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 provision undermines Title IX's potence 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 could 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).

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0032
All Sections: 6.2.8

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[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. Additionally, it 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 way, women and men may fully embrace the demands of motherhood or fatherhood. This means, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0033
All Sections: 6.2.8, 7.8.4

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Bold: Title IX and Chemical Abortion Pills]

The abortion procedure itself has changed significantly since 1972. Given the rules' ambiguity and the change in terminology in "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 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 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 pills, does the department believe the existing federal law protects conscience rights for clinic employees who do not wish to be party to an abortion procedure? Or does the department believe that such an employee could find themselves accused of Title IX discrimination for opting out of assisting students in aborting their unborn children?

The chemical abortion process is often bloody and painful; abortion providers routinely downplay the significance of the physical process. Under new protocols, failure to evaluate women in-person means that more women will take abortion pills past the 10-week cutoff, at which point the risk of complications exponentially increases. Women who order pills online without undergoing an ultrasound may take the pills despite the fact that she may have an undiagnosed ectopic pregnancy (which, in turn, can be a fatal complication).
If the department envisions the proposed rule being used to bolster access to abortion pills in campus health clinics, the department must provide an estimate of the cost increase to campus health centers and address how they will respond to an increase in harmful side effects experienced with chemical abortion pills.

Does the department believe campus health centers are equipped to handle women experiencing post-abortion physical and mental health complications?
Can the department provide a cost estimate for the increased toll on health and counseling

centers caring for post-abortive women – and/or her roommate(s) – who were traumatized and experience adverse mental health consequences after undergoing a dorm room abortion?

Section 6.2.9 - Disparate Impact

No comments are associated with this issue

Section 6.2.10 - Case law discussion, including Bostock, Franciscan Alliance, Religious Sisters, Whitman Walker, Walker v. Azar, BAGLY

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0011
All Sections: 6.2.3, 6.2.10
(b)(5)

Organization: Colors+

Excerpt Text:
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 discrimination is inherently sex-based.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0011
All Sections: 6.2.6, 6.2.3, 6.2.10, 6.2.5
(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[Bold: B. Protecting LGBTQ 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 47,858. [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.

Comment Number: HHS-OS-2022-0012-DRAFT-66316-0002
All Sections: 6.2.10
(b)(5)

Organization: American Association of Christian Schools

Excerpt Text:
[Italics: Proposed rule's faulty legal justification:]

The HHS proposed rule justifies its radical departure from longstanding law on sex discrimination by citing the Supreme Court's finding in Bostock vs. Clayton County (2020) that the sex discrimination prohibition 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 reinterpretation of the word sex in Title VII to mean sexual orientation and gender identity discrimination only to employment law. In his 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 2: 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 educational institutions, their faculty, and their students.

Additionally, our institutions are deeply concerned with the HHS proposed rule's expansion of health care providers to include health care insurers. The trickle-down effect of this proposed rule could affect school contracts with hospital systems, contracted on-campus clinics, school

nurses, and supplemental student insurance programs. We request clarification from the Department that the requirements placed upon these contracts and programs will not cause a violation of our institutions' and students' conscience and religious liberty rights.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0020
All Sections: 6.2.6, 6.2.3, 6.2.10, 6.2.5
(b)(5)

Organization: Center for American Progress

Excerpt Text:
X. The Proposed Rule Correctly Strengthens the Definition of Sex Discrimination

a. Sex Discrimination Based on Sexual orientation, Gender Identity, and Sex Characteristics

We commend the Department for articulating a clear and expansive explanation of discrimination on the basis of sex. The Proposed Rule correctly clarifies that Section 1557's prohibition of discrimination on the basis of sex includes discrimination based on sex stereotypes, sexual orientation, gender identity, and sex characteristics, including intersex traits. We strongly support the explicit inclusion of discrimination based on these grounds. Supreme Court case law, including Price Waterhouse v. Hopkins and Bostock v. Clayton County, make clear that federal sex discrimination law includes sex stereotypes, sexual orientation, and gender identity, including transgender status [Footnote 29: Price Waterhouse v. Hopkins, 490 U.S. 228 (May 1, 1989), available at https://supreme.justia.com/cases/federal/us/490/228/] [Footnote 30: Bostock v. Clayton County, 590 U.S. ___ (June 15, 2020), p. 1, available at https://www.supremecourt.gov/opinions/19pdf/17-1618_hfci.pdf]. We also support the explicit inclusion of discrimination based on sex characteristics, including intersex traits, because discrimination based on an individual's sex characteristics is inherently sex-based.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0007
All Sections: 6.2.10
(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
[Italics: A. Adopting an Inclusive Definition of "on the basis of sex" will Further Create Consistency and Ensure that the Law is Not Confusing or Misconstrued.]

Federal courts and agencies have determined that discrimination based on sex necessarily includes sexual orientation and/or gender identity. [Footnote 4: E.g., Bostock v. Clayton County, Georgia, 140 S. Ct. 1731 (2020) (The Court stated, "it is impossible to discriminate against a

person for being homosexual or transgender without discriminating against that individual based on sex); Whitaker v. Kenosha Unified School District, 858 F.3d 1034 (7th Cir. 2017), Dodds v. U.S. Dept. of Education, 845 F.3d 217 (6th Cir. Dec.16, 2016), Schwenk v. Hartford, 204 F.3d 1187 (9th Cir. Feb. 29, 2000) Schroer v. Billington, 577 F. Supp. 2d 293, 300 (D.D.C. 2008) .] Most notably, the Supreme Court of the United States in [Italics: Bostock v. Clayton County] held that an employer who fires or otherwise discriminates against an individual merely for being gay or transgender violates Title VII's prohibition on sex discrimination. [Footnote 5: Bostock v. Clayton County, Georgia, 140 S. Ct. 1731, 1744 (2020) (Citing Phillips v. Martin Mariette Corp., 400 U.S. 542 (1971) (stating that it is irrelevant what an employer labels discriminatory and non-discriminatory), City of Los Angeles, Dept. of Water and Power v. Manhart, 435 U.S. 702 (1978) (stating that an employer could not merely point to a different non-protected trait as being the primary cause to escape liability), Oncale v. Sundowner Offshore Services, Inc., 523 U.S. 75 (1998) (stating that an employer cannot escape liability by demonstrating it treats males and females comparably as groups).] In considering the definition of "on the basis of sex," the Court stated that in order for one to discriminate based on sexual orientation or gender identity, the discriminating individual must necessarily rely on the sex of the victim in question as it would require the discriminator to take adverse action because the victims are either both of the same sex or because the victim does not identify with the sex assigned at birth. [Footnote 6: Id.] In other words, because discrimination based on sexual orientation requires the discriminator to specifically consider the sex of the people the target of discrimination is attracted to, it qualifies as sex discrimination. Additionally, because discrimination based on a person's transgender status requires the discriminatory to consider the sex the target of discrimination identifies with, it similarly qualifies as sex discrimination. Even before the Supreme Court's decision in Bostock, the vast majority of federal courts to determine the issue in the context of Section 1557 have reached the same conclusion: The ACA's sex discrimination prohibition "necessarily" encompasses bias based on sexual orientation, gender identity, or transgender status. [Footnote 7: Rumble v. Fairview Health Servs., No. 14–cv–2037, 2015 WL 1197415, at *2 (D. Minn. Mar. 16, 2015), Fabian v. Hosp. of Cent. Conn., 172 F. Supp. 3d 509 (D. Conn. Mar. 18, 2016) Cruz v. Zucker, 195 F.Supp.3d 554 (S.D.N.Y. Jul. 5, 2016) Prescott v. Rady Children's Hospital San Diego, 265 F. Supp. 3d 1090 (S.D. Cal. Sept. 27, 2017) Tovar v. Essentia Health, No. 16-cv-00100-DWF-LIB (D. Minn. Sept. 20, 2018) and Boyden v. Conlin, No. 17-cv-264-wmc (W.D. Wis. Sept. 18, 2018).]

Section 6.2.11 - Criteria and methods of administration, impairing the accomplishment of the objectives of the program or activity

No comments are associated with this issue

Section 6.2.12 - Site location

No comments are associated with this issue

Section 7.6 - Equal Program Access on the Basis of Sex (§92.206)

No comments are associated with this issue

Section 7.6.1 - Generally

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0013
All Sections: 7.6.5, 7.6.1
(b)(5)

Organization: American Academy of Family Physicians

Excerpt Text:
Equal Program Access on the Basis of Sex (§ 92.206)

HHS is proposing to clarify that covered entities may not deny or limit health services on the basis of sex, "including those that are offered exclusively to individuals of one sex, to an individual based on the individual's sex assigned at birth, gender identity, or gender otherwise recorded." HHS provides a clarification about what actions would be discriminatory and therefore would be prohibited, including but not limited to:

- Denial or limitation of a health service based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded, including those that are exclusively offered to individuals of one sex,

- An entity restricting a health professional's ability to provide care based on their patient's sex assigned at birth, gender identity, or gender otherwise recorded, including punishing or discipling a provider for providing clinically appropriate care,

- Separating or treating individuals based on their sex in a manner that subjects them to more than de minimis harm, a legal definition meaning having no more than minimal impact:

o HHS gives the example that providing a clinical treatment to a patient based on their currently present sex characteristics is generally not more than de minimis harm,

- Denying or limiting gender-affirming care that would otherwise be provided for another purpose.

HHS further proposes to clarify that health professionals are not required to provide any service when it is deemed not clinically appropriate for that individual patient, or for other non-discriminatory reasons. HHS further notes that compliance with state or local laws does not constitute sufficient judgement for a basis that a service is not clinically appropriate.

[Bold: The AAFP supports the majority of this proposal and finds the clarification to be necessary to eliminate sex-based discrimination]. The AAFP agrees that physicians should not be compelled to provide services when they determine on an individual basis that it is not clinically appropriate. [Bold: However, our interpretation of the proposed rule is that a physician's conduct may be considered discriminatory if they refuse to provide a service that may be clinically appropriate but is banned by (or otherwise in violation of) state or local law].

This provision would place physicians in an impossible position by either requiring that they violate state or local laws or face possible penalties for violating federal non-discrimination regulations.

The AAFP opposes the categorical bans on gender-affirming care and abortion in states because of the interference with evidence-based medicine and the patient-physician relationship. Moreover, it is clear that the criminalization and penalization of patients and clinicians disrupts and detracts from medical care. Unfortunately, requiring physicians to violate state and local laws in order to comply with this regulation will not meaningfully protect patients from the negative impacts of these harmful laws. Under some state laws, physicians who provide services addressed in this provision face time and cost-consuming lawsuits, criminal charges, loss of their medical license, and other negative ramifications which take physicians away from their practice and their patients. The AAFP appreciates HHS' efforts to minimize the harm of state and local regulations and bans on evidence-based care, but finalizing this provision will not achieve this goal. Further, HHS has not provided clear guidance or legal support to protect physicians providing evidence-based health care. [Bold: Therefore, the AAFP strongly urges HHS to clarify in the final rule that physicians who decline to provide clinically appropriate non-emergency services, in order to comply with state and local laws will not be considered discriminatory nor penalized under federal non- discrimination regulations. We also request HHS provide clarification, guidance, and support for physicians navigating compliance with changing federal, state, and local regulations when compliance with this and other federal regulations and guidance contradicts state or local laws].

OCR seeks comment on what sex-based distinctions, if any, should be permitted in the context of health programs and activities, and whether additional regulatory language should be added to specifically address the circumstance in which a provider offers a particular health treatment, service or procedure for certain purposes, but refuses to offer that same treatment, service or procedure for gender-transition or other gender-affirming care purposes because they believe it would not be clinically appropriate.

The AAFP believes an individualized-approach to gender-affirming care is appropriate in all contexts. The AAFP also believes that the provision of any care, especially preventive care, should be based on the patient's current anatomy, with verbal affirmation of a patient's gender identity. As proposed, this provision allows for medically appropriate care and shared decision making between a patient and a physician. The AAFP also appreciates that HHS provides a detailed explanation of de minimis harm and the difference between clinical care for a patient based on their anatomy and verbal or other forms of affirmation of their gender identity.

OCR seeks comment on if this section adequately addresses the forms of pregnancy-related discrimination. [Bold: The AAFP recommends HHS provide additional clarifications or examples of prohibited discriminatory behavior or action directed toward an individual who has experienced or received treatment for a pregnancy-related conditions]. However, we again note that any finalized language should not place physicians in the impossible position of either violating federal regulations or state and local laws.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0014
All Sections: 7.6.1

(b)(5)

Organization: Colors+

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0015
All Sections: 15.2, 7.6.1

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0018
All Sections: 7.6.1

(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
Equal 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69547-0002
All Sections: 7.6.1, 2

(b)(5)

Organization: Congressman Mike Quigley

Excerpt Text:
In 2013, the American Society for Reproductive Medicine defined infertility as "a 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, 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's or 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, 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 [Italicized: 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 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 identity. Consistent with the Supreme

Court's decision in Bostock, HHS rightly clarifies that nondiscrimination protections on the basis of sex include sexual orientation and gender identity.

One of the primary reasons for HHS' undertaking this rulemaking is to ensure consistency with the Bostock decision. We applaud HHS for its efforts, but we believe additional clarity is necessary to ensure covered entities properly comply with the law. We believe that HHS should be more specific about the policies and practices that are mandated or prohibited as a result of Section 1557 and the Bostock decision, such as cases of AR coverage where LGBTQI+ Americans have historically met pervasive discrimination. HHS could do so by including a discussion of fertility care at 42 CFR 92.206(b) in the final rule. The ACA's protections as passed by Congress extend to LGBTQI+ individuals and couples who wish to have children, including via AR. LGBTQI+ Americans deserve the same opportunity as heterosexual and cisgender Americans to start a family, and burdensome and unnecessary requirements that do not contemplate fertility as it relates to LGBTQI+ individuals and couples should not stand in their way.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0024
All Sections: 6.2.4, 7.7.1, 7.6.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:
ii. The Final Rule must explicitly name discrimination on the basis of termination of pregnancy as part of sex discrimination.

While the Department acknowledges that discrimination based on "pregnancy or related conditions" includes protections against discrimination based on termination of pregnancy, the Department does not make that explicit in the regulatory text. Just as the Department should standardize its definition of "pregnancy or related conditions" throughout the regulatory text, it must also make clear that "termination of pregnancy" is specifically named in that definition. There are several places where the Department should clarify and further amend the Proposed Rule to make clear these and other reproductive and sexual health-related protections, including § 92.101(a)(2), and § 92.206 and § 92.207, and in a separate stand-alone provision on pregnancy or related conditions.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0027
All Sections: 7.8.1, 7.7.1, 7.6.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:
iii. The Department should make clear the scope of Section 1557's protections against discrimination on the basis of pregnancy or related conditions, including termination of pregnancy.

In the Proposed Rule's discussion of § 92.208, the Department asks whether there should be a provision to "specifically address discrimination on the basis of pregnancy-related conditions" [Footnote 47: Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824, 47878 (proposed August 4, 2022) (to be codified at 45 C.F.R. pt. 92)]. We are concerned that including such a provision under § 92.208 could cause policies that are biased against people seeking abortions. In our comments below, we recommend that HHS add new provisions on discrimination related to pregnancy or related conditions, including termination of pregnancy, under § 92.206 and § 92.207 instead. Further, we would support the Department's decision to include an additional provision elsewhere in the Final Rule to "specifically address discrimination on the basis of pregnancy-related conditions" and the broad scope of protected services that fall under this form of care.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0029
All Sections: 4.3.1.2.1, 7.7.1, 7.6.1, 4.3.1.2.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:
iv. The Final Rule must enumerate specific forms of discrimination related to pregnancy or other related conditions, including termination of pregnancy.

Throughout the Final Rule, we urge the Department to specifically name and include – both in the text and preamble, including the language specified in § 92.206 and § 92.207 – examples of discrimination related to the full range of reproductive health care and type of services. The Final Rule must name the full range of reproductive health care protected from discrimination. Section 1557's protection against sex discrimination includes protections against discrimination relating to all reproductive health decisions. Specifically, the Final Rule must explicitly name that Section 1557 reaches discrimination related to fertility care, contraception, mistreatment in maternity care, and sex discrimination in access to medications and treatments for disabilities and emergency medical conditions.

With respect to discrimination against people seeking or accessing fertility treatment, it is essential that the Final Rule explicitly name that Section 1557's protects against discrimination on this basis because discrimination persists in the context of accessing infertility diagnosis, treatment, and services including assisted reproductive technology. Sex discrimination in the context of fertility care can take many forms. Some insurance companies refuse to cover certain

types of care that are traditionally used by women (e.g., in vitro fertilization (IVF)) [Footnote 48: Gabriela Weigel et al., Kaiser Family Foundation, Coverage and Use of Fertility Services in the U.S. (2020), https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/. These benefit exclusions disproportionately affect women of color due to racial disparities in the rate of certain diseases that may cause infertility. See Jennifer O'Hara, Mayo Clinic Q&A Podcast: The Link Between Racial Disparities and Cervical Cancer, Mayo Clinic News Network (Jan. 10, 2022), https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-qa-podcast-the-link-between-racial-disparities-and-cervical-cancer/#:~:text=Hispanic%20women%20have%20the%20highest,Race%20is%20a%20social%20construct(describing that Hispanic women have the highest incidence rate of cervical cancer, followed by non-Hispanic Black women)]. Even in those states that do require insurance providers to provide IVF, some insurance providers require that patients use their "spouse's sperm" to fertilize their eggs to be eligible for IVF insurance coverage, discriminating against patients based on their marital status, sexual orientation, and gender identity [Footnote 49: E.g., Haw. Rev. Stat. § 431:10A-116.5 (1987); Ark. Code R. 054.00.1–5(B) (1991). Furthermore, Texas, which only requires insurance providers to offer IVF insurance, also includes this same eligibility requirement. See Tex. Ins. Code Ann. § 1366.005]. In a recent example of discrimination on the basis of sexual orientation and marital status, OSF HealthCare, a self-insured Catholic hospital system with facilities in Illinois and Michigan, recently adopted an insurance policy for its employees that limits IVF coverage to "married couple[s] of opposite sex spouses" [Footnote 50: Shira Stein, Hospital Chain Blocks Fertility Coverage for Its LGBTQ Employees, Bloomberg L. (July 18, 2022), https://news.bloomberglaw.com/health-law-and-business/hospital-chain-blocks-fertility-coverage-for-its-lgbt-employees https://www.bgov.com/core/news_articles/RF7N4HT0G1LX].

Additionally, public and private insurers often discriminate against patients based on sex by requiring that they meet outdated and heteronormative definitions of infertility before providing IVF coverage. For example, relying on a 2013 definition of infertility that has since been rescinded by the American Society of Reproductive Medicine, many insurer require simply that patients in different-sex relationships attest that they have unsuccessfully tried to become pregnant by having unprotected sex for six months or a year, depending on their age, but require same-sex couples and single individuals to undergo six to twelve unsuccessful cycles of intrauterine insemination (IUI) at their own expense before deeming them eligible for IVF coverage [Footnote 51: Compare Practice Committee of the American Society for Reproductive Medicine, Definitions of Infertility and Recurrent Pregnancy Loss: A Committee Opinion, 99 Fertility & Sterility 63, 63 (2013) (defining infertility as "a disease defined by failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination," with Practice Committee of the American Society for Reproductive Medicine, Definitions of Infertility and Recurrent Pregnancy Loss: A Committee Opinion, 113 Fertility & Sterility 533, 533 (2020) (defining infertility as "a disease historically defined by the failure to achieve a successful pregnancy after 12 months or more of regular, unprotected sexual intercourse or due to an impairment of a person's capacity to reproduce either as an individual or with her/his partner")]. These patients are thereby forced to absorb exorbitant costs out of pocket and are delayed or denied access to IVF coverage benefits solely due to their sexual orientation [Footnote 52: See Goidel complaint, supra note TK, at ¶ 8 (describing that a

patient was forced to pay out of pocket $45,000 to achieve a successful pregnancy after she was denied coverage for the benefits in her plan because, as a queer woman, she could not attest to engaging in heterosexual sex)].

Studies have found that physicians may consciously or unconsciously block patients from accessing fertility treatment by making assumptions or possessing biases about who can or deserves to be a parent and who wants or deserves fertility treatment. For example, women of color "have reported 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 53: The Ethics Committee of the American Society for Reproductive Medicine, Disparities in Access to Effective Treatment for Infertility in the United States: An Ethics Committee Opinion, 116 FERTILITY & STERILITY 54, 57 (2021) (discussing the various inequitable barriers to fertility care), 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]. We urge the Department to clarify in the regulatory text that such discrimination in health care, including in the context of seeking or accessing fertility care, is impermissible discrimination on the basis of sex under Section 1557, and to include examples of a broad range of impermissible sex discrimination in the context of seeking or accessing fertility care in the Final Rule.

With respect to contraception, the Final Rule must make clear that Section 1557 prohibits discrimination against those seeking contraception or specific types of contraception. The Final Rule also should include the examples included in the guidance that the Department issued on July 13, 2022, to retail pharmacies, responding to incidents occurring after Dobbs, and explicit clarification of other types of discrimination against those seeking contraception [Footnote 54: U.S. DEPT. OF HEALTH & HUM. SERVS., GUIDANCE TO NATION'S RETAIL PHARMACIES: OBLIGATIONS UNDER FED. C.R. L. TO ENSURE ACCESS TO COMPREHENSIVE REPRODUCTIVE HEALTH CARE SERVS. (Jul. 13, 2022), https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html#:~:text=Pharmacies%2C%20therefore%2C%20may%20not%20discriminate,medications%20and%20how%20to%20take]. Additional examples could include: a state program that otherwise provides coverage of contraceptives but excludes a specific contraceptive because of an assertion that the contraception causes an abortion or a provider network that would only include facilities that refuse to perform female sterilization procedures [Footnote 55: In addition to violating section 1557, a state program in this instance may also be violating the ACA contraceptive coverage requirement. The Department has already made clear that the ACA contraceptive coverage requirement is a floor for coverage. Should a state restriction on contraceptives make compliance with the ACA's contraceptive coverage requirement impossible, the federal government will step in to enforce the ACA. Dep'ts of Lab., Health & Hum. Serv., & Treasury, FAQs About Affordable Care Act Implementation Part 54 (July 28, 2022) at 7, https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf]. The Department must also specify that items or services related to contraception are also protected [Footnote 56: In the context of insurance coverage requirements, the Department already recognizes that any item or service necessary to access contraception is

part of contraception. Dep'ts of Lab., Health & Hum. Serv., & Treasury, supra note 22, at 10]. Additional medications or services are often needed to facilitate use of contraception, such as anesthetics for insertion of long-acting reversible contraceptives. For example, a pharmacy refusal to provide misoprostol to a patient who was prescribed it in order to make IUD insertion easier could be a Section 1557 violation.

Additionally, the Final Rule must make clear that Section 1557 prohibits discrimination where a patient is denied medications or treatments for care unrelated to abortion because the medicine is also used for abortion care. Dobbs emboldened covered entities to start denying medications and treatments for chronic health conditions and other disabilities that could prevent, complicate, or end pregnancies or fertility. As the Department has already recognized in its July 13, 2022 guidance, Section 1557 prohibits discrimination in the form of refusing to fill prescriptions for medications that are considered "abortifacients" but may be prescribed to treat other health conditions, such as cancer, arthritis, and ulcers [Footnote 57: U.S. DEPT. OF HEALTH & HUM. SERVS., supra note 21]. This form of discrimination has occurred in states where abortion is now banned [Footnote 58: Katie Shepherd & Frances Stead Sellers, Abortion Bans Complicate Access to Drugs for Cancer, Arthritis, Even Ulcers, WASH POST (Aug. 8, 2022), https://www.washingtonpost.com/health/2022/08/08/abortion-bans-methotrexate-mifepristone-rheumatoid-arthritis/]. Similarly, the drug mifepristone is currently being tested for treating breast cancer, brain cancer, prostate cancer, alcoholism, post-traumatic stress disorder, and depression, among other conditions [Footnote 59: Caroline Hopkins, The 'Abortion Pill' May Treat Dozens of Diseases, but Roe Reversal Might Upend Research, ABC NEWS (June 25, 2022), https://www.nbcnews.com/health/health-news/abortion-pill-may-treat-dozens-diseases-roe-reversal-might-upend-resea-rcna34812]. It also is approved for termination of pregnancies. Following the Dobbs decision, patients who could be pregnant are at risk when seeking mifepristone for purposes besides abortion. Patients being refused any form of health care—because of stereotyping that the patient could be pregnant and having an abortion—falls under Section 1557's protections. To this end, the Final Rule must include language in § 92.206 and § 92.207 addressing the denial of medications or treatments that could prevent, complicate, or end pregnancies yet are prescribed for purposes beyond sexual and reproductive health care, including treatment for severe chronic conditions [Footnote 60: See U.S. DEPT. OF HEALTH & HUM. SERVS., supra note 21; see also Shepherd & Sellers, supra note 25].

The Final Rule should make clear that Section 1557 protects against discriminatory refusals to provide information or referrals about abortion and other reproductive health care. Section 1557 prohibits refusing to provide information, resources, or referrals about abortion care and other reproductive health care. Such discriminatory refusal of care constitutes discrimination based on pregnancy or related conditions. For example, many Indigenous individuals rely on Indian Health Service for health care, but IHS facilities often fail to provide information to patients about abortion care or counseling about pregnancy options [Footnote 61: Ex. F Decl. of Rachael Lorenzo 15, Nov. 18, 2020, 1:20-cv-11297-PBS]. These are forms of sex-based discrimination that Section 1557 protects against. Providers who operate in states that ban abortion may also be emboldened to deny information about abortion that a patient can receive outside of their state, even if such information is not unlawful to provide. It is critical for the Final Rule to make clear to providers, hospitals, and other entities subject to Section 1557 requirements their

responsibility to continue providing information and referrals relating to a pregnancy, including termination of pregnancy.

The Final Rule should also make clear that Section 1557 protects against discrimination based on a person's actual or perceived decision relating to abortion care. In the preamble discussion of § 92.206, the Department should include examples making clear that it is discriminatory to refuse to provide health care because of a patient's actual or perceived abortion care history, because doing so is discrimination based on sex. Patient health suffers when a provider's own biases against abortion are substituted for necessary medical care. Not only is the patient denied the immediate care they need, but also the patient's trust in the health care system erodes when they do not feel safe with their providers and may even fear consequences for disclosing their medical history. This is precisely the discrimination that Section 1557 was meant to address.

Additionally, the Final Rule should make clear that Section 1557 prohibits discrimination related to discrimination in maternity care. Pregnant Black, Indigenous, Latina/x, 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 mistreatment during labor and delivery [Footnote 62: Saraswathi Vedam, et al. The Giving Voice to Mothers study: inequity and mistreatment during pregnancy and childbirth in the United States. Reprod Health 16, 77 (2019). https://doi.org/10.1186/s12978-019-0729-2]. For example, in a 2018 California survey, Black, Asian, and Pacific Islander women who gave birth in hospitals reported higher rates of unfair treatment, harsh language, and rough handling than white women [Footnote 63: Carol Sakala et al., National Partnership for Women & Families, Listening to Mothers in California: A Population-Based Survey of Women's Childbearing Experiences, Full Survey Report, 64-65 (Sept. 2018) https://www.chcf.org/wp-content/uploads/2018/09/ListeningMothersCAFullSurveyReport2018.pdf]. Among subspecialty provider offices, 44 percent of gynecology offices were inaccessible due to factors such as inaccessible equipment and lack of transfer assistance, leaving wheelchair users unable to access abortion or maternal care [Footnote 64: Tara Lagu, MD, MPH, et al. Access to Subspecialty Care for Patients With Mobility Impairment, Annals of Internal Medicine, (2013). https://www.acpjournals.org/doi/10.7326/0003-4819-158-6-201303190-00003]. Section 1557 implementing regulations must address this discrimination.

Comment Number: HHS-OS-2022-0012-DRAFT-66244-0003
All Sections: 7.6.1

(b)(5)

Organization: Association of American Medical Colleges (AAMC)

Excerpt Text:
[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 on 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 [Italics: de minimus] 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 inclusive 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 an 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-66750-0003
All Sections: 7.6.1, 7.8.4

(b)(5)

Organization: Jacobs Institute of Women's Health

Excerpt Text:
- Explicitly indicate that prohibited forms of discrimination include fertility care, contraception, mistreatment in maternity care, and sex discrimination in access to medications and treatments for disabilities and emergency medical conditions.
- Include in the rule descriptions of discrimination that can affect access to contraception in the retail pharmacy setting, using language from the July 13, 2022 guidance. [Footnote 13: U.S. Department of Health and Human Services. (2022). Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services, Jul. 13, 2022. https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html]
- Include explicit clarification of other types of discrimination against those seeking contraception, such as a state program that otherwise provides coverage of contraceptives but excludes a specific contraceptive because of an assertion that the contraception causes an

abortion or a provider network that would only include facilities that refuse to perform female sterilization procedures.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0035
All Sections: 4.3.1.2.1, 7.7.1, 7.6.1, 4.3.1.2.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:

b. Addressing Critical Gaps in the Forms of Prohibited Sex Discrimination Enumerated

We appreciate HHS' enumeration of specific forms of sex discrimination prohibited in § 92.206(b) and § 92.207(b). 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 not refuse gender-affirming care to a patient based on a personal 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(b) and § 92.207(b) to prevent covered entities from using state or local laws that ban 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 Dobbs, we also urge you to add enumerated specific forms of discrimination related to pregnancy and related conditions. In this section of our comments, we offer analysis on how discrimination related to pregnancy and related conditions undermines program access and recommend amendments to the proposed regulatory text. Under § 92.207, we build on this analysis and recommend amendments to address discrimination related to pregnancy and related conditions in health insurance and other health-related coverage.

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, 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, 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 mistreatment during labor and delivery [Footnote 75: Vedam, S., Stoll, K., Taiwo, T.K. et al. The Giving Voice to Mothers study: inequity and mistreatment during pregnancy and childbirth in the United States. Reprod Health 16, 77 (2019). https://doi.org/10.1186/s12978-019-0729-2]. People with disabilities often experience multiple barriers to sexual and reproductive health care [Footnote 76: Agaronnik N, Pendo E, Lagu T, DeJong C, Perez-Caraballo A, Iezzoni LI. Ensuring the Reproductive Rights of Women with Intellectual Disability. J Intellect Dev Disabil. 2020;45(4):365-376. doi: 10.3109/13668250.2020.1762383. Epub 2020 Jun 10. PMID: 35046755; PMCID: PMC8765596.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8765596/]. For example, among subspecialty provider offices, 44 percent of gynecology offices were inaccessible due to factors such as inaccessible equipment and lack of transfer assistance, leaving wheelchair users unable to access abortion or maternal care [Footnote 77: Lagu, Tara, et al. "Access to subspecialty care for patients with mobility impairment: a survey." Annals of Internal Medicine 158.6 (2013): 441-446, available at https://www.acpjournals.org/doi/10.7326/0003-4819-158-6-201303190-00003]. Discrimination persists for many people when accessing infertility diagnosis, treatment, and services, including assisted reproductive technology. It is essential that the Final Rule explicitly name this as prohibited sex discrimination.

When the Supreme Court overturned the constitutional right to abortion in Dobbs, it provoked covered entities to begin discriminatorily denying or erecting barriers to medications and treatments that can prevent, complicate, or end pregnancies. Covered entities are struggling to understand their compliance with rapidly changing state laws. The impacts of Dobbs are compounding preexisting barriers to abortions, contraception, miscarriage management, fertility care, and other sexual and reproductive health care, particularly for communities of color, people with disabilities, the LGBTQI+ community (especially transgender people), and more [Footnote 78: Bella Isaacs-Thomas, "For many pregnant trans people, competent medical care is hard to find," PBS News Hour, May 26, 2021, available at https://www.pbs.org/newshour/health/for-many-pregnant-trans-people-competent-medical-care-is-hard-to-find]. For example, people with disabilities are increasingly denied or subjected to unconscionable barriers to methotrexate, which is regularly used to treat cancer and autoimmune conditions [Footnote 79: Laura Weiss, "Pharmacists and Patients Are Freaking Out Over New Medication Restrictions Post-Roe" The New Republic, July 27, 2022, available at https://newrepublic.com/article/167165/dobbs-pharmacists-walgreens-methotrexate]. We expect that under Dobbs, people with disabilities will face increasing discriminatory denials of and barriers to the vast array of medications and treatments prescribed for their conditions that happen to prevent, complicate, or end pregnancies or fertility. Accordingly, we urge you to amend proposed § 92.206(b) as follows:

(3) 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, italic: 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, [bold, italic: fertility care, or any health services], [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, [bold, underline: transgender status] or gender otherwise recorded.

(5) [Bold, italic: 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, that could 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].

In addition, HHS must strengthen the language pertaining to providers complying with a state or local law as a justification for denying gender-affirming care, abortions, or other reproductive or sexual health care to state unequivocally that Section 1557, as federal law, preempts any such state or local law restricting access to this care.

Comment Number: HHS-OS-2022-0012-DRAFT-66750-0004
All Sections: 7.7.1, 7.6.1
(b)(5)

Organization: Jacobs Institute of Women's Health

Excerpt Text:
- Include language in § 92.206 and § 92.207 addressing the denial of medications or treatments that could prevent, complicate, or end pregnancies yet are prescribed for purposes beyond sexual and reproductive health care, including treatment for severe chronic conditions.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0044
All Sections: 7.6.1
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
- [Bold: Provider beliefs and medical judgment (which conflict with ideology-based "standards of care"):] The entire rule is premised on gender ideology, a "gender identity-based" 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 conscience-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 ideologically-favored "guidelines" or "standards" will be count. [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.)

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0049
All Sections: 7.6.1

(b)(5)

Organization: Justice in Aging

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0007
All Sections: 7.6.6, 7.6.1, 7.6.7

(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:
II. [Bold: Addressing Critical Gaps in the Forms of Prohibited Sex Discrimination 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 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 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 ban 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, 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 health care. For example, among subspecialty provider offices, 44% of gynecology [embedded hyperlink text (https://www.acpjournals.org/doi/10.7326/0003-4819-158-6-201303190-00003)] offices were inaccessible due to factors such as lack of equipment or transfer assistance, leaving wheelchair users unable to access abortion or maternity care. In addition, discrimination persists for many people when attempting to access infertility diagnosis, treatment, and services, including assisted reproductive technology. It is essential that the final rule explicitly name this as prohibited sex discrimination.

When the Supreme Court overturned the constitutional right to abortion in [Italics: Dobbs], it provoked covered entities to begin discriminatorily denying or erecting barriers to medications and treatments that can prevent, complicate, or end pregnancies. Covered entities are struggling to understand their compliance with rapidly changing state laws. The impacts of [Italics: Dobbs] are compounding preexisting barriers to abortions, contraception, miscarriage management, fertility care, and other sexual and reproductive health care, particularly for communities of color, people with disabilities, the LGBTQ+ community (especially transgender people [embedded hyperlink text (https://www.pbs.org/newshour/health/for-many-pregnant-trans-people-competent-medical-care-is-hard-to-find)]), and more. For example, all people, but particularly people with disabilities, are increasingly denied or subjected to unconscionable barriers [embedded hyperlink text (https://newrepublic.com/article/167165/dobbs-pharmacists-walgreens-methotrexate)]to methotrexate, which is regularly used to treat cancer and autoimmune conditions. We expect that under [Italics: Dobbs], people with disabilities will face increasing discriminatory denials of and barriers to the vast array of medications and treatments prescribed for their conditions that happen to prevent, complicate, or end pregnancies or fertility.

RECOMMENDATION: Accordingly, we urge you to amend proposed § 92.206(b) as follows:
(3) 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 [Italics: de minimis harm], including 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, [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, [Italics: 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) [Italics: 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) [Italics: 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) [Italics: Deny or limit services, or a health care professional's ability to provide services, that could 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.]

In addition, HHS must strengthen the language pertaining to providers complying with a state or local law as a justification for denying gender-affirming care, abortions, or other reproductive or sexual health care to state unequivocally that Section 1557, as federal law, preempts any such state or local law restricting access to this care.

Section 7.6.2 - Equal program access (including access to facilities, hospital rooms)

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0020
All Sections: 7.6.2
(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0004
All Sections: 7.6.2, 6.2.4, 6.2.6, 6.2.3, 6.2.5
(b)(5)

Organization: Covered California

Excerpt Text:
- 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, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0007
All Sections: 7.6.2, 7.6.7
(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:
[Bold: Specific Applications to Health Programs and Activities] - [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.

Section 7.6.3 - Deny or limit health services (§92.206(b)(1))

Comment Number: HHS-OS-2022-0012-DRAFT-44558-0010
All Sections: 7.6.3, 7.6.7, 7.6.4
(b)(5)

(b)(5)

Organization: Equitas Health

Excerpt Text:
[Subpart C—Specific Applications to Health Programs and Activities] Equal 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 [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 [italic: 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(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 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, [italic, 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, [italic, bold: 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, [italic, bold: transgender status], or gender otherwise recorded."

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0011
All Sections: 7.6.3

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
Indeed, the Proposed would contradict and render null an [Italics: existing] Voluntary Resolution Agreement OCR entered into with Michigan State University under Section 1557 regarding the Larry Nasser 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/vra-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 biological men who identify 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 but "experience significant forms of 'discrimination, stigma, and erasure'" in pregnancy care thus necessitating the Proposed Rule. [Footnote 24: 87 Fed. Reg. 47865.] 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 room with biological women because to do otherwise would be more than [Italics: de minimis] harm.

Comment Number: HHS-OS-2022-0012-DRAFT-69031-0011
All Sections: 13.2, 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Howard Brown Health

Excerpt Text:
[Italic: Whether, and if so how, the proposed rule addresses clarity and confusion over compliance requirements and rights of people to be free from discrimination on 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 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 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 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 information, facts, surveys, audits, or reports:]

The addition of intersectional discrimination is much appreciated inclusion, and we feel it would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. The concept of intersectional stigma involves examining when a patient possesses multiple stigmatized identities. This includes co- existing health conditions such as HIV, mental illness or substance use; demographics such as race, ethnicity, gender, or sexual orientation; and behaviors or experiences such as substance use and sex work [Footnote 14: "Promoting Reductions in Intersectional Stigma (Prism) to Improve the HIV Prevention Continuum." National Institute of Mental Health, U.S. Department of Health and Human Services, www.nimh.nih.gov/funding/grant-writing-and-application-process/concept-clearances/2018/promoting- reductions-in-intersectional-stigma-prism-to-improve-the-hiv-prevention-continuum]. According to the Center for American Progress (CAP), 24% of LGBTQ people of color reported some form of negative or discriminatory treatment from a doctor or health care provider in the year prior [Footnote 15: Lindsay Mahowald, et al. "LGBTQ People of Color Encounter Heightened Discrimination." Center for American Progress, 22 Aug. 2022, www.americanprogress.org/article/lgbtq-people-color-encounter- heightened-discrimination/]. This is in comparison with 17% of white LGBTQ respondents [Footnote 16: Ibid]. In addition to the previously mentioned language revision to section 92.101(a)(1), it would strengthen the rule to include more specific examples of what constitutes intersectional discrimination. Intersectional discrimination can take many forms such as a trans person of color living with HIV being discriminated against due to their gender identity as a trans person, their race, and

HIV status. Similarly, we would also recommend adding specific examples and best practices around addressing discrimination specifically against people with nonbinary gender identities.

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0012
All Sections: 7.6.3

(b)(5)

Organization: The Century Foundation

Excerpt Text:
Second, the final regulation should establish explicit protections against related discrimination by providers and insurers. In the aftermath of the Dobbs decision, some patients have been denied access to needed medication 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 discrimination under section 1557 as well. The finalized rule should amend section 92.206(b) to include the following new language for providers:

- (3) 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, that could 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0014
All Sections: 7.6.3

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
In 2020 OCR, reviewed all available evidence and found no denials of access based on identity 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72212-0014
All Sections: 7.6.3

(b)(5)

Organization: Senate Democrats

Excerpt Text:
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, termination of pregnancy, miscarriage management, fertility care, maternity care, and other health services [Footnote 31: Id. at 47858, 47918 (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.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0015
All Sections: 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Colors+

Excerpt Text:
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;

(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, 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: t ransgender 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, complicate, or end a patient's fertility or pregnancy.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0015
All Sections: 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
4. In addition to section 92.101(a)(2), we reccommend 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), because even if a claimant cannot show that the care in question was on other occasions provided for other purposes, the provider could engage in a discriminatory denial of care. We recommend the following change to 92.206:

"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, [Underline: 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, [Underline: transgender status,] or gender otherwise recorded [Strikethrough: i f 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, [Underline: transgender status,] or gender otherwise recorded."

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0016
All Sections: 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
[Subpart C—Specific Applications to Health Programs and Activities]

[Bold: Equal 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 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 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: 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 [struck through: 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 [struck through: 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, [Bold: 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, complicate, or end a patient's fertility or pregnancy.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0019
All Sections: 7.6.3, 7.6.7, 7.6.4
(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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/underlined: 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/underlined: 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."

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0019
All Sections: 6.2.1, 7.6.3, 7.6.7, 7.7.4, 7.6.4
(b)(5)

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: C. The proposed rule should include transgender status as a protected 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 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).] 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; [Underline: 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 §156.1230 by the 2020 rule. However, because the proposed language of these protections differs from the language proposed under §92, we urge the Department to here, too, adopt language in the final rule consistent with the language in §92.101 to avoid confusion and ensure consistency of implementation.

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0002
All Sections: 7.6.3, 7.6.7, 7.7.4, 7.6.4

(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:
[Bold: TPCA recommends also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).]

Comment Number: HHS-OS-2022-0012-DRAFT-39933-0002
All Sections: 7.6.3, 7.6.7, 7.7.4, 7.6.4

(b)(5)

Organization: Minnesota Association of Community Health Centers

Excerpt Text:
[Bold: MNACHC recommends also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).

Comment Number: HHS-OS-2022-0012-DRAFT-43609-0003
All Sections: 7.6.5, 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Endocrine Society

Excerpt Text:
Impact on Access to Care

If 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0003
All Sections: 6.2.6, 7.6.3, 7.6.7, 7.7.4, 7.6.4, 6.2.5

(b)(5)

(b)(5)

Organization: Health Care For All

Excerpt Text:
Protections against Discrimination on Basis of Sex

Sex discrimination disproportionately impacts women of color, LGBTQI+ 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 improper 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 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 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 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, therefore, recommend also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0034
All Sections: 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Center for American Progress

Excerpt Text:
XI. Equal Program Access of the Basis of Sex (§ 92.206)

We strongly support the inclusion of this section, which will help to address the many forms of harmful discrimination described above. Below we address specific provisions related to equal

access for LGBTQI+ communities and access to gender-affirming care, as well as the need to address critical gaps in the forms of prohibited sex discrimination enumerated.

a. Equal Access for LGBTQI+ Communities and Access to Gender-Affirming Care

We support the Proposed Rule requirements that covered entities ensure equal access to their health programs and activities for LGBTQI+ people and that it enumerates specific discriminatory actions that are prohibited on the basis of sex, including gender identity, sex assigned at birth, or gender recorded in the person's medical record. CAP's nationally representative survey data highlight the importance of these protections. For example, 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 [Footnote 72: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/].

The protections outlined in this section may also help to address the many challenges that transgender and nonbinary people encounter when seeking access to gender-affirming care from providers. According to CAP's data, in the past year 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 refusal by a health care provider [Footnote 73: Ibid]. These kinds of refusals can include a range of experiences. For example, in the past year [Footnote 74: Ibid]:

? 21 percent of transgender or nonbinary respondents, including 28 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to provide reproductive or sexual health services due to their gender identity.

? 20 percent of transgender or nonbinary respondents, including 27 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to document evidence of gender dysphoria or readiness to receive gender-affirming care.

? 19 percent of transgender or nonbinary respondents, including 27 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to assist the respondent in forming a family due to the respondent's actual or perceived gender identity.

? 15 percent of transgender or nonbinary respondents, including 22 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to provide gender-affirming care—for instance, hormone therapy, surgery, puberty delay medications, or mental health services.

? 10 percent of transgender or nonbinary respondents, including 17 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to see them because of their actual or perceived gender identity.

Importantly, this section clarifies that although providers may exercise clinical judgment when determining whether a specific 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. Notably, 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 § 92.101(a)(2) above, we suggest that "transgender status" be added to § 92.206(b)(1), (b)(2) and (b)(4). We also believe that § (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(b) 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;

(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, underline: 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, [bold, underline: transgender status], or gender otherwise recorded."

As explained in more detail below, we also believe that § 92.206(b)(4) should be amended to include "fertility care or any health services."

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0007
All Sections: 7.6.3

(b)(5)

Organization: Concerned Women for America

Excerpt Text:
The Department must answer these questions: How can the Rule threaten with violations a covered entity for providing health care based on sex, male and female, when sex is an integral

part of appropriate care? How can you threaten covered entities with violations using a standard that lacks any basis in law and admittedly cannot be defined? Have you calculated the costs to covered entities for such claims?

The Rule sets up a direct attack on the status and dignity of women and our female sex by specifically mandating: "For example, a hospital that assigns patients to dual-occupancy rooms based on sex would be prohibited from requiring a transgender woman to share a room with a cisgender man, regardless of how her sex is recorded in her insurance or medical records."

Make no mistake, any male who declares he is a woman should NOT be admitted to a dual room where a vulnerable woman could be sexually assaulted. This is just another example of how this Administration and this Rule literally erases the assurance of protections for women on the basis of sex. This is more than an insult to women; it imposes a regime of harm.

What the Department has established, virtually the only point of clarity in this Rule, is this: any male who identifies as a woman is a superior protected class and granted superior protections over any human female.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0009
All Sections: 7.6.6, 7.6.5, 7.6.3

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 "deny[ing] or limit[ing] 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 [Italics: 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, biological or otherwise, unless they can prove it "does not cause more than [Italics: de minimis harm.] And even that narrow, practically meaningless, exception does not apply if the sex-based distinction results in a denial or limitation of services.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0009
All Sections: 7.6.3
(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: A. The final rule should enumerate these specific forms of discrimination in sections §92.206 and §92.207.]

Clear nondiscrimination protections related to pregnancy or related conditions, including termination of pregnancy, fertility care, contraception, and prenatal, birthing, and postpartum care are critically necessary in this moment of crisis for reproductive health care access. We support the Department's enumeration of specific forms of sex discrimination prohibited in § 92.206(b) and § 92.207(b). 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):

[Underline: (5) Adopt or apply any policy or practice that subjects people to discriminatory treatment during pregnancy, childbirth, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0009
All Sections: 7.6.3, 7.6.7, 7.6.4
(b)(5)

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
2. [Bold: Adopting clearer language regarding denial of gender-affirming care and 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. 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 cannot 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, [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."

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0009
All Sections: 15.2, 7.6.3, 7.6.7
(b)(5)

(b)(5)

Organization: Concerned Women for America

Excerpt Text:
Section 92.206 and 92.207 of the Rule require that a covered entity must not 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, 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, refashion 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 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 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 nondiscrimination-based care cannot go one way. This Rule must obligate covered entities for any health service or procedure that helps 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 that refashion a body to desired appearances or it would be discriminatory.

Section 7.6.4 - Deny or limit a health care professional's ability to provide health services (§92.206(b)(2))

Comment Number: HHS-OS-2022-0012-DRAFT-44558-0010
All Sections: 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Equitas Health

Excerpt Text:
[Subpart C—Specific Applications to Health Programs and Activities] Equal 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 [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 [italic: 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(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 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, [italic, 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, [italic, bold: 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, [italic, bold: transgender status], or gender otherwise recorded."

Comment Number: HHS-OS-2022-0012-DRAFT-72212-0010
All Sections: 7.6.4
(b)(5)

(b)(5)

Organization: Senate Democrats

Excerpt Text:
We also appreciate the Department's inclusion of equal program access which explicitly includes provisions that programs may not deny or limit services based on sex assigned at birth, gender identity, or gender [Footnote 24: Id. 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 their actual or perceived gender identity, to discriminatory attacks on gender affirming care as well as litigation 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69031-0011
All Sections: 13.2, 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Howard Brown Health

Excerpt Text:
[Italic: Whether, and if so how, the proposed rule addresses clarity and confusion over compliance requirements and rights of people to be free from discrimination on 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 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 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 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 information, facts, surveys, audits, or reports:]

The addition of intersectional discrimination is much appreciated inclusion, and we feel it would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. The concept of intersectional stigma involves examining when a patient possesses multiple stigmatized identities. This includes co- existing health conditions such as HIV, mental illness or substance use; demographics such as race, ethnicity, gender, or sexual orientation; and behaviors or experiences such as substance use and sex work [Footnote 14: "Promoting Reductions in Intersectional Stigma (Prism) to Improve the HIV Prevention Continuum." National Institute of Mental Health, U.S. Department of Health and Human Services, www.nimh.nih.gov/funding/grant-writing-and-application-process/concept-clearances/2018/promoting- reductions-in-intersectional-stigma-prism-to-improve-the-hiv-prevention-continuum]. According to the Center for American Progress (CAP), 24% of LGBTQ people of color reported some form of negative or discriminatory treatment from a doctor or health care provider in the year prior [Footnote 15: Lindsay Mahowald, et al. "LGBTQ People of Color Encounter Heightened Discrimination." Center for American Progress, 22 Aug. 2022, www.americanprogress.org/article/lgbtq-people-color-encounter- heightened-discrimination/]. This is in comparison with 17% of white LGBTQ respondents [Footnote 16: Ibid]. In addition to the previously mentioned language revision to section 92.101(a)(1), it would strengthen the rule to include more specific examples of what constitutes intersectional discrimination. Intersectional discrimination can take many forms such as a trans person of color living with HIV being discriminated against due to their gender identity as a trans person, their race, and HIV status. Similarly, we would also recommend adding specific examples and best practices around addressing discrimination specifically against people with nonbinary gender identities.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0015
All Sections: 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Colors+

Excerpt Text:
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;

(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, 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: t ransgender 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, complicate, or end a patient's fertility or pregnancy.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0015
All Sections: 7.6.3, 7.6.7, 7.6.4
(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
4. In addition to section 92.101(a)(2), we reccommend 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), because even if a claimant cannot show that the care in question was on other occasions provided for other purposes, the provider could engage in a discriminatory denial of care. We recommend the following change to 92.206:

"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, [Underline: 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, [Underline: transgender status,] or gender otherwise recorded [Strikethrough: i f 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, [Underline: transgender status,] or gender otherwise recorded."

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0016
All Sections: 7.6.3, 7.6.7, 7.6.4
(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
[Subpart C—Specific Applications to Health Programs and Activities]

[Bold: Equal 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 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 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: 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 [struck through: 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 [struck through: 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, [Bold: 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, complicate, or end a patient's fertility or pregnancy.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0019
All Sections: 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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/underlined: 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/underlined: 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."

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0019
All Sections: 6.2.1, 7.6.3, 7.6.7, 7.7.4, 7.6.4

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: C. The proposed rule should include transgender status as a protected 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 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).] 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; [Underline: 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 §156.1230 by the 2020 rule. However, because the proposed language of these protections differs from the language proposed under §92, we urge the Department to here, too, adopt language in the final rule consistent with the language in §92.101 to avoid confusion and ensure consistency of implementation.

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0002
All Sections: 7.6.3, 7.6.7, 7.7.4, 7.6.4

(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:
[Bold: TPCA recommends also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).]

Comment Number: HHS-OS-2022-0012-DRAFT-39933-0002
All Sections: 7.6.3, 7.6.7, 7.7.4, 7.6.4

(b)(5)

Organization: Minnesota Association of Community Health Centers

Excerpt Text:
[Bold: MNACHC recommends also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).

Comment Number: HHS-OS-2022-0012-DRAFT-43609-0003
All Sections: 7.6.5, 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Endocrine Society

Excerpt Text:
Impact on Access to Care

If 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0003
All Sections: 6.2.6, 7.6.3, 7.6.7, 7.7.4, 7.6.4, 6.2.5

(b)(5)

Organization: Health Care For All

Excerpt Text:
Protections against Discrimination on Basis of Sex

Sex discrimination disproportionately impacts women of color, LGBTQI+ 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 improper 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 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 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 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, therefore, recommend also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0034
All Sections: 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Center for American Progress

Excerpt Text:

XI. Equal Program Access of the Basis of Sex (§ 92.206)

We strongly support the inclusion of this section, which will help to address the many forms of harmful discrimination described above. Below we address specific provisions related to equal access for LGBTQI+ communities and access to gender-affirming care, as well as the need to address critical gaps in the forms of prohibited sex discrimination enumerated.

a. Equal Access for LGBTQI+ Communities and Access to Gender-Affirming Care

We support the Proposed Rule requirements that covered entities ensure equal access to their health programs and activities for LGBTQI+ people and that it enumerates specific discriminatory actions that are prohibited on the basis of sex, including gender identity, sex assigned at birth, or gender recorded in the person's medical record. CAP's nationally representative survey data highlight the importance of these protections. For example, 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 [Footnote 72: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/].

The protections outlined in this section may also help to address the many challenges that transgender and nonbinary people encounter when seeking access to gender-affirming care from providers. According to CAP's data, in the past year 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 refusal by a health care provider [Footnote 73: Ibid]. These kinds of refusals can include a range of experiences. For example, in the past year [Footnote 74: Ibid]:

? 21 percent of transgender or nonbinary respondents, including 28 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to provide reproductive or sexual health services due to their gender identity.

? 20 percent of transgender or nonbinary respondents, including 27 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to document evidence of gender dysphoria or readiness to receive gender-affirming care.

? 19 percent of transgender or nonbinary respondents, including 27 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to assist the respondent in forming a family due to the respondent's actual or perceived gender identity.

? 15 percent of transgender or nonbinary respondents, including 22 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to provide gender-affirming care—for instance, hormone therapy, surgery, puberty delay medications, or mental health services.

? 10 percent of transgender or nonbinary respondents, including 17 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to see them because of their actual or perceived gender identity.

Importantly, this section clarifies that although providers may exercise clinical judgment when determining whether a specific 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. Notably, 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 § 92.101(a)(2) above, we suggest that "transgender status" be added to § 92.206(b)(1), (b)(2) and (b)(4). We also believe that § (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(b) 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;

(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, underline: 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, [bold, underline: transgender status], or gender otherwise recorded."

As explained in more detail below, we also believe that § 92.206(b)(4) should be amended to include "fertility care or any health services."

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0009
All Sections: 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
2. [Bold: Adopting clearer language regarding denial of gender-affirming care and 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. 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 cannot 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, [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."

Section 7.6.5 - Sex-based distinctions (single-sex program or sex-specific program); treating individuals differently or separating them based on sex (§ 92.206(b)(3))

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0010
All Sections: 7.6.5

(b)(5)

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 21: Id.] 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 men 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 health care and merit special treatment, but to allow people who identify as transgender, or non-binary, or asexual, or two-spirit, [Italics: etc.] to use the facilities of [Italics: their] choosing, regardless of how people around them feel about it.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0013
All Sections: 7.6.5

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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- described 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.

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0013
All Sections: 7.6.5, 7.6.1

(b)(5)

(b)(5)

Organization: American Academy of Family Physicians

Excerpt Text:
Equal Program Access on the Basis of Sex (§ 92.206)

HHS is proposing to clarify that covered entities may not deny or limit health services on the basis of sex, "including those that are offered exclusively to individuals of one sex, to an individual based on the individual's sex assigned at birth, gender identity, or gender otherwise recorded." HHS provides a clarification about what actions would be discriminatory and therefore would be prohibited, including but not limited to:

- Denial or limitation of a health service based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded, including those that are exclusively offered to individuals of one sex,

- An entity restricting a health professional's ability to provide care based on their patient's sex assigned at birth, gender identity, or gender otherwise recorded, including punishing or discipling a provider for providing clinically appropriate care,

- Separating or treating individuals based on their sex in a manner that subjects them to more than de minimis harm, a legal definition meaning having no more than minimal impact:

o HHS gives the example that providing a clinical treatment to a patient based on their currently present sex characteristics is generally not more than de minimis harm,

- Denying or limiting gender-affirming care that would otherwise be provided for another purpose.

HHS further proposes to clarify that health professionals are not required to provide any service when it is deemed not clinically appropriate for that individual patient, or for other non-discriminatory reasons. HHS further notes that compliance with state or local laws does not constitute sufficient judgement for a basis that a service is not clinically appropriate.

[Bold: The AAFP supports the majority of this proposal and finds the clarification to be necessary to eliminate sex-based discrimination]. The AAFP agrees that physicians should not be compelled to provide services when they determine on an individual basis that it is not clinically appropriate. [Bold: However, our interpretation of the proposed rule is that a physician's conduct may be considered discriminatory if they refuse to provide a service that may be clinically appropriate but is banned by (or otherwise in violation of) state or local law].

This provision would place physicians in an impossible position by either requiring that they violate state or local laws or face possible penalties for violating federal non-discrimination regulations.

The AAFP opposes the categorical bans on gender-affirming care and abortion in states because of the interference with evidence-based medicine and the patient-physician relationship. Moreover, it is clear that the criminalization and penalization of patients and clinicians disrupts and detracts from medical care. Unfortunately, requiring physicians to violate state and local laws in order to comply with this regulation will not meaningfully protect patients from the negative impacts of these harmful laws. Under some state laws, physicians who provide services addressed in this provision face time and cost-consuming lawsuits, criminal charges, loss of their medical license, and other negative ramifications which take physicians away from their practice and their patients. The AAFP appreciates HHS' efforts to minimize the harm of state and local regulations and bans on evidence-based care, but finalizing this provision will not achieve this goal. Further, HHS has not provided clear guidance or legal support to protect physicians providing evidence-based health care. [Bold: Therefore, the AAFP strongly urges HHS to clarify in the final rule that physicians who decline to provide clinically appropriate non-emergency services, in order to comply with state and local laws will not be considered discriminatory nor penalized under federal non- discrimination regulations. We also request HHS provide clarification, guidance, and support for physicians navigating compliance with changing federal, state, and local regulations when compliance with this and other federal regulations and guidance contradicts state or local laws].

OCR seeks comment on what sex-based distinctions, if any, should be permitted in the context of health programs and activities, and whether additional regulatory language should be added to specifically address the circumstance in which a provider offers a particular health treatment, service or procedure for certain purposes, but refuses to offer that same treatment, service or procedure for gender-transition or other gender-affirming care purposes because they believe it would not be clinically appropriate.

The AAFP believes an individualized-approach to gender-affirming care is appropriate in all contexts. The AAFP also believes that the provision of any care, especially preventive care, should be based on the patient's current anatomy, with verbal affirmation of a patient's gender identity. As proposed, this provision allows for medically appropriate care and shared decision making between a patient and a physician. The AAFP also appreciates that HHS provides a detailed explanation of de minimis harm and the difference between clinical care for a patient based on their anatomy and verbal or other forms of affirmation of their gender identity.

OCR seeks comment on if this section adequately addresses the forms of pregnancy-related discrimination. [Bold: The AAFP recommends HHS provide additional clarifications or examples of prohibited discriminatory behavior or action directed toward an individual who has experienced or received treatment for a pregnancy-related conditions]. However, we again note that any finalized language should not place physicians in the impossible position of either violating federal regulations or state and local laws.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0002
All Sections: 7.6.5

(b)(5)

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
The Rule would require pregnant women who identify as men to be treated "consistent with the individual's gender identity" [Footnote 3: Proposed § 92.206(b)(3).] 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 complications misdiagnosed because the hospital treated her consistent with her preferred gender identity of male, resulting in a stillbirth of the child. [Footnote 4: 85 FR 37189-37190.]

Comment Number: HHS-OS-2022-0012-DRAFT-43609-0003
All Sections: 7.6.5, 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Endocrine Society

Excerpt Text:
Impact on Access to Care

If 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0035
All Sections: 7.6.5

(b)(5)

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 politics 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 37190.] HHS also found that using non-discrimination rationales to impose a gender identity rule "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.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0040
All Sections: 7.6.5

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
The arbitrary decision by HHS to refract "discrimination" through the prism of "gender identity" jeopardizes essential aspects of care that depend 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:

- [Bold: 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 on, HHS spells out the discriminatory nature of "incorrect [factual] assumptions," noting that "[p]roviders and issuers frequently formulate]Italics: incorrect

assumptions] about transgender and gender non-conforming individual's bodies when assessing medical necessity for sex-specific preventive care." [Footnote 101: 87 Fed. Reg. 47871 n.451 (emphasis added).]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0047
All Sections: 7.6.5

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:

[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 unscientific 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 113: 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 to the evaluation of diseases and treatments—until science recognized the impact of "sex as a biological variable" that must be taken into account if medicine is to benefit females, in particular.

Comment Number: HHS-OS-2022-0012-DRAFT-66854-0007
All Sections: 7.6.5, 7.6.7

(b)(5)

Organization: Wisconsin Primary Health Care Association

Excerpt Text:

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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0009
All Sections: 7.6.6, 7.6.5, 7.6.3
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 "deny[ing] or limit[ing] 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 [Italics: 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, biological or otherwise, unless they can prove it "does not cause more than [Italics: de minimis harm.] And even that narrow, practically meaningless, exception does not apply if the sex-based distinction results in a denial or limitation of services.

Section 7.6.6 - De minimis harm (§92.206(b)(3))

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0011
All Sections: 7.6.6, 7.6.7, 7.7.4

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:
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)(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, birth-assigned, or recorded gender.

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0014
All Sections: 7.6.6

(b)(5)

Organization: Concerned Women for America

Excerpt Text:
Tying the hands of America's health care system and any ethically-minded health provider with a sweeping mandate that anything less than accommodating self-defined gender identity could violate "more than [Italics: de minimus] 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0043
All Sections: 7.6.6

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[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 it discriminatory when such inquiries

result in more than "de minimis harm." [Footnote 105: 87 Fed. Reg 47867.] 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 47868.] Put differently, if a healthcare provider asks the wrong question or asks an appropriate 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 47868.] This amounts to an arbitrary and capricious extension of the grounds for sex discrimination claims.

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0006
All Sections: 7.6.6

(b)(5)

Organization: Concerned Women for America

Excerpt Text:
[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, 147.104, 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 minimus] 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 statue 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 health care demands treatment according to sex.

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0007
All Sections: 7.6.6, 7.6.1, 7.6.7

(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:

II. [Bold: Addressing Critical Gaps in the Forms of Prohibited Sex Discrimination 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 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 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 ban 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, 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 health care. For example, among subspecialty provider offices, 44% of gynecology [embedded hyperlink text (https://www.acpjournals.org/doi/10.7326/0003-4819-158-6-201303190-00003)] offices were inaccessible due to factors such as lack of equipment or transfer assistance, leaving wheelchair users unable to access abortion or maternity care. In addition, discrimination persists for many people when attempting to access infertility diagnosis, treatment, and services, including assisted reproductive technology. It is essential that the final rule explicitly name this as prohibited sex discrimination.

When the Supreme Court overturned the constitutional right to abortion in [Italics: Dobbs], it provoked covered entities to begin discriminatorily denying or erecting barriers to medications and treatments that can prevent, complicate, or end pregnancies. Covered entities are struggling to understand their compliance with rapidly changing state laws. The impacts of [Italics: Dobbs] are compounding preexisting barriers to abortions, contraception, miscarriage management, fertility care, and other sexual and reproductive health care, particularly for communities of color, people with disabilities, the LGBTQ+ community (especially transgender people [embedded hyperlink text (https://www.pbs.org/newshour/health/for-many-pregnant-trans-people-competent-medical-care-is-hard-to-find)]), and more. For example, all people, but

particularly people with disabilities, are increasingly denied or subjected to unconscionable barriers [embedded hyperlink text (https://newrepublic.com/article/167165/dobbs-pharmacists-walgreens-methotrexate)]to methotrexate, which is regularly used to treat cancer and autoimmune conditions. We expect that under [Italics: Dobbs], people with disabilities will face increasing discriminatory denials of and barriers to the vast array of medications and treatments prescribed for their conditions that happen to prevent, complicate, or end pregnancies or fertility.

RECOMMENDATION: Accordingly, we urge you to amend proposed § 92.206(b) as follows: (3) 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 [Italics: de minimis harm], including 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, [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, [Italics: 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) [Italics: 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) [Italics: 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) [Italics: Deny or limit services, or a health care professional's ability to provide services, that could 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.]

In addition, HHS must strengthen the language pertaining to providers complying with a state or local law as a justification for denying gender-affirming care, abortions, or other reproductive or sexual health care to state unequivocally that Section 1557, as federal law, preempts any such state or local law restricting access to this care.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0009
All Sections: 7.6.6, 7.6.5, 7.6.3

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:

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 "deny[ing] or limit[ing] 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 [Italics: 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, biological or otherwise, unless they can prove it "does not cause more than [Italics: de minimis harm.] And even that narrow, practically meaningless, exception does not apply if the sex-based distinction results in a denial or limitation of services.

Section 7.6.7 - Deny or limit health services for gender transition/gender-affirming care, including comments on terminology (§92.206(b)(4))

Comment Number: HHS-OS-2022-0012-DRAFT-44558-0010
All Sections: 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Equitas Health

Excerpt Text:
[Subpart C—Specific Applications to Health Programs and Activities] Equal 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 [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 [italic: 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(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 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, [italic, 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, [italic, bold: 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, [italic, bold: transgender status], or gender otherwise recorded."

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0011
All Sections: 7.6.6, 7.6.7, 7.7.4

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:
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)(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, birth-assigned, or recorded gender.

Comment Number: HHS-OS-2022-0012-DRAFT-69031-0011
All Sections: 13.2, 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Howard Brown Health

Excerpt Text:
[Italic: Whether, and if so how, the proposed rule addresses clarity and confusion over compliance requirements and rights of people to be free from discrimination on 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 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 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 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 information, facts, surveys, audits, or reports:]

The addition of intersectional discrimination is much appreciated inclusion, and we feel it would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. The concept of intersectional stigma involves examining when a patient

possesses multiple stigmatized identities. This includes co- existing health conditions such as HIV, mental illness or substance use; demographics such as race, ethnicity, gender, or sexual orientation; and behaviors or experiences such as substance use and sex work [Footnote 14: "Promoting Reductions in Intersectional Stigma (Prism) to Improve the HIV Prevention Continuum." National Institute of Mental Health, U.S. Department of Health and Human Services, www.nimh.nih.gov/funding/grant-writing-and-application-process/concept-clearances/2018/promoting- reductions-in-intersectional-stigma-prism-to-improve-the-hiv-prevention-continuum]. According to the Center for American Progress (CAP), 24% of LGBTQ people of color reported some form of negative or discriminatory treatment from a doctor or health care provider in the year prior [Footnote 15: Lindsay Mahowald, et al. "LGBTQ People of Color Encounter Heightened Discrimination." Center for American Progress, 22 Aug. 2022, www.americanprogress.org/article/lgbtq-people-color-encounter- heightened-discrimination/]. This is in comparison with 17% of white LGBTQ respondents [Footnote 16: Ibid]. In addition to the previously mentioned language revision to section 92.101(a)(1), it would strengthen the rule to include more specific examples of what constitutes intersectional discrimination. Intersectional discrimination can take many forms such as a trans person of color living with HIV being discriminated against due to their gender identity as a trans person, their race, and HIV status. Similarly, we would also recommend adding specific examples and best practices around addressing discrimination specifically against people with nonbinary gender identities.

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0013
All Sections: 7.6.7

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:
We greatly appreciate HHS's effort to make clear that covered entities may not adopt discriminatory practices that single out gender-affirming care for denial or exclusion.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0013
All Sections: 7.6.7

(b)(5)

Organization: Colors+

Excerpt Text:
[Subpart C—Specific Applications to Health Programs and Activities] Equal 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0015
All Sections: 7.6.7

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
We strongly support the inclusion of proposed Section 92.206, which requires equal program access on the basis of sex and addresses the conditions that lead to health disparities among transgender people more broadly. [Footnote 10: Fed. Reg. at 47865-68; Proposed Sec. 92.206.] This section 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.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0015
All Sections: 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Colors+

Excerpt Text:
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;

(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, 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: t ransgender 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, complicate, or end a patient's fertility or pregnancy.

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0015
All Sections: 7.6.7
(b)(5)

Organization: Concerned Women for America

Excerpt Text:
What exactly is the requirement for fully informed consent for a minor age 18 and under for specific types of "gender affirming care"? Use of puberty blockers and cross sex hormones are entirely experimental on youth. The FDA has not approved drugs for these purposes. The FDA warnings for puberty blockers include the potential of increased suicide for children taking these potent drugs. A study in The New Bioethics, "Puberty Blockers for Children – Can They Consent?" concludes that minors are not able to give informed consent required by law (see https://www.tandfonline.com/doi/full/10.1080/20502877.2022.2088048).

Parents should never be allowed to consent on behalf of a child to medical treatment that compromises the normal development of a healthy body that erodes mental, physical, and sexual capacities, including lowering IQ, compromised bone structure and sterilization. This is where "gender affirming care" has become Frankenstein medicine. How does the Department justify medical surgeries that experiment on children to fashion fake vaginas or penises, that remove healthy reproductive organs, and casually give double mastectomies to teen girls distressed by their appearance?

Transition regret is real (see for example the documentary Detransition Diaries, https://vimeo.com/ondemand/detransitiondiaries). This will only increase as more young girls seek to remove their healthy breasts under the insidious marketing of "top surgery" to "relieve distress". A study by University of Chicago researchers admits to recruiting girls ages 13-24 for "gender confirming" breast removal. News headlines reporting on the study published in [Italics: JAMA Pediatrics] boast that participants feel "less distress" three months after double mastectomies as proof benefit (https://jamanetwork.com/journals/jamapediatrics/fullarticle/2796426). Only three months? What about three years? This is the kind of junk science that your department is using to defend heinous, unthinkable practices like "gender confirming" mastectomies on teen girls and mandating without limitation under this Rule. It is among the reasons this Rule should be stopped in its tracks.

The Department must calculate the cost of irreversible damage to young people, as well as the future obligations to taxpayers and medical providers, including associated malpractice liability, when procedures like breast removal at one age could result in reconstructive surgery at another as profiled recently in [Italics: The New York Times] (9-26-22):
"Jamie, a 24-year-old college student in Maryland, was raised as a girl and began identifying as a transgender boy in the eighth grade. After being sexually assaulted and dropping out in her junior year of high school, she said she started taking testosterone. Three months later, just after she turned 18, she underwent top surgery at a private practice in Massachusetts.
For the next few years, Jamie said, she thrived. Testosterone made her feel energetic, and her anxiety dissipated. She went back to school and got certified as an emergency medical technician.
But when she was 21, her father, who was dying of Alzheimer's, no longer recognized her. She fixated on her wide hips, which she worried stood out next to her facial hair and deep voice. After a date where she had sex with a straight man, she said, she realized she had made a mistake.
"I realized I lost something about myself that I could have loved, I could have enjoyed, I could have
used to feed children," Jamie said. She said she grieved for months and contemplated suicide. This spring, after a year of fighting her insurance company to cover the procedure, she had surgery to reconstruct her breasts. She never told her original surgeon that she had changed her mind, partly because she also blamed herself. Sometimes, she said, "I still don't like being a woman."
Many surgeons say that they rarely hear about patients with regret. But it's unclear how many, like
Jamie, never inform them."

This real account should not be dismissed. What long-term research justifies the costs over the benefits of this Rule, including the related risks and actual harm to physical and mental health that are a direct result of taking puberty blockers, cross sex hormones, and surgeries? Without this analysis, these so- called nondiscrimination mandates on providers of health programs and activities cannot be justified, especially for minors.

Again, this Rule cannot ignore the growing evidence of bodily and psychological harm that use of these unapproved drugs cause, yet that is what the Rule requires of covered entities by defining any withholding of "treatment" an act of "discrimination" on the basis of "gender identity." Transition regret will only increase as a lucrative and unregulated market for "gender affirming care" increases, especially under threat of federal civil rights violation. This will force employers, health insurers, and every person enrolled in their plans to pay for the fallout of this destructive medical practice.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0015
All Sections: 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
4. In addition to section 92.101(a)(2), we reccommend 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), because even if a claimant cannot show that the care in question was on other occasions provided for other purposes, the provider could engage in a discriminatory denial of care. We recommend the following change to 92.206:

"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, [Underline: 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, [Underline: transgender status,] or gender otherwise recorded [Strikethrough: i f 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, [Underline: transgender status,] or gender otherwise recorded."

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0016
All Sections: 7.6.3, 7.6.7, 7.6.4
(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
[Subpart C—Specific Applications to Health Programs and Activities]

[Bold: Equal 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 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 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: 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 [struck through: 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 [struck through: 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, [Bold: 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, complicate, or end a patient's fertility or pregnancy.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0017
All Sections: 7.6.10, 7.6.7, 7.7.4
(b)(5)
Organization: Center for Reproductive Rights

Excerpt Text:
Denials of access to and coverage for gender-affirming care are among the most common forms of discrimination against the LGBTQI+ communities. Therefore, the NPRM's proposal 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0018
All Sections: 7.6.7

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Bold: Medical Providers]

[Italics: Forcing physicians to act against their medical judgment and insurance to pay for it]

The proposed regulations would disregard reasonable medical decisions and instead open medical professionals to extensive litigation and potential liability if they decline to participate in a transgender-identified individual's demands for a "sex change."

In 2016, the Department explained how a hypothetical gynecologist's office would be required to change its policy under the proposed regulations to "provide a medically necessary hysterectomy for a transgender man...in the same manner it provides the procedure for other individuals." [Footnote 46: Ibid., 54204.] What constitutes a "medically necessary" procedure was not defined.

However, in a preceding section of the preamble of the 2016 Proposed Rule, the Department suggested that health insurance plans could be forced to cover procedures involved in sex-reassignment surgeries provided at least one medical professional deems the procedure "medically necessary" to treat gender dysphoria.

The Department explained:

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 will evaluate the extent of the plan's coverage of hysterectomies under other circumstances. OCR will also carefully scrutinize whether the covered entity's explanation for the denial or limitation of coverage for transition-related care is legitimate and not a pretext for discrimination. [Footnote 47: Ibid., 54190.]

Without further clarification, such regulatory language could force gynecologists who perform hysterectomies for some purposes, such as to treat uterine or ovarian cancer, to perform the surgery for gender-reassignment purposes if the patient has a referral from a psychologist. Gynecologists who decline to perform hysterectomies in such cases because of conscientious

objections or because they judge them medically inappropriate could nevertheless face litigation under the proposed regulations, as would insurers that decline to pay for the procedures.

Similarly, physicians or insurers who regularly prescribe or cover hormones for some purposes, for example, to treat conditions associated with aging in men and women, could face liability under the proposed regulation if they refuse to provide or pay for such hormones for gender-transition reasons. Could psychologists or counselors who recommend, in their best medical judgment, that patients with gender dysphoria [Italics: affirm], rather than reject, their sex be liable for supposed "discrimination" under the proposed regulation?

Similarly, may an endocrinologist recommend that patients with gender dysphoria try hormone treatments that reinforce instead of counteract their sex without being subject to a lawsuit under the regulation? At the very least, the lack of clarity would likely invite expensive litigation on these and similar questions. As a result, the proposed regulation could very well subordinate professional medical judgments to the rulings of HHS bureaucrats or federal judges.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0019
All Sections: 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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/underlined: 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/underlined: 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."

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0019
All Sections: 6.2.1, 7.6.3, 7.6.7, 7.7.4, 7.6.4
(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: C. The proposed rule should include transgender status as a protected 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 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).] 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; [Underline: 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 §156.1230 by the 2020 rule. However, because the proposed language of these protections differs from the language proposed under §92, we urge the Department to here, too, adopt language in the final rule consistent with the language in §92.101 to avoid confusion and ensure consistency of implementation.

Comment Number: HHS-OS-2022-0012-DRAFT-0636-0002
All Sections: 7.6.7
(b)(5)

(b)(5)

Organization:

Excerpt Text:
" 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 profoundly evil to attempt to force people to say things they believe are lies. Alexander Solzhenitsyn pointed out how the communist regime 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."

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0002
All Sections: 7.6.3, 7.6.7, 7.7.4, 7.6.4

(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:
[Bold: TPCA recommends also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).]

Comment Number: HHS-OS-2022-0012-DRAFT-39933-0002
All Sections: 7.6.3, 7.6.7, 7.7.4, 7.6.4

(b)(5)

Organization: Minnesota Association of Community Health Centers

Excerpt Text:
[Bold: MNACHC recommends also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).

Comment Number: HHS-OS-2022-0012-DRAFT-67813-0003
All Sections: 7.6.7, 5.4.5.2

(b)(5)

Organization: Pennsylvania Health Insurance Exchange Authority d/b/a Pennie

Excerpt Text:
[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 benefits 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 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 like hormone therapy, gender reassignment surgeries, and behavioral health care.

Comment Number: HHS-OS-2022-0012-DRAFT-43609-0003
All Sections: 7.6.5, 7.6.3, 7.6.7, 7.6.4

(b)(5)

Organization: Endocrine Society

Excerpt Text:
Impact on Access to Care

If 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0003
All Sections: 6.2.6, 7.6.3, 7.6.7, 7.7.4, 7.6.4, 6.2.5
(b)(5)

Organization: Health Care For All

Excerpt Text:
Protections against Discrimination on Basis of Sex

Sex discrimination disproportionately impacts women of color, LGBTQI+ 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 improper 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 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 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 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, therefore, recommend also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0034
All Sections: 7.6.3, 7.6.7, 7.6.4
(b)(5)

(b)(5)

Organization: Center for American Progress

Excerpt Text:

XI. Equal Program Access of the Basis of Sex (§ 92.206)

We strongly support the inclusion of this section, which will help to address the many forms of harmful discrimination described above. Below we address specific provisions related to equal access for LGBTQI+ communities and access to gender-affirming care, as well as the need to address critical gaps in the forms of prohibited sex discrimination enumerated.

a. Equal Access for LGBTQI+ Communities and Access to Gender-Affirming Care

We support the Proposed Rule requirements that covered entities ensure equal access to their health programs and activities for LGBTQI+ people and that it enumerates specific discriminatory actions that are prohibited on the basis of sex, including gender identity, sex assigned at birth, or gender recorded in the person's medical record. CAP's nationally representative survey data highlight the importance of these protections. For example, 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 [Footnote 72: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/].

The protections outlined in this section may also help to address the many challenges that transgender and nonbinary people encounter when seeking access to gender-affirming care from providers. According to CAP's data, in the past year 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 refusal by a health care provider [Footnote 73: Ibid]. These kinds of refusals can include a range of experiences. For example, in the past year [Footnote 74: Ibid]:

? 21 percent of transgender or nonbinary respondents, including 28 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to provide reproductive or sexual health services due to their gender identity.

? 20 percent of transgender or nonbinary respondents, including 27 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to document evidence of gender dysphoria or readiness to receive gender-affirming care.

? 19 percent of transgender or nonbinary respondents, including 27 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to assist the respondent in forming a family due to the respondent's actual or perceived gender identity.

? 15 percent of transgender or nonbinary respondents, including 22 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to provide gender-affirming care—for instance, hormone therapy, surgery, puberty delay medications, or mental health services.

? 10 percent of transgender or nonbinary respondents, including 17 percent of transgender or nonbinary respondents of color, reported that a health care provider refused to see them because of their actual or perceived gender identity.

Importantly, this section clarifies that although providers may exercise clinical judgment when determining whether a specific 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. Notably, 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 § 92.101(a)(2) above, we suggest that "transgender status" be added to § 92.206(b)(1), (b)(2) and (b)(4). We also believe that § (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(b) 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;

(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, underline: 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, [bold, underline: transgender status], or gender otherwise recorded."

As explained in more detail below, we also believe that § 92.206(b)(4) should be amended to include "fertility care or any health services."

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0041
All Sections: 7.6.7

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
- [Bold: Ethical basis for determining care:] HHS has arbitrarily decided that 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 impair 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 facilitate an individual's gender-identity-based request for medical or surgical interventions. This amounts to giving the person experiencing "gender dysphoria" or 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 nondiscriminatory 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 decision to pursue a different "gender-affirming" pathway (social transition). HHS 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 (or 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." 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 their challenged action or practice." [Footnote 102: 87 Fed. Reg. 47867.]

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0005
All Sections: 7.6.7

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Italics: Unsettled questions about gender dysphoria]

Serious concerns raised by 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 unaccountable agency action and then coercively impose that judgment on all medical professionals.

Paul McHugh, MD, 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 psychological condition. They had much the same problems with relationships, work, and emotions as before. The hope that they would emerge now from their emotional difficulties to flourish psychologically had not been fulfilled. We saw the results as demonstrating that just as these men enjoyed cross-dressing as women before the operation, so they enjoyed cross-living after it. But they were no better in their psychological integration or any easier to live with. [Footnote 14: Paul R. McHugh, "Surgical Sex," First Things, November 2004, http://www.firstthings.com/article/2004/11/surgical-sex]

Seeing little to no positive impact on the psychological health of transgender adults, McHugh could not justify continuing to surgically alter or remove healthy and fully functioning organs at the patients' requests. McHugh concluded that Johns Hopkins's practice of sex-reassignment surgeries, instead of helping patients, "was fundamentally cooperating with a mental illness" and the hospital stopped prescribing and performing the procedure. [Footnote 15: Ibid.]

Concurring with the observations made at Johns Hopkins, a 2011 long-term study of individuals who underwent sex-reassignment surgery documented sustained mental hardships of transgender-identifying individuals. Conducted over a 30-year period in Sweden, the study found that 10 years to 30 years after sex-reassignment surgery "the most striking result was the high

mortality rate." This was due in significant part to post-operative transitioned individuals having suicide rates nearly 20 times higher than their peers. [Footnote 16: Cecilia Dhejne et al., "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," PLOS ONE, Vol. 6, No. 2 (February 2011), http://www.plosone.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pone.0016885&representation=PDF (accessed October 27, 2015).]

McHugh addressed the question of proper treatment in the context of civil rights:

[P]olicy makers and the media are doing no favors either to the public or the transgendered by treating their confusions as a right in need of defending rather than as a mental disorder that deserves understanding, treatment and prevention.

Claiming that this is [a] civil-rights matter and encouraging surgical intervention is in reality to collaborate with and promote a mental disorder. [Footnote 17: Paul McHugh, "Transgender Surgery Isn't the Solution," The Wall Street Journal, June 12, 2014, http://www.wsj.com/articles/paul-mchugh-transgender-surgery-isnt-the-solution-1402615120]

The proposed version of the 2016 Rule made no mention of the professionals who argue that there are serious medical and psychological concerns surrounding sex-reassignment surgery and gender-transition treatments. [Footnote 18: 80 FR 54189–54190. Indeed, the only medical evidence cited in the preamble to the proposed regulation was a citation to an HHS Departmental Appeals Board decision to invalidate Medicare's previous exclusion of sex reassignment coverage, which in turn cites the opinion of only one medical group that advances transgender surgeries.] There are now even more prominent critics of the strict "gender-affirming approach. Thus, it would be negligent for a rule issued in 2022 to ignore these scientifically grounded criticisms.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0052
All Sections: 7.6.7

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
This is especially troubling because the HHS analysis ["Equal Program Access on the Basis of Sex (§ 92.206)] appears to anticipate including access to gender-affirming care and other undefined "services" [Footnote 132: 87 Fed. Reg. 47865.] 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0053
All Sections: 7.6.7

(b)(5)

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:

[Bold: 4. The Proposed Rule uses nondiscrimination regulations to impose a 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 presumptive 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 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.139.]

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, Transgender, and Gender-Nonconforming People, pp. 68–71 (7th Version 2012) [hereinafter WPATH Standards], https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English2012.pdf?_t=1613669341 (last visited Feb. 7, 2022)).]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0054
All Sections: 7.6.7

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
However, HHS's arbitrary decision to use the Proposed Rule as a mechanism 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0007
All Sections: 7.6.7

(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0007
All Sections: 7.6.6, 7.6.1, 7.6.7

(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:
II. [Bold: Addressing Critical Gaps in the Forms of Prohibited Sex Discrimination 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 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 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 ban 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, 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 health care. For example, among subspecialty provider offices, 44% of gynecology [embedded hyperlink text (https://www.acpjournals.org/doi/10.7326/0003-4819-158-6-201303190-00003)] offices were inaccessible due to factors such as lack of equipment or transfer assistance, leaving wheelchair users unable to access abortion or maternity care. In addition, discrimination persists for many people when attempting to access infertility diagnosis, treatment, and services, including assisted reproductive technology. It is essential that the final rule explicitly name this as prohibited sex discrimination.

When the Supreme Court overturned the constitutional right to abortion in [Italics: Dobbs], it provoked covered entities to begin discriminatorily denying or erecting barriers to medications and treatments that can prevent, complicate, or end pregnancies. Covered entities are struggling to understand their compliance with rapidly changing state laws. The impacts of [Italics: Dobbs] are compounding preexisting barriers to abortions, contraception, miscarriage management, fertility care, and other sexual and reproductive health care, particularly for communities of color, people with disabilities, the LGBTQ+ community (especially transgender people [embedded hyperlink text (https://www.pbs.org/newshour/health/for-many-pregnant-trans-people-competent-medical-care-is-hard-to-find)]), and more. For example, all people, but particularly people with disabilities, are increasingly denied or subjected to unconscionable barriers [embedded hyperlink text (https://newrepublic.com/article/167165/dobbs-pharmacists-walgreens-methotrexate)]to methotrexate, which is regularly used to treat cancer and autoimmune conditions. We expect that under [Italics: Dobbs], people with disabilities will face increasing discriminatory denials of and barriers to the vast array of medications and treatments prescribed for their conditions that happen to prevent, complicate, or end pregnancies or fertility.

RECOMMENDATION: Accordingly, we urge you to amend proposed § 92.206(b) as follows:
(3) 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 [Italics: de minimis harm], including 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, [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, [Italics: 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) [Italics: 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) [Italics: 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) [Italics: Deny or limit services, or a health care professional's ability to provide services, that could 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.]

In addition, HHS must strengthen the language pertaining to providers complying with a state or local law as a justification for denying gender-affirming care, abortions, or other reproductive or sexual health care to state unequivocally that Section 1557, as federal law, preempts any such state or local law restricting access to this care.

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0007
All Sections: 7.6.2, 7.6.7

(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:
[Bold: Specific Applications to Health Programs and Activities] - [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.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0007
All Sections: 7.6.7
(b)(5)
Organization: The Heritage Foundation

Excerpt Text:
[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 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 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 violates 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 failing to cover talk therapy coverage, is an equal rights anti-discrimination violation. Additionally, to the extent coverage of transitioning treatments is required or compelled, Section 1557 should provide for detransitioners.

Comment Number: HHS-OS-2022-0012-DRAFT-66854-0007
All Sections: 7.6.5, 7.6.7
(b)(5)
Organization: Wisconsin Primary Health Care Association

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-39933-0008
All Sections: 7.6.7

(b)(5)

Organization: Minnesota Association of Community Health Centers

Excerpt Text:
Specific Applications to Health Programs and Activities] – [Italics: Equal Program Access on the Basis of Sex (§92.206)]

[Bold: MNACHC 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0008
All Sections: 7.6.7

(b)(5)

Organization: Concerned Women for America

Excerpt Text:
[Underline: Imposes radical, sweeping, unlimited requirements for "gender affirming care"]

The Rule admits that no limitation on the definition of "gender identity" is possible, which makes it impossible to even define the limits of "gender affirming care."
Relevant clinical guidelines acknowledge that not all individuals for whom such care is clinically appropriate will specifically identify as transgender, nor will all gender-affirming care specifically be related to transition from one binary gender to another. For example, people seeking gender-affirming care may refer to their gender identity using terms other than "transgender," such as "nonbinary," "gender nonconforming," "genderqueer," or "genderfluid."

The Rule places all these so-called "identities" in quotes - there is no attempt to isolate the meaning of any of these terms. What is the definition of transgender or queer or nonbinary or genderqueer? What is the difference between them? How is any covered entity expected to understand clinically appropriate care for a fabricated and evolving class of identities for which this Rule requires coverage as a matter of sex discrimination?

The only logical conclusion is that anything goes for a claim and entities are expected to comply. It's simply a matter of claiming "gender fill in the blank." This mandate is preposterous as a matter of health care and federal rulemaking, especially in a rulemaking intended to clarify the meaning and obligations under the nondiscrimination provisions of federal health care programs, not make them entirely arbitrary and capricious with unbounded obligations that cannot be equally or consistently enforced.

What is the specific definition of "gender affirming care"? The Rule cites additional concepts of "gender- affirming health services" or "transition-related care" but these do not define with any clarity the meaning or scope of this mandate. Does such incorporate behavioral health care services and mental health counseling that assist in realigning an individual's gender perception with his/her biological sex? If so, why is this not clearly stated in the Rule? If not, why not, knowing that this alignment will reduce costs and negate the required life-long medical treatment and documented long-term health detriments of drugs and surgeries required to refashion one's body to resemble one's personal perception of gender?

What medical diagnosis is required in order to qualify for procedures deemed "gender affirming care"? Is it gender dysphoria? This must be explained fully. What specific treatments and for what ages are these treatments and procedures warranted? What scientific method-based research is the basis for these determinations? What long-term evidence that includes desistance justifies the mandate for "gender affirming care"? The Department must answer all the above questions. Without clear, definitive, objective criteria, no recipient or provider can be expected to operate under the regime mandated by this Rule, and it is, therefore, arbitrary and capricious.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0009
All Sections: 7.6.3, 7.6.7, 7.6.4
(b)(5)
Organization: 38 Members of Congress

Excerpt Text:
2. [Bold: Adopting clearer language regarding denial of gender-affirming care and 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. 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 cannot 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, [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."

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0009
All Sections: 15.2, 7.6.3, 7.6.7
(b)(5)

Organization: Concerned Women for America

Excerpt Text:
Section 92.206 and 92.207 of the Rule require that a covered entity must not 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, 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, refashion 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 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 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 nondiscrimination-based care cannot go one way. This Rule must obligate covered entities for any health service or procedure that helps 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 that refashion a body to desired appearances or it would be discriminatory.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0009
All Sections: 7.6.7
(b)(5)
Organization: Human Rights Campaign

Excerpt Text:
[Italics: B. Providing for Equal Program Access on the Basis of Sex Ensures Necessary Protections for Transgender and Non-Binary People]

Inclusion of the Equal Program Access on the Basis of Sex is necessary to ensure that transgender and non-binary people receive full protection of the law. This section will help to

address the myriad forms of harmful discrimination described below. 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 as a federal law Section 1557 preempts any such state or local law restricting access to this care.

Section 7.6.8 - OCR framework for analyzing complaints; legitimate, nondiscriminatory reason; pretext

No comments are associated with this issue

Section 7.6.9 - Bona-fide treatment decision; medical necessity/clinically appropriate

No comments are associated with this issue

Section 7.6.10 - Legitimate, nondiscriminatory reason/clinically appropriate related to §92.206(c)

Comment Number: HHS-OS-2022-0012-DRAFT-66818-0001
All Sections: 7.6.10
(b)(5)
Organization: NCPA

Excerpt Text:
[Bold: Equal Program Access on the Basis of Sex (§ 92.206)]
In the proposed rule, HHS OCR proposes to include a section clarifying covered entities' obligation to ensure equal access to their health programs and activities without discrimination on the basis of sex, including pregnancy, sexual orientation, gender identity, and sex characteristics. As stated in the proposed rule, this provision primarily relates to covered entities that are directly engaged in the provision of health care services. The proposed rule explicitly includes pharmacies as covered entities.

The proposed rule further states that if the HHS OCR Director finds that a covered entity has discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of Section 1557 or this part, such covered entity must take such remedial action as the Director may require to overcome the effects of the discrimination under Section 92.6 of the proposed rule. Further, Section 92.301 of the proposed rule states that 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, and the Age Discrimination Act of 1975 shall apply for purposes of Section 1557 as implemented by this propose rule.

[Bold: NCPA asks HHS OCR to provide assurances that pharmacists can use reasonable clinical judgement to treat patients within their scope of practice, and not be subject to additional administrative burden and legal liability.]

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0011
All Sections: 7.6.10

(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:
Recommendation 3:

BCBSA recommends that the Final Rule clarify that programs 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. BCBSA and its Plans strongly agree with HHS that it is critical to progress beyond consideration of broad demographic categories in our 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 health concern, or targeted quality programs and investment of resources to ensure accessibility of certain services in a particular geographical area or for a population subgroup. We request that HHS clarify in the Final Rule that such actions taken to reduce health disparities will not violate the nondiscrimination requirements.

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0012
All Sections: 7.6.10, 7.7.6

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:
[Bold: 1. HHS should clarify the distinction between sex-based discrimination and nondiscriminatory 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 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 (or 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; that the use of the phrase "legitimate, nondiscriminatory reason" in these sections should not be construed in any way to limit the method of proof for any Section 1557 claim to the [Italics: McDonnell-Douglas] burden-shifting framework; and that this method cannot be used to defend an express sex-based classification that causes injury.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0017
All Sections: 7.6.10, 7.6.7, 7.7.4

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
Denials of access to and coverage for gender-affirming care are among the most common forms of discrimination against the LGBTQI+ communities. Therefore, the NPRM's proposal 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0019
All Sections: 5.2.2, 5.2.3, 7.6.10

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Bold: Procedural Concerns]

The department considers how its proposed 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 oversight, choice, or due to a state law. [Footnote 48: Morrison, "HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate in Health Care." https://fedsoc.org/commentary/fedsoc-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 133,000 health care facilities;
- "[A]lmost 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 a through a Medicaid managed care contract) or indirectly (through subsidies provided to its customers as is the case with Medicare Advantage and exchange plans). However, the 2020 Rule narrowed the scope of application to insurers. [Footnote 51: Ibid., 54174–54175 and 54195.]

Because the federal government now extensively subsidizes both medical care and health insurance coverage it would be nearly impossible for medical professionals to work free from these regulations.

Comment Number: HHS-OS-2022-0012-DRAFT-43609-0005
All Sections: 7.6.10

(b)(5)

Organization: Endocrine Society

Excerpt Text:
Additionally, we support the changes that ensure that providers inquiries about a patient's medical history, health status, or physical traits when providing care be limited to their

relationship to the underlying condition and not asked in a manner that is hostile or disregards patient privacy.

Comment Number: HHS-OS-2022-0012-DRAFT-52236-0005
All Sections: 7.6.10

(b)(5)

Organization: Arkansas Department of Human Services

Excerpt Text:
The proposed rules will harm Arkansas's most vulnerable residents

The 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. If a state sets public policy through the legislative acts 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 in federal healthcare funding that protects its most vulnerable residents. This is an untenable situation that attempts to coerce 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0050
All Sections: 7.6.10

(b)(5)

Organization: Justice in Aging

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0008
All Sections: 7.6.10

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
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.

Section 7.6.11 - Provider's determination GAC care is medically contraindicated

No comments are associated with this issue

Section 7.6.12 - Disparate impact

Comment Number: HHS-OS-2022-0012-DRAFT-43142-0004
All Sections: 7.6.12
(b)(5)
Organization: American Psychological Association

Excerpt Text:
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 chronic pain, 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].

Section 7.6.13 - Case law discussion

Comment Number: HHS-OS-2022-0012-DRAFT-52236-0006
All Sections: 7.6.13

(b)(5)

Organization: Arkansas Department of Human Services

Excerpt Text:
The proposed rules can be compared to the Department's actions at issue in Burwell v. Hobby Lohby, 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.

Section 7.7 - Nondiscrimination in Health Insurance and Other Health-Related Coverage (§92.207)

No comments are associated with this issue

Section 7.7.1 - Generally

Comment Number: HHS-OS-2022-0012-DRAFT-39789-0001
All Sections: 7.7.3, 10.1, 7.7.1

(b)(5)

Organization: American Federation of State, County and Municipal Employees

Excerpt Text:
Scope and Application

Section 1557 of the ACA establishes protections against discrimination across a wide swath of health programs and activities, including those that receive federal funding. The proposed rule extends the reach of nondiscrimination protections to match the expansive intent of the provisions set forth in the statute.

We agree that the nondiscrimination protections should be extended to all programs and activities conducted by HHS. In particular, we agree with the proposal to include Medicare Part B in the definition of federal financial assistance for the purposes of determining the application of nondiscrimination protections. This provision will eliminate any potential confusion as to the

application of nondiscrimination protections and ensure that they are applied equally, regardless of whether an individual enrolls in traditional Medicare or a Medicare Advantage plan. Additionally, we agree that insurers who take federal financial assistance should be subject to the nondiscrimination protections across all their activities. This will limit, to the greatest extent possible, insurers' adoption of discriminatory plan benefit designs.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0011
All Sections: 7.10.1, 7.7.1, 6.1

(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
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 antidiscrimination 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0013
All Sections: 7.7.1

(b)(5)

Organization: The Century Foundation

Excerpt Text:
Similarly, the finalized rule should amend section 92.207(b) 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; or. . .

- [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 restriction 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0013
All Sections: 7.7.3, 7.7.2, 7.7.1, 6.1

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:

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)(2).

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0013
All Sections: 7.7.3, 7.7.2, 7.7.1, 6.1, 7.7.4

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:

2. In section 92.101(a)(1) we recommend adopting the following change: "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, [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), (b)(2), and (b)(3). Utilizing this language will strengthen the rule by clarifying that discrimination motivated by multiple characteristics is prohibited.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0014
All Sections: 7.7.1, 6.1
(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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 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/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).

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0017
All Sections: 7.7.1
(b)(5)

Organization: Colors+

Excerpt Text:
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 their 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0018
All Sections: 6.2.1, 7.7.3, 7.7.2, 7.7.1, 6.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:
VII. Discrimination Prohibited (§ 92.101)

In the preamble of the Proposed Rule, the Department rightly notes that people may experience intersectional discrimination in health care when they are discriminated against because of the combination of two or more protected bases. This can include individuals who experience heath care discrimination stemming from 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), ableism, or ageism. For instance, women with physical disabilities often report a range of barriers to accessing maternity and reproductive care like a lack of provider training – and this can be heightened for disabled women of color [Footnote 26: Mariëlle Heideveld-Gerritsen and others, "Maternity care experiences of women with physical disabilities: A systematic review," Midwifery 96 (2021), available at https://www.sciencedirect.com/science/article/pii/S0266613821000176].

We believe that the proposed rule would be strengthened by including more explicit references to intersectional discrimination within the regulatory text. As such, we propose the following change to § 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, [strikethrough, bold: 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 §§ 92.207(a), (b)(1), and (b)(2).

Comment Number: HHS-OS-2022-0012-1003-0002
All Sections: 1.1, 7.7.3, 7.7.2, 7.7.1

(b)(5)

Organization: URAC

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0021
All Sections: 7.10.1, 7.7.1, 4.3.1.1
(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0024
All Sections: 6.2.4, 7.7.1, 7.6.1
(b)(5)

Organization: Center for American Progress

Excerpt Text:
ii. The Final Rule must explicitly name discrimination on the basis of termination of pregnancy as part of sex discrimination.

While the Department acknowledges that discrimination based on "pregnancy or related conditions" includes protections against discrimination based on termination of pregnancy, the Department does not make that explicit in the regulatory text. Just as the Department should standardize its definition of "pregnancy or related conditions" throughout the regulatory text, it must also make clear that "termination of pregnancy" is specifically named in that definition. There are several places where the Department should clarify and further amend the Proposed Rule to make clear these and other reproductive and sexual health-related protections, including § 92.101(a)(2), and § 92.206 and § 92.207, and in a separate stand-alone provision on pregnancy or related conditions.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0027
All Sections: 7.8.1, 7.7.1, 7.6.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:

iii. The Department should make clear the scope of Section 1557's protections against discrimination on the basis of pregnancy or related conditions, including termination of pregnancy.

In the Proposed Rule's discussion of § 92.208, the Department asks whether there should be a provision to "specifically address discrimination on the basis of pregnancy-related conditions" [Footnote 47: Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824, 47878 (proposed August 4, 2022) (to be codified at 45 C.F.R. pt. 92)]. We are concerned that including such a provision under § 92.208 could cause policies that are biased against people seeking abortions. In our comments below, we recommend that HHS add new provisions on discrimination related to pregnancy or related conditions, including termination of pregnancy, under § 92.206 and § 92.207 instead. Further, we would support the Department's decision to include an additional provision elsewhere in the Final Rule to "specifically address discrimination on the basis of pregnancy-related conditions" and the broad scope of protected services that fall under this form of care.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0029
All Sections: 4.3.1.2.1, 7.7.1, 7.6.1, 4.3.1.2.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:

iv. The Final Rule must enumerate specific forms of discrimination related to pregnancy or other related conditions, including termination of pregnancy.

Throughout the Final Rule, we urge the Department to specifically name and include – both in the text and preamble, including the language specified in § 92.206 and § 92.207 – examples of discrimination related to the full range of reproductive health care and type of services. The Final Rule must name the full range of reproductive health care protected from discrimination. Section 1557's protection against sex discrimination includes protections against discrimination relating to all reproductive health decisions. Specifically, the Final Rule must explicitly name that Section 1557 reaches discrimination related to fertility care, contraception, mistreatment in maternity care, and sex discrimination in access to medications and treatments for disabilities and emergency medical conditions.

With respect to discrimination against people seeking or accessing fertility treatment, it is essential that the Final Rule explicitly name that Section 1557's protects against discrimination on this basis because discrimination persists in the context of accessing infertility diagnosis, treatment, and services including assisted reproductive technology. Sex discrimination in the context of fertility care can take many forms. Some insurance companies refuse to cover certain types of care that are traditionally used by women (e.g., in vitro fertilization (IVF)) [Footnote 48: Gabriela Weigel et al., Kaiser Family Foundation, Coverage and Use of Fertility Services in the U.S. (2020), https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/. These benefit exclusions disproportionately affect women of color due to racial disparities in the rate of certain diseases that may cause infertility. See Jennifer O'Hara, Mayo Clinic Q&A Podcast: The Link Between Racial Disparities and Cervical Cancer, Mayo Clinic News Network (Jan. 10, 2022), https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-qa-podcast-the-link-between-racial-disparities-and-cervical-cancer/#:~:text=Hispanic%20women%20have%20the%20highest,Race%20is%20a%20social%20construct(describing that Hispanic women have the highest incidence rate of cervical cancer, followed by non-Hispanic Black women)]. Even in those states that do require insurance providers to provide IVF, some insurance providers require that patients use their "spouse's sperm" to fertilize their eggs to be eligible for IVF insurance coverage, discriminating against patients based on their marital status, sexual orientation, and gender identity [Footnote 49: E.g., Haw. Rev. Stat. § 431:10A-116.5 (1987); Ark. Code R. 054.00.1–5(B) (1991). Furthermore, Texas, which only requires insurance providers to offer IVF insurance, also includes this same eligibility requirement. See Tex. Ins. Code Ann. § 1366.005]. In a recent example of discrimination on the basis of sexual orientation and marital status, OSF HealthCare, a self-insured Catholic hospital system with facilities in Illinois and Michigan, recently adopted an insurance policy for its employees that limits IVF coverage to "married couple[s] of opposite sex spouses" [Footnote 50: Shira Stein, Hospital Chain Blocks Fertility Coverage for Its LGBTQ Employees, Bloomberg L. (July 18, 2022), https://news.bloomberglaw.com/health-law-and-business/hospital-chain-blocks-fertility-coverage-for-its-lgbt-employees https://www.bgov.com/core/news_articles/RF7N4HT0G1LX].

Additionally, public and private insurers often discriminate against patients based on sex by requiring that they meet outdated and heteronormative definitions of infertility before providing IVF coverage. For example, relying on a 2013 definition of infertility that has since been rescinded by the American Society of Reproductive Medicine, many insurer require simply that patients in different-sex relationships attest that they have unsuccessfully tried to become pregnant by having unprotected sex for six months or a year, depending on their age, but require same-sex couples and single individuals to undergo six to twelve unsuccessful cycles of intrauterine insemination (IUI) at their own expense before deeming them eligible for IVF coverage [Footnote 51: Compare Practice Committee of the American Society for Reproductive Medicine, Definitions of Infertility and Recurrent Pregnancy Loss: A Committee Opinion, 99 Fertility & Sterility 63, 63 (2013) (defining infertility as "a disease defined by failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination," with Practice Committee of the American Society for Reproductive Medicine, Definitions of Infertility and Recurrent Pregnancy Loss: A Committee Opinion, 113 Fertility & Sterility 533, 533 (2020) (defining infertility as "a disease historically

defined by the failure to achieve a successful pregnancy after 12 months or more of regular, unprotected sexual intercourse or due to an impairment of a person's capacity to reproduce either as an individual or with her/his partner")]. These patients are thereby forced to absorb exorbitant costs out of pocket and are delayed or denied access to IVF coverage benefits solely due to their sexual orientation [Footnote 52: See Goidel complaint, supra note TK, at ¶ 8 (describing that a patient was forced to pay out of pocket $45,000 to achieve a successful pregnancy after she was denied coverage for the benefits in her plan because, as a queer woman, she could not attest to engaging in heterosexual sex)].

Studies have found that physicians may consciously or unconsciously block patients from accessing fertility treatment by making assumptions or possessing biases about who can or deserves to be a parent and who wants or deserves fertility treatment. For example, women of color "have reported 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 53: The Ethics Committee of the American Society for Reproductive Medicine, Disparities in Access to Effective Treatment for Infertility in the United States: An Ethics Committee Opinion, 116 FERTILITY & STERILITY 54, 57 (2021) (discussing the various inequitable barriers to fertility care), 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]. We urge the Department to clarify in the regulatory text that such discrimination in health care, including in the context of seeking or accessing fertility care, is impermissible discrimination on the basis of sex under Section 1557, and to include examples of a broad range of impermissible sex discrimination in the context of seeking or accessing fertility care in the Final Rule.

With respect to contraception, the Final Rule must make clear that Section 1557 prohibits discrimination against those seeking contraception or specific types of contraception. The Final Rule also should include the examples included in the guidance that the Department issued on July 13, 2022, to retail pharmacies, responding to incidents occurring after Dobbs, and explicit clarification of other types of discrimination against those seeking contraception [Footnote 54: U.S. DEPT. OF HEALTH & HUM. SERVS., GUIDANCE TO NATION'S RETAIL PHARMACIES: OBLIGATIONS UNDER FED. C.R. L. TO ENSURE ACCESS TO COMPREHENSIVE REPRODUCTIVE HEALTH CARE SERVS. (Jul. 13, 2022), https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html#:~:text=Pharmacies%2C%20therefore%2C%20may%20not%20discriminate,medications%20and%20how%20to%20take]. Additional examples could include: a state program that otherwise provides coverage of contraceptives but excludes a specific contraceptive because of an assertion that the contraception causes an abortion or a provider network that would only include facilities that refuse to perform female sterilization procedures [Footnote 55: In addition to violating section 1557, a state program in this instance may also be violating the ACA contraceptive coverage requirement. The Department has already made clear that the ACA contraceptive coverage requirement is a floor for coverage. Should a state restriction on contraceptives make compliance with the ACA's contraceptive coverage requirement impossible, the federal government will step in to enforce the ACA. Dep'ts of Lab., Health &

Hum. Serv., & Treasury, FAQs About Affordable Care Act Implementation Part 54 (July 28, 2022) at 7, https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf]. The Department must also specify that items or services related to contraception are also protected [Footnote 56: In the context of insurance coverage requirements, the Department already recognizes that any item or service necessary to access contraception is part of contraception. Dep'ts of Lab., Health & Hum. Serv., & Treasury, supra note 22, at 10]. Additional medications or services are often needed to facilitate use of contraception, such as anesthetics for insertion of long-acting reversible contraceptives. For example, a pharmacy refusal to provide misoprostol to a patient who was prescribed it in order to make IUD insertion easier could be a Section 1557 violation.

Additionally, the Final Rule must make clear that Section 1557 prohibits discrimination where a patient is denied medications or treatments for care unrelated to abortion because the medicine is also used for abortion care. Dobbs emboldened covered entities to start denying medications and treatments for chronic health conditions and other disabilities that could prevent, complicate, or end pregnancies or fertility. As the Department has already recognized in its July 13, 2022 guidance, Section 1557 prohibits discrimination in the form of refusing to fill prescriptions for medications that are considered "abortifacients" but may be prescribed to treat other health conditions, such as cancer, arthritis, and ulcers [Footnote 57: U.S. DEPT. OF HEALTH & HUM. SERVS., supra note 21]. This form of discrimination has occurred in states where abortion is now banned [Footnote 58: Katie Shepherd & Frances Stead Sellers, Abortion Bans Complicate Access to Drugs for Cancer, Arthritis, Even Ulcers, WASH POST (Aug. 8, 2022), https://www.washingtonpost.com/health/2022/08/08/abortion-bans-methotrexate-mifepristone-rheumatoid-arthritis/]. Similarly, the drug mifepristone is currently being tested for treating breast cancer, brain cancer, prostate cancer, alcoholism, post-traumatic stress disorder, and depression, among other conditions [Footnote 59: Caroline Hopkins, The 'Abortion Pill' May Treat Dozens of Diseases, but Roe Reversal Might Upend Research, ABC NEWS (June 25, 2022), https://www.nbcnews.com/health/health-news/abortion-pill-may-treat-dozens-diseases-roe-reversal-might-upend-resea-rcna34812]. It also is approved for termination of pregnancies. Following the Dobbs decision, patients who could be pregnant are at risk when seeking mifepristone for purposes besides abortion. Patients being refused any form of health care—because of stereotyping that the patient could be pregnant and having an abortion—falls under Section 1557's protections. To this end, the Final Rule must include language in § 92.206 and § 92.207 addressing the denial of medications or treatments that could prevent, complicate, or end pregnancies yet are prescribed for purposes beyond sexual and reproductive health care, including treatment for severe chronic conditions [Footnote 60: See U.S. DEPT. OF HEALTH & HUM. SERVS., supra note 21; see also Shepherd & Sellers, supra note 25].

The Final Rule should make clear that Section 1557 protects against discriminatory refusals to provide information or referrals about abortion and other reproductive health care. Section 1557 prohibits refusing to provide information, resources, or referrals about abortion care and other reproductive health care. Such discriminatory refusal of care constitutes discrimination based on pregnancy or related conditions. For example, many Indigenous individuals rely on Indian Health Service for health care, but IHS facilities often fail to provide information to patients about abortion care or counseling about pregnancy options [Footnote 61: Ex. F Decl. of Rachael Lorenzo 15, Nov. 18, 2020, 1:20-cv-11297-PBS]. These are forms of sex-based discrimination

that Section 1557 protects against. Providers who operate in states that ban abortion may also be emboldened to deny information about abortion that a patient can receive outside of their state, even if such information is not unlawful to provide. It is critical for the Final Rule to make clear to providers, hospitals, and other entities subject to Section 1557 requirements their responsibility to continue providing information and referrals relating to a pregnancy, including termination of pregnancy.

The Final Rule should also make clear that Section 1557 protects against discrimination based on a person's actual or perceived decision relating to abortion care. In the preamble discussion of § 92.206, the Department should include examples making clear that it is discriminatory to refuse to provide health care because of a patient's actual or perceived abortion care history, because doing so is discrimination based on sex. Patient health suffers when a provider's own biases against abortion are substituted for necessary medical care. Not only is the patient denied the immediate care they need, but also the patient's trust in the health care system erodes when they do not feel safe with their providers and may even fear consequences for disclosing their medical history. This is precisely the discrimination that Section 1557 was meant to address.

Additionally, the Final Rule should make clear that Section 1557 prohibits discrimination related to discrimination in maternity care. Pregnant Black, Indigenous, Latina/x, 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 mistreatment during labor and delivery [Footnote 62: Saraswathi Vedam, et al. The Giving Voice to Mothers study: inequity and mistreatment during pregnancy and childbirth in the United States. Reprod Health 16, 77 (2019). https://doi.org/10.1186/s12978-019-0729-2]. For example, in a 2018 California survey, Black, Asian, and Pacific Islander women who gave birth in hospitals reported higher rates of unfair treatment, harsh language, and rough handling than white women [Footnote 63: Carol Sakala et al., National Partnership for Women & Families, Listening to Mothers in California: A Population-Based Survey of Women's Childbearing Experiences, Full Survey Report, 64-65 (Sept. 2018) https://www.chcf.org/wp-content/uploads/2018/09/ListeningMothersCAFullSurveyReport2018.pdf]. Among subspecialty provider offices, 44 percent of gynecology offices were inaccessible due to factors such as inaccessible equipment and lack of transfer assistance, leaving wheelchair users unable to access abortion or maternal care [Footnote 64: Tara Lagu, MD, MPH, et al. Access to Subspecialty Care for Patients With Mobility Impairment, Annals of Internal Medicine, (2013). https://www.acpjournals.org/doi/10.7326/0003-4819-158-6-201303190-00003]. Section 1557 implementing regulations must address this discrimination.

Comment Number: HHS-OS-2022-0012-DRAFT-66192-0003
All Sections: 7.7.2, 7.7.1

(b)(5)

Organization: Kidney Care Partners

Excerpt Text:
Providing this clarification is extremely important because State-based Marketplaces have approved plans that discriminate against individuals with kidney failure who require dialysis treatments. KCP has raised concerns in previous years about plans that adopt policies that result in individuals being forced to enroll in Medicare after a diagnosis of kidney failure. Some plans raise co-insurance costs on services that only dialysis patients require. Other plans refuse to accept charitable assistance for individuals who require dialysis, even though the plans continue to accept it for patients with other chronic conditions. More recently, our members report that some plans apply "utilization management techniques" that seek to justify denying or restricting medically necessary services that only dialysis patients receive. We have even seen some plans try to apply prior authorization for dialysis treatments themselves.
These are only a few examples of the problems individuals with kidney failure who require dialysis treatments have shared. We ask that OCR/HHS in the final rule make clear that any of these policies when applied in a manner that directly or indirectly result in a restriction of access to medically necessary dialysis services or result in an enrollee losing primary coverage with their plan constitute discrimination and are inconsistent with the requirements of Section 1557.

It is also important that the Sections 1557 protections apply to all insurers. We ask that OCR/HHS not finalize the proposed exemption for employer liability and clarify that the protections apply to group health plans, including self-funded plans.

Individuals with kidney failure who rely upon dialysis treatments should be allowed to retain their choice of plans. There are many reasons an individual may prefer their current plan over Medicare. These reasons include: potentially lower premiums, deductibles, and copayments, as well as different benefits that may not be available to them under the Medicare program. Switching to the Medicare program may also negatively impact their family members. For example, the costs an individual would incur as a Medicare beneficiary would not count against the Marketplace plan deductible of the family, increasing the overall cost of health insurance for them all.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0035
All Sections: 4.3.1.2.1, 7.7.1, 7.6.1, 4.3.1.2.3
(b)(5)
Organization: Center for American Progress

Excerpt Text:
b. Addressing Critical Gaps in the Forms of Prohibited Sex Discrimination Enumerated

We appreciate HHS' enumeration of specific forms of sex discrimination prohibited in § 92.206(b) and § 92.207(b). 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 not refuse gender-affirming care to a patient based on a personal 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(b) and § 92.207(b) to prevent covered entities from using state or local laws that ban 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 Dobbs, we also urge you to add enumerated specific forms of discrimination related to pregnancy and related conditions. In this section of our comments, we offer analysis on how discrimination related to pregnancy and related conditions undermines program access and recommend amendments to the proposed regulatory text. Under § 92.207, we build on this analysis and recommend amendments to address discrimination related to pregnancy and related conditions in health insurance and other health-related coverage.

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, 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, 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 mistreatment during labor and delivery [Footnote 75: Vedam, S., Stoll, K., Taiwo, T.K. et al. The Giving Voice to Mothers study: inequity and mistreatment during pregnancy and childbirth in the United States. Reprod Health 16, 77 (2019). https://doi.org/10.1186/s12978-019-0729-2]. People with disabilities often experience multiple barriers to sexual and reproductive health care [Footnote 76: Agaronnik N, Pendo E, Lagu T, DeJong C, Perez-Caraballo A, Iezzoni LI. Ensuring the Reproductive Rights of Women with Intellectual Disability. J Intellect Dev Disabil. 2020;45(4):365-376. doi: 10.3109/13668250.2020.1762383. Epub 2020 Jun 10. PMID: 35046755; PMCID: PMC8765596. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8765596/]. For example, among subspecialty provider offices, 44 percent of gynecology offices were inaccessible due to factors such as inaccessible equipment and lack of transfer assistance, leaving wheelchair users unable to access abortion or maternal care [Footnote 77: Lagu, Tara, et al. "Access to subspecialty care for patients with mobility impairment: a survey." Annals of Internal Medicine 158.6 (2013): 441-446, available at https://www.acpjournals.org/doi/10.7326/0003-4819-158-6-201303190-00003]. Discrimination persists for many people when accessing infertility diagnosis, treatment, and services, including assisted reproductive technology. It is essential that the Final Rule explicitly name this as prohibited sex discrimination.

When the Supreme Court overturned the constitutional right to abortion in Dobbs, it provoked covered entities to begin discriminatorily denying or erecting barriers to medications and treatments that can prevent, complicate, or end pregnancies. Covered entities are struggling to understand their compliance with rapidly changing state laws. The impacts of Dobbs are compounding preexisting barriers to abortions, contraception, miscarriage management, fertility care, and other sexual and reproductive health care, particularly for communities of color, people

with disabilities, the LGBTQI+ community (especially transgender people), and more [Footnote 78: Bella Isaacs-Thomas, "For many pregnant trans people, competent medical care is hard to find," PBS News Hour, May 26, 2021, available at https://www.pbs.org/newshour/health/for-many-pregnant-trans-people-competent-medical-care-is-hard-to-find]. For example, people with disabilities are increasingly denied or subjected to unconscionable barriers to methotrexate, which is regularly used to treat cancer and autoimmune conditions [Footnote 79: Laura Weiss, "Pharmacists and Patients Are Freaking Out Over New Medication Restrictions Post-Roe" The New Republic, July 27, 2022, available at https://newrepublic.com/article/167165/dobbs-pharmacists-walgreens-methotrexate]. We expect that under Dobbs, people with disabilities will face increasing discriminatory denials of and barriers to the vast array of medications and treatments prescribed for their conditions that happen to prevent, complicate, or end pregnancies or fertility. Accordingly, we urge you to amend proposed § 92.206(b) as follows:

(3) 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, italic: 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, [bold, italic: fertility care, or any health services], [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, [bold, underline: transgender status] or gender otherwise recorded.

(5) [Bold, italic: 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, that could 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].

In addition, HHS must strengthen the language pertaining to providers complying with a state or local law as a justification for denying gender-affirming care, abortions, or other reproductive or sexual health care to state unequivocally that Section 1557, as federal law, preempts any such state or local law restricting access to this care.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0038
All Sections: 7.7.1
(b)(5)

(b)(5)

Organization: Center for American Progress

Excerpt Text:
We agree 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. Thus, we strongly support HHS' restoration of and improvements to § 92.207, including its inclusion of specific forms of prohibited discrimination. However, as with proposed § 92.206, HHS must strengthen the text of proposed § 92.207 to address sex discrimination related to pregnancy or related conditions, such as discrimination related to abortion, fertility care, and contraception.

We urge HHS to amend proposed § 92.207(b) as follows:

(4) Have or implement a categorical coverage exclusion or limitation for [strikethrough, bold: all] services related to gender transition or other gender-affirming care, [bold, italic: 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, italic: 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) [Bold, italic: 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 restriction results in discrimination on the basis of sex.]

In addition, we urge HHS to specify in the preamble that the health services addressed in our proposed § 92.207(b)(7) include both the full spectrum of reproductive and sexual health services and treatments and medications for people with disabilities that may prevent, complicate, or end fertility or pregnancies.

Comment Number: HHS-OS-2022-0012-DRAFT-66244-0004
All Sections: 7.7.1, 5.2.1

(b)(5)

Organization: Association of American Medical Colleges (AAMC)

Excerpt Text:
[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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66854-0004
All Sections: 7.7.1
(b)(5)
Organization: Wisconsin Primary Health Care Association

Excerpt Text:
[Underlined: Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage (§92.207)]

WPHCA 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, 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 wipe 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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66750-0004
All Sections: 7.7.1, 7.6.1

(b)(5)

Organization: Jacobs Institute of Women's Health

Excerpt Text:
- Include language in § 92.206 and § 92.207 addressing the denial of medications or treatments that could prevent, complicate, or end pregnancies yet are prescribed for purposes beyond sexual and reproductive health care, including treatment for severe chronic conditions.

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0005
All Sections: 7.7.1

(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:
[Bold: TPCA 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66244-0005
All Sections: 7.7.1

(b)(5)

Organization: Association of American Medical Colleges (AAMC)

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0006
All Sections: 7.7.1, 7.7.5

(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:
[Bold: TPCA 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.

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: Thus TPCA strongly supports HHS' restoration of and improvements to § 92.207, including its inclusion of specific forms of prohibited discrimination.]

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0008
All Sections: 7.7.1, 7.7.14, 7.7.4

(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:
III. [Bold: Sex Discrimination Coverage]

U.S. health insurance and other health-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 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 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_us-pdfmembers.pdf)] that providers do not take their fertility concerns seriously, instead "emphasiz[ing] 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 programs and contraceptive coverage mandates. This results in discrimination against people of color and people with low- incomes who face higher rates [embedded hyperlink text (https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception)] of unintended pregnancy and adverse reproductive health outcomes due to these barriers. Robust enforcement of Section 1557 is necessary to ensure health entities and providers do not perpetuate discriminatory policies against contraceptive care.

PRH agree 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. Thus, we strongly support HHS' restoration of and improvements to § 92.207, including its inclusion of specific forms of prohibited discrimination. However, as with proposed § 92.206, HHS must strengthen the text of proposed §
92.207 to address sex discrimination related to pregnancy or related conditions, such as discrimination related to abortion, fertility care, and contraception.

RECOMMENDATION: We urge HHS 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, [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, [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; or

(7) [Italics: 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 restriction results in discrimination on the basis of sex.]

In addition, we urge HHS to specify in the preamble that the health services addressed in our proposed § 92.207(b)(7) include both the full spectrum of reproductive and sexual health services and treatments and medications for patients that may prevent, complicate, or end fertility or pregnancies.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0008
All Sections: 5.4.5.1, 7.7.1, 5.4.4.1, 2

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
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 nondiscrimination requirements in health insurance coverage and other health-related coverage, as discussed further below.

Comment Number: HHS-OS-2022-0012-DRAFT-44558-0008
All Sections: 7.7.1, 6.1

(b)(5)

Organization: Equitas Health

Excerpt Text:
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, it 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, [bold, italic: 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 92.207(a), (b)(1), and (b)(2) to ensure consistency.

Section 7.7.2 - Deny/cancel/limit/refuse coverage (§ 92.207(b)(1))

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0010
All Sections: 7.7.2

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
We also strongly support the Department's restoration 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, [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;

(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 on 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-67996-0011
All Sections: 7.7.2, 7.7.5

(b)(5)

Organization: The Alabama Disabilities Advocacy Program

Excerpt Text:
While ADAP's experience with Medicare Part C and Exchange plans is admittedly limited, we have seen barriers to accessing health care through the state's Medicaid program, both in the managed and traditional context. Alabama has started operating a managed Medicaid system through a 1915(b) waiver [Hyperlink: https://medicaid.alabama.gov/content/5.0_Managed_Care/default.aspx]. Called the Alabama Coordinated Health Networks (ACHN), the goal of the delivery system is to be "a more flexible and cost- efficient effort." While the specifics of this delivery method have yet to borne out in specific issues, it is likely that the ACHN will continue and potentially increase the barriers of access to care in the traditional Medicaid sphere.

A specific ad hoc policy that has pervaded the Medicaid delivery space is barriers in accessing durable medical equipment (DME). ADAP has two recent examples regarding these hurdles. In both cases, the client was trying to receive a wheelchair, and both clients qualified under the DME conditions enumerated in the Medicaid Provider Manual's DME section [Hyperlink: https://medicaid.alabama.gov/content/Gated/7.6.1G_Provider_Manuals/7.6.1.4G_Oct2022/Oct22_14.pdf]. However, in both cases, the state's agencies were recalcitrant to providing the needed wheelchair.

First, T.C. is an adult in her sixties who had diabetic complications resulting in the amputation of her leg. A recipient of general Medicaid, she tried to obtain a prior authorization to receive her wheelchair. The first request was denied, and the reason given was unrelated to any of the criteria Medicaid lists in its coverage requirements, but rather related to the cost of the wheelchair by a specific provider. Eventually, we were able to discuss the issue with both the provider in question and the state agency, leading to T.C. being fitted for and receiving the wheelchair she needed.

Second. K.G. is a child who has the diagnoses of acute flaccid myelitis, chronic respiratory failure (resulting in her being dependent on a ventilator), quadriplegia, dysphagia, hypertension, gaseous abdominal distention, idiopathic constipation, dysmotility, osteoporosis, generalized anxiety disorder with panic attacks, bilateral dry eye syndrome, Postural Tachycardia Syndrome (POTS), recurrent vertigo, and autonomic dysfunction. She needed a wheelchair both to be involved in her community and to make it to the numerous appointments related to her

diagnoses. Despite being 11 years-old and having grown a fair bit, she was relying on a wheelchair provided for her when she was five. Again, her situation met the criteria spelled out in the DME section of the provider manual (and arguably should have been covered through EPSDT's "medical necessity" provision), but her request took months to be processed. The timeline was so lengthy that it functioned as an effective denial. When the agency finally reached out, they insisted that she has to be fitted for the wheelchair and that would include her passing a usability test (something not present in the manual at all). The insistence that she pass this test to receive the wheelchair was arbitrary, and constituted discrimination of the basis of her disability, leaving her at great risk of institutionalization.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0013
All Sections: 7.7.3, 7.7.2, 7.7.1, 6.1

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
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)(2).

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0013
All Sections: 7.7.3, 7.7.2, 7.7.1, 6.1, 7.7.4

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
2. In section 92.101(a)(1) we recommend adopting the following change: "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, [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), (b)(2), and (b)(3). Utilizing this language will strengthen the rule by clarifying that discrimination motivated by multiple characteristics is prohibited.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0018
All Sections: 6.2.1, 7.7.3, 7.7.2, 7.7.1, 6.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:
VII. Discrimination Prohibited (§ 92.101)

In the preamble of the Proposed Rule, the Department rightly notes that people may experience intersectional discrimination in health care when they are discriminated against because of the combination of two or more protected bases. This can include individuals who experience heath care discrimination stemming from 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), ableism, or ageism. For instance, women with physical disabilities often report a range of barriers to accessing maternity and reproductive care like a lack of provider training – and this can be heightened for disabled women of color [Footnote 26: Mariëlle Heideveld-Gerritsen and others, "Maternity care experiences of women with physical disabilities: A systematic review," Midwifery 96 (2021), available at https://www.sciencedirect.com/science/article/pii/S0266613821000176].

We believe that the proposed rule would be strengthened by including more explicit references to intersectional discrimination within the regulatory text. As such, we propose the following change to § 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, [strikethrough, bold: 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 §§ 92.207(a), (b)(1), and (b)(2).

Comment Number: HHS-OS-2022-0012-1003-0002
All Sections: 1.1, 7.7.3, 7.7.2, 7.7.1
(b)(5)

Organization: URAC

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-74948-0002
All Sections: 7.7.2
(b)(5)

Organization: Center for Health and Welfare Policy, The Heritage Foundation

Excerpt Text:
[Bold: Assigning the burden of proof to covered entities]

In its discussion of enforcement, the Department states its intent to use "circumstantial evidence" of discrimination, including "evidence of disparate impact," and that the burden of proof is effectively assigned to the covered entity which "must articulate a legitimate, nondiscriminatory reason for its actions." [Footnote 6: Ibid. pp. 47827, 47865, and 47870.]

The proposed new § 92.303 also incorporates by reference the "procedures are found at 45 CFR through 80.11 and part 81 of this subchapter," and for the Age Act the procedures "found at 45 CFR 91.41 through 91.50." [Footnote 7: Ibid. proposed 45 CFR § 92.203.] Those procedures include requirements that covered entities submit to the Department compliance reports and data and authorize the Department to conduct periodic compliance reviews of covered entities. [Footnote 8: See: 45 CFR § 80.6, § 80.7, and § 91.41.]

The Department is effectively declaring that its enforcement of the provisions of the proposed rule will be based on the presumption that any business decisions made a covered entity is either intentionally discriminatory or has an impermissible discriminatory effect, unless and until the entity can demonstrate otherwise to the Department's satisfaction.

[Bold: Imposition of new regulatory oversight on numerous business decisions

With respect to the ability of health insurers to deny, cancel, limit, or refuse to issue or renew health insurance coverage, Sec. 1557 (and this proposed rule) add nothing to other, existing federal and state laws and regulations that govern such matters.

However, this proposed rule would go further than those other laws by imposing new "non-discrimination" tests on insurer business decisions that resulted in the denial or limitation of payment for a claim, on variations in cost sharing under the terms of a health plan, or on the imposition of (unspecified) "other limitations or restrictions on coverage." [Footnote 9: "Nondiscrimination in Health Programs and Activities," proposed 45 CFR § 92.207(b)(1).]

The proposed rule would also impose (unspecified) non-discrimination tests on insurance "benefit designs." [Footnote 10: Ibid. proposed 45 CFR § 92.207(b)(2).] In the preamble, the Department writes that, "the Department does not propose defining these terms in this rule and intends to interpret them broadly. Examples of benefit design features include, but are not 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."[Footnote 11: Ibid. p. 47869.]

Thus, the Department is announcing its intent to engage in expansive and detailed regulation of numerous insurer business decisions in an arbitrary and capricious manner.

In the same vein, the proposed rule also includes new sections that would impose non-discrimination tests on "the use of clinical algorithms in decision-making," and on "the delivery of health programs and activities through telehealth services." [Footnote 12: Ibid. proposed 45 CFR § 92.210 and § 92.211.]

In addition, the preamble states that, "Plan choices regarding provider networks may also violate Section 1557." [Footnote 13: Ibid. p. 47877.] It further comments that, "Provider networks that limit or deny access to care for individuals with certain disabilities, such as by excluding certain providers from the network that treat high-cost enrollees, raise discrimination concerns."

Having raised the topic, the Department then states that, "we do not propose to prescribe specific network adequacy requirements for covered entities under this rule. However, to ensure compliance with Section 1557, payers must develop their networks in a manner that does not discriminate against enrollees on the basis of race, color, national origin, sex, age, or disability." [Footnote 14: Ibid. p. 47878.]

The Department concludes, "We generally seek comment on how Section 1557 might apply to: provider networks; how provider networks are developed, including factors that are considered in the creation of the network and steps taken to ensure that an adequate number of providers and facilities that treat a variety of health conditions are included in the network; 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; and the extent to which the lack of availability of accessible medical diagnostic equipment in a provider network limits or denies access to care for individuals with disabilities." [Footnote 15: Ibid. p. 47878.]

In sum, the Department has signaled its interest in extending its construct of "non-discrimination" tests to plan network decisions in future rule making.

The collective effect of all the foregoing would be to impose an expansive, arbitrary, and capricious new regulatory regime on numerous, operational level business decisions of health insurers.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0021
All Sections: 7.7.2
(b)(5)
Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-66192-0003
All Sections: 7.7.2, 7.7.1
(b)(5)
Organization: Kidney Care Partners

Excerpt Text:
Providing this clarification is extremely important because State-based Marketplaces have approved plans that discriminate against individuals with kidney failure who require dialysis treatments. KCP has raised concerns in previous years about plans that adopt policies that result in individuals being forced to enroll in Medicare after a diagnosis of kidney failure. Some plans raise co-insurance costs on services that only dialysis patients require. Other plans refuse to accept charitable assistance for individuals who require dialysis, even though the plans continue to accept it for patients with other chronic conditions. More recently, our members report that

some plans apply "utilization management techniques" that seek to justify denying or restricting medically necessary services that only dialysis patients receive. We have even seen some plans try to apply prior authorization for dialysis treatments themselves.
These are only a few examples of the problems individuals with kidney failure who require dialysis treatments have shared. We ask that OCR/HHS in the final rule make clear that any of these policies when applied in a manner that directly or indirectly result in a restriction of access to medically necessary dialysis services or result in an enrollee losing primary coverage with their plan constitute discrimination and are inconsistent with the requirements of Section 1557.

It is also important that the Sections 1557 protections apply to all insurers. We ask that OCR/HHS not finalize the proposed exemption for employer liability and clarify that the protections apply to group health plans, including self-funded plans.

Individuals with kidney failure who rely upon dialysis treatments should be allowed to retain their choice of plans. There are many reasons an individual may prefer their current plan over Medicare. These reasons include: potentially lower premiums, deductibles, and copayments, as well as different benefits that may not be available to them under the Medicare program. Switching to the Medicare program may also negatively impact their family members. For example, the costs an individual would incur as a Medicare beneficiary would not count against the Marketplace plan deductible of the family, increasing the overall cost of health insurance for them all.

Comment Number: HHS-OS-2022-0012-DRAFT-39933-0005
All Sections: 7.7.2

(b)(5)

Organization: Minnesota Association of Community Health Centers

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0005
All Sections: 4.3.1.2.5, 7.7.2, 7.7.4, 4.3.1.2.3

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
The Department's proposal to once again recognize Section 1557's application to private insurance continues this 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-lgbtqi-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.

Comment Number: HHS-OS-2022-0012-DRAFT-66854-0005
All Sections: 7.7.2

(b)(5)

Organization: Wisconsin Primary Health Care Association

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-66750-0005
All Sections: 7.7.2

(b)(5)

Organization: Jacobs Institute of Women's Health

Excerpt Text:
- Specify that covered entities may not refuse care to individuals because of their actual or perceived abortion history or suspicion that they might have an abortion in the future.
- Specify that covered entities may not deny or limit coverage, or impose additional barriers to 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65765-0005
All Sections: 7.7.3, 7.7.2

(b)(5)

Organization: Genentech

Excerpt Text:
[underlined: Third], as discussed in detail above, AFM benefit designs, specifically, discriminate against patients with disabling health conditions. AFMs are a systematic denial of coverage for medically appropriate care for patients with a disabling disease that deny coverage or condition coverage for a medically necessary therapy on the patient attempting and failing to obtain their medicine from scarce CDP resources.
Furthermore, unlike certain utilization management techniques that may rely on evidence-based clinical guidelines, AFMs are used to categorically deny access to life-saving medications for the sole purpose of shifting costs away from health plans.

As noted above, AFMs delay and interrupt patient access to medically necessary care by forcing patients who have insurance to work through a vendor to access safety net CDPs intended for uninsured or underinsured patients. This additional administrative burden can cause unnecessary psychological distress and potential delays to or interruptions in therapy (or even abandonment of therapies that are working for the patient), resulting in worse health outcomes for patients. Moreover, as discussed above, AFMs may compromise patient safety by disrupting the care coordination infrastructure built into provider and insurance models and adding additional administrative requirements for pharmacists and/or providers to manage complex disabling health conditions.

In short, AFMs cause individuals living with serious health conditions that meet the "disability" under section 1557 and the proposed rule to undergo additional burdensome and stressful processes when coverage for a medically necessary treatment is denied for cost-saving reasons without any clinical justification, leading to delays and disruptions in therapy (assuming the patients ultimately receive their medication at all) and placing these patients at risk of disease progression and poorer health outcomes. For these reasons, AFMs constitute a benefit design that discriminates on the basis of disability, and are therefore prohibited under Section 92.207(b) and ACA 1557 when designed or administered by a covered entity.

[Italics/underlined: HHS Should Deem AFMs To Be a Presumptively Discriminatory Practice Under Section 1557]

As described above, AFMs constitute discriminatory benefit designs that disproportionately impact patients living with disabling health conditions who need specialty and high-cost medications.
Specifically, AFMs deny these patients access to life-saving and other critical therapies for reasons unrelated to clinical considerations, putting them at increased risk for poor health outcomes. [underlined: Accordingly, we urge HHS to specify explicitly in the final rule that AFMs are one example of a presumptively discriminatory benefit design under Section 1557. By doing so, HHS may help ensure that covered entities do not use AFMs to seek cost-savings at the expense of vulnerable patients with disabling health conditions and thereby curb the growth of this disturbing discriminatory practice.]

Comment Number: HHS-OS-2022-0012-DRAFT-43609-0007
All Sections: 7.7.3, 7.7.2

(b)(5)

Organization: Endocrine Society

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0009
All Sections: 7.7.3, 7.7.2, 7.7.5

(b)(5)

Organization: National Health Council

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-67996-0009
All Sections: 7.7.3, 7.7.2, 7.7.6

(b)(5)

Organization: The Alabama Disabilities Advocacy Program

Excerpt Text:
ADAP strongly supports the proposed restoration of broad language prohibiting benefit design discrimination on the basis of disability or any other protected basis. People with disabilities have historically endured discrimination in health insurance, ranging from outright denial of coverage to exorbitant premiums to exclusions, coverage caps, and "special" co-pays, higher co-insurance, and arbitrary exemptions that don't count toward a deductible, all triggered by the mere fact of having a disability or chronic condition [Hyperlink: https://scholarship.law.nd.edu/ndjlepp/vol25/iss2/16/].

Insurers were not required to share actuarial calculations justifying denials or imposing greater costs on people with disabilities, nor did they have to undertake any kind of individualized assessment of any applicant's health. While the ACA prohibited some of the worst discriminatory insurance behavior, such as outright denial of coverage or dropping people with disabilities from coverage, it did impose new benefit design prohibitions on top of existing discriminatory practices that had already endured for decades. We have an existing

discriminatory insurance system being slowly dragged into the light, not a requirement to issue new insurance policies that have been scrubbed of discriminatory language, practice, and reimbursement policies.

For example, just looking at the small area of durable medical equipment coverage, private insurers place unique annual coverage caps on items such as wheelchairs, commonly fail to provide any coverage for items such as hearing aids for adults, and place stringent utilization management controls on medications that are primarily used by people with specific chronic conditions such as AIDS/HIV. People with disabilities bear the brunt of these kinds of benefit design decisions or omissions, and they also bear the burden of factually establishing discrimination when data either doesn't exist at all or the issuer holds the data on details of coverage, denial rates, reasons for denial, and the presence or total absence of "a legitimate, nondiscriminatory reason for determining that such health service fails to meet applicable coverage requirements in any given individual case," as detailed in § 92.07(c).

Section 7.7.3 - Marketing practices or benefit design (§92.207(b)(2)

Comment Number: HHS-OS-2022-0012-DRAFT-71242-0001
All Sections: 7.7.3

(b)(5)

Organization: National Alliance on Mental Illness

Excerpt Text:
[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 their 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 (b)(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.

Comment Number: HHS-OS-2022-0012-DRAFT-72212-0001
All Sections: 5.2.2, 5.2.3, 7.7.3, 7.7.8

(b)(5)

Organization: Senate Democrats

Excerpt Text:
The Proposed Rule Clarifies and Expands 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 like 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)].

Comment Number: HHS-OS-2022-0012-DRAFT-39789-0001
All Sections: 7.7.3, 10.1, 7.7.1

(b)(5)

Organization: American Federation of State, County and Municipal Employees

Excerpt Text:
Scope and Application

Section 1557 of the ACA establishes protections against discrimination across a wide swath of health programs and activities, including those that receive federal funding. The proposed rule extends the reach of nondiscrimination protections to match the expansive intent of the provisions set forth in the statute.

We agree that the nondiscrimination protections should be extended to all programs and activities conducted by HHS. In particular, we agree with the proposal to include Medicare Part B in the definition of federal financial assistance for the purposes of determining the application of nondiscrimination protections. This provision will eliminate any potential confusion as to the application of nondiscrimination protections and ensure that they are applied equally, regardless of whether an individual enrolls in traditional Medicare or a Medicare Advantage plan. Additionally, we agree that insurers who take federal financial assistance should be subject to the

nondiscrimination protections across all their activities. This will limit, to the greatest extent possible, insurers' adoption of discriminatory plan benefit designs.

Comment Number: HHS-OS-2022-0012-DRAFT-70479-0012
All Sections: 7.7.3

(b)(5)

Organization: National Disability Rights Network

Excerpt Text:
[Bold: § 92.207(b)(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.

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0012
All Sections: 7.7.3

(b)(5)

Organization: National Health Council

Excerpt Text:
The inclusion of benefit design under 1557 is an important expansion of protections. Too often, barriers to health care can be based 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 protection 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0013
All Sections: 7.7.3

(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
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 define 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 the first time. Covered entities should not be able to deny or limit health services based on an individual's disability.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0013
All Sections: 7.7.3, 7.7.2, 7.7.1, 6.1

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
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)(2).

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0013
All Sections: 7.7.3, 7.7.2, 7.7.1, 6.1, 7.7.4

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
2. In section 92.101(a)(1) we recommend adopting the following change: "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, [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), (b)(2), and (b)(3). Utilizing this language will strengthen the rule by clarifying that discrimination motivated by multiple characteristics is prohibited.

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0014
All Sections: 7.7.3

(b)(5)

Organization: American Academy of Family Physicians

Excerpt Text:
Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage (§ 92.207)

HHS proposes to reinstate prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability by health insurance plans or related coverage by addressing benefit design. Under this proposal, a covered entity would not be able to provide a categorical exclusion or limitation for all gender transition or gender-affirming care when not applied to the same services provided for other reasons. Under (b)(3) of this section, HHS clarifies that a health insurer may inquire about an individual's relevant medical history and physical traits to determine medical necessity of a service.

[Bold: The AAFP finds the majority of this proposal to be appropriate and necessary to ensure access to gender-affirming care, but we have concerns with the proposal to allow health plans to use prior authorization, step therapy, and durational or quantity limits to care when applied in nondiscriminatory manners]. The decision about the medical necessity of a service or procedure should be made between a patient and their physician. Under this provision HHS clarifies that issuers can use prior authorization, step therapy, and durational or quantity limits to care when applied in nondiscriminatory manners. The AAFP recognizes that health plans use these strategies to contain costs by restricting access to expensive services or treatments. However, these strategies result in administrative burden for physicians and the aforementioned delays in care for patients. There is some evidence to suggest that prior authorization worsens health disparities, and the AAFP is concerned that prior authorization may be used inappropriately as it relates to gender-affirming care [Footnote 10: McManus KA, Powers S, Killelea A, Tello-Trillo S, Rogawski McQuade E. Regional Disparities in Qualified Health Plans' Prior Authorization Requirements for HIV Pre-exposure Prophylaxis in the United States. JAMA Netw Open. 2020;3(6):e207445. doi:10.1001/jamanetworkopen.2020.7445

] [Footnote 11: Association of Black Cardiologists. (2019.) "Identifying How Prior Authorization Impacts Treatment of Underserved and Minority Patients." http://abcardio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf].

Family physicians using appropriate clinical knowledge, training, and experience should be able to prescribe medications and order medical equipment without being subjected to prior authorizations. In the rare circumstances when a prior authorization is clinically relevant, the AAFP believes the prior authorization must be evidence-based, transparent, and administratively efficient to ensure timely access to promote ideal patient outcomes. The AAFP further believes step therapy protocols, in which insurers encourage less expensive prescription drugs to be prescribed prior to more costly alternatives, delay access to treatment and hinder adherence [Footnote 12: Sinsky, C., Colligan, L., Li, L., Prgomet, M., Reynolds, S., Goeders, L., … Hingle, S. (2016, December 6). Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties. Annals of Internal Medicine. https://www.acpjournals.org/doi/10.7326/M16-0961]. Therefore, step therapy should not be mandatory for patients already on a working course of treatment and generic medications should not require prior authorization. Ongoing care should continue while prior authorization approvals or step therapy overrides are obtained, and patients should not be required to repeat or retry step

therapy protocols that failed under previous benefit plans. The AAFP strongly urges HHS to use its existing authority to help streamline prior authorization, step therapy, and durational or quantity limits to care and hold health plans accountable for timely responses and actions on the aforementioned measures. To minimize care delays, [bold: HHS should also work with ONC and EHR vendors to ensure physicians can clearly differentiate between anatomy and gender-identity in a patient's EHR and in communication with a patient's insurance provider in a way that does not harm the patient].

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0018
All Sections: 6.2.1, 7.7.3, 7.7.2, 7.7.1, 6.1

(b)(5)

Organization: Center for American Progress

Excerpt Text:
VII. Discrimination Prohibited (§ 92.101)

In the preamble of the Proposed Rule, the Department rightly notes that people may experience intersectional discrimination in health care when they are discriminated against because of the combination of two or more protected bases. This can include individuals who experience heath care discrimination stemming from 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), ableism, or ageism. For instance, women with physical disabilities often report a range of barriers to accessing maternity and reproductive care like a lack of provider training – and this can be heightened for disabled women of color [Footnote 26: Mariëlle Heideveld-Gerritsen and others, "Maternity care experiences of women with physical disabilities: A systematic review," Midwifery 96 (2021), available at https://www.sciencedirect.com/science/article/pii/S0266613821000176].

We believe that the proposed rule would be strengthened by including more explicit references to intersectional discrimination within the regulatory text. As such, we propose the following change to § 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, [strikethrough, bold: 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 §§ 92.207(a), (b)(1), and (b)(2).

Comment Number: HHS-OS-2022-0012-1003-0002
All Sections: 1.1, 7.7.3, 7.7.2, 7.7.1

(b)(5)

Organization: URAC

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-65765-0002
All Sections: 7.7.3
(b)(5)

Organization: Genentech

Excerpt Text:
[Italics/underlined: Description of Alternative Funding Mechanisms]

AFMs are an emerging feature of many benefit designs used by plans, sponsors and TPAs (including PBMs) that attempt to reduce a plan's specialty drug spend by carving out coverage of certain specialty or high-cost medicines from the plan's benefits to force patients who need those medicines to seek alternative funding from a third party. [Footnote 5 See, e.g., Fein, Adam J., The Shady Business of Specialty Carve-Outs, Drug Channels (Aug. 2022), available at https://www.drugchannels.net/2022/08/the-shady-business-of-specialty-carve.html#more; Fredel, Josh, Multiple Specialty Vendors Mean More Headaches, Fierce Healthcare (June 2020), available at https://www.fiercehealthcare.com/sponsored/multiple-specialty-vendors-mean-more-headaches; Industry Experts Question Alternative Funding Companies that Carve Out Some Specialty Drugs, "Abuse" Charities, available at https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/industry-experts-question-alternative-funding- companies-that-carve-out-some-specialty-drugs-abuse-charities/; Holcombe, Dawn, Patients in Financial Tug of War Under PBM Alternate Funding Programs, Oncology Practice Management (Dec. 2021), available at https://oncpracticemanagement.com/issues/2021/december-2021-vol-11-no-12/2497-patients-in-financial-tug-of- war-under-pbm-alternate-funding-programs; Understanding Alternative Funding for Specialty Medications, available at https://www.rxbenefits.com/ebooks/understanding-alternative-funding-for-specialty/.] Under an AFM, the plan automatically denies claims for a prescribed, "excluded" drug and refers the patient to a for-profit AFM vendor to seek an alternative way to acquire the medicine in order to shift costs away from the plan.

AFMs are a relatively new practice with some variation in their details; however, typically AFMs are administered by a specific AFM vendor [Footnote 6 Our understanding is that currently over twenty AFM vendors exist, including, e.g., ImpaxRx, PaydHealth, PayerMatrix, RxFree4me, SHARx, and Script Sourcing. See Industry Experts Question Alternative Funding

Companies that Carve Out Some Specialty Drugs, "Abuse" Charities, available at https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/industry-experts-question-alternative-funding- companies-that-carve-out-some-specialty-drugs-abuse-charities/.] that contracts with the plan sponsor, self-insured employer, or a TPA (such as a PBM operating on the plan's behalf). The vendor is reimbursed a portion of the amount that the plan saves by denying coverage for the medicine, essentially earning a commission each time it can successfully divert a patient to an alternative funding source.

Ultimately if the vendor cannot find alternative funding (which is often likely given that many of these insured patients do not meet the strict financial hardship eligibility criteria set by charitable funds), the patient may be responsible for the full cost of the medication or the denial of coverage may be reversed -- for no other reason other than the plan's attempts to shift cost to charitable funds was unsuccessful. The most common alternative funding sources sought are manufacturer free medicine programs or other charitable foundations free drug programs (together, charitable drug programs, CDPs). These CDPs are a safety net of last resort intended to serve uninsured or underinsured patients with financial hardship, not patients with insurance coverage, and are typically administered by non-commercial pharmacy vendors who dispense the free product either directly to the patient or to the administering site of care. By diverting insured patients to these CDPs, AFMs put new demands on CDP resources that make it more difficult for CDPs to help indigent patients. CDP resources are intentionally set aside to help needy patients with no other options, not to support AFMs that financially benefit health plans and hurt their own enrollees by carving out coverage of previously covered specialty medications.

Products excluded under AFMs include medications that already are subject to burdensome utilization management techniques (e.g., prior authorizations, step-edits, and appeals), such as treatments for specific rare or high-cost disease states or products above a certain cost threshold. Critically, AFM coverage denials are determined not based on nondiscriminatory review of clinical evidence (such as FDA label, medical guidelines, peer-reviewed literature) or patient-specific medical considerations and characteristics, but rather on blanket discriminatory policies that deny a subset of high-need patients with serious, often disabling health conditions access to prescribed, medically appropriate medications. Indeed, the diversion of patients to CDPs underscores a plan's belief that the medication is in fact medically necessary, but not a cost that the plan wants to incur. AFMs then result in the differential and discriminatory treatment of patients with serious health care needs, who despite paying premiums like every other enrollee, are being denied coverage for medically necessary and appropriate care and diverted to CDPs that are meant to serve as a last resort for patients without insurance coverage.

Although AFMs are a relatively new benefit design, they are growing rapidly. According to a 2022 report from Pharmaceutical Strategies Group, 8 percent of health plan respondents said they are currently using an AFM, and 31 percent of respondents are exploring their use. [Footnote 7 See Pharmaceutical Strategies Group, Trends in Specialty Drug Benefit Design report (Mar. 2022) (co-sponsored by Genentech), available at https://www.psgconsults.com/2022specialtyresearch.] A Gallagher Research & Insights' 2022 Employer market Trends study found that 10 percent of self-insured plans with at least 5,000 employees use AFMs, 8 percent are planning to use them within the next two years, and 19 percent are considering their use in three to five years. [Footnote 8 See Gallagher Research &

Insights, Employer Market Trends Report (June 2022), available at https://mailchi.mp/benfield/2022-trends-data-alt-funding-vendors-8996663.] Therefore, this discriminatory benefit design is [underlined: on the rise and likely to affect a growing number of patients with disabling health conditions in the coming years.]

Notably, AFMs delay and interrupt patient access to care. Patients forced to work with AFM vendors to obtain alternative funding for their prescribed medicine face delays in care and must endure the psychological and emotional stress of learning that the treatment prescribed by their doctor has been denied for no discernable clinical reason. They then are faced with the burden of having to discuss their personal financial and medical history with the AFM vendors and overcome additional administrative barriers to access the prescribed product. Facing these additional steps patients may face delays or interruptions in treatment, or not start on therapy at all. All of which can lead to worse outcomes, particularly in hemophilia, multiple sclerosis, respiratory illnesses, and cancer. As summarized in a recent article on AFMs:

[indented: Patients face delays in their care and must endure the stress of learning that the appropriate treatment for their condition has been denied. They are then faced with the burden of having to discuss their financial and medical situations with an external entity (or several entities), who must search for funding sources for the medication. If the funding sources are not identified, the patient may face additional and steps, which can result in disease progression and a decline in health status. In some cases, the employer ends up covering the treatment after all, but precious time will have been lost in getting the patient started on therapy. [Footnote 9 Holcombe, Dawn, Patients in Financial Tug of War Under PBM Alternate Funding Programs, Oncology Practice Management (Dec. 2021), available at https://oncpracticemanagement.com/issues/2021/december-2021-vol-11-no- 12/2497-patients-in-financial-tug-of-war-under-pbm-alternate-funding-programs.]]

Moreover, AFMs may compromise patient care and safety by disrupting the infrastructure for integrated, coordinated care. Specifically, AFMs displace the provider or pharmacist from the integrated care team required for comprehensive care and management of serious health conditions. Care coordination and medication management services usually are provided by specialty pharmacies and clinicians when they are adequately reimbursed for the services they are providing in addition to dispensing or administering a medicine. However, in our experience removing coverage for the drug typically removes reimbursement for these types of related services, which can lead to suboptimal patient care and may ultimately limit the sustainability of comprehensive care services.

Comment Number: HHS-OS-2022-0012-DRAFT-68054-0002
All Sections: 7.7.3

(b)(5)

Organization: Washington Health Benefit Exchange

Excerpt Text:

The 2020 rule also eliminated explicit nondiscrimination protections for LGBTQ people in several rules on benefit design and implementation and insurer marketing practices. WAHBE strongly supports the restoration of these protections.

Comment Number: HHS-OS-2022-0012-DRAFT-66437-0020
All Sections: 7.7.3, 7.7.5

(b)(5)

Organization: Center for Elder Law & Justice

Excerpt Text:
[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 dissuading 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 $18,000 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65765-0003
All Sections: 7.7.3

(b)(5)

Organization: Genentech

Excerpt Text:

[italics/underlined: Alternative Funding Mechanisms are Benefit Designs Under Section 1557 that Discriminate Against Patients with Disabling Health Conditions]

Proposed 45 CFR section 92.207(b) outlines some of the specific discriminatory practices that covered entities that provide or administer health-related insurance or other health-related coverage must not engage in. Among other things, covered entities that provide or administer health-related insurance or other health-related coverage shall not "limit … health insurance coverage … or deny or limit coverage of a claim, or impose additional … limitations or restrictions on coverage, on the basis of … disability"; and shall not "have or implement … benefit designs that discriminate on the basis of … disability." [Footnote 10 Proposed 45 CFR 92.207(b)(87 Fed. Reg. at 47918).] [underlined: As described below, AFMs constitute a benefit design (or a "limit" or "additional limitation or restriction" on health insurance) that discriminates against patients with disabling health conditions, and HHS should clarify in its final rule that such AFMs constitute presumptively discriminatory benefit designs.]

[underlined: First], AFMs are a type of plan benefit design. Benefit designs are rules that structure health insurance coverage and dictate how and under what conditions patients can gain access to medically appropriate health care items and services, including prescription drugs. Like the non-exhaustive list of benefit design examples articulated in the preamble (e.g., prescription drug formularies, cost sharing, utilization management techniques (such as step therapy and prior authorization)), [Footnote 11 Proposed 45 CFR 92.207(b)(87 Fed. Reg. at 47918).] AFMs dictate how a plan enrollee can access certain specialty prescription drugs by requiring patients to seek help from alternative funding sources before accessing their medically necessary prescribed therapy through their insurance coverage. Therefore, AFMs are benefit designs to which Section 1557 nondiscrimination provisions apply, and we urge HHS to list AFMs specifically as another example of a benefit design subject to Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0045
All Sections: 7.7.3
(b)(5)
Organization: Ethics & Public Policy Center

Excerpt Text:
[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 109: 87 Fed. Reg 47870.] HHS asserts that discrimination "against transgender people in health insurance and other health-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. 47870.] HHS produces scant 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0046
All Sections: 7.7.3

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[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 (ERD) for Catholic Health Care Services. The ERD's 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." [Footnote 112: 87 Fed. Reg 47866.] 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 immoral, 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, ethics, or even malpractice risks.

Comment Number: HHS-OS-2022-0012-DRAFT-74948-0005
All Sections: 7.7.3

(b)(5)

Organization: Center for Health and Welfare Policy, The Heritage Foundation

Excerpt Text:
[Bold: Effect on health insurance markets]

Health insurers that are covered entities under the proposed rule could face substantial costs. Not only would they incur compliance costs, but they could also incur significant additional claims costs as a result of the proposed rule forcing them to alter their coverages and business practices. Higher claims costs are, in turn, the principal driver of higher premiums.

Furthermore, given that under the proposed rule the Department would engage in expansive and detailed regulation of numerous insurer business decisions in an arbitrary and capricious manner, any insurer that is a covered entity should expect to face heightened business risks and increased liability exposure.

There are three lines of private insurance that meet the criteria of the proposed rule for receiving federal financial assistance; Medicaid managed care plans, Medicare Advantage plans, and individual market Qualified Health Plans (QHPs). While federal funding is delivered in different ways for each of those three product lines, the common denominator is that federal funding for all three comes from mandatory appropriations. As a practical matter, that means that insurers offering one or more of those coverages will be able to pass back onto the federal government the bulk of any additional costs that they incur due to the proposed rule.

In contrast, coverages and services that do not receive federal financial assistance—most notably, fully insured and self-insured employer group plans—have to pass any cost increases onto customers and enrollees.

Given the foregoing, it is reasonable to expect that finalizing the proposed rule in its current form will cause health insurers to reevaluate their current business strategies and product offerings.

The first, and most fundamental, decision each insurer will have to make is whether it is comfortable with being a covered entity subject to these new regulations.

While those decisions cannot be projected with complete certainty, they can be reasonably approximated. That can be done by assessing the extent of each insurer's regulatory exposure—a good metric for which is the distribution of insurer enrollment by product line—and assigning probabilities accordingly.

It stands to reason that an insurer with a large share of its enrollment in products receiving federal financial assistance is more likely to continue offering those products. Conversely, it also stands to reason that an insurer with a small share of its enrollment in products receiving federal financial assistance is more likely exit those products and markets.

The enrollment profiles of two major national carriers illustrate the point:

• Centene is the fourth largest insurer nationally and is the carrier with both the largest number of Medicaid Managed Care enrollees and the largest enrollment in QHPs. Fully, 97 percent of Centene's enrollees are in plans receiving federal financial assistance.

• Cigna is the sixth largest insurer nationally and the carrier that services the fourth largest number of enrollees in self-insured employer plans. Only six percent of Cigna's enrollees are in plans receiving federal financial assistance.

Given that Centene already operates almost entirely as a government contractor and can expect to transfer any costs resulting from the proposed regulation back onto price-insensitive payers (government entitlement programs), there is little reason to expect Centene to alter its current business strategy in response to the proposed rule.

In contrast, given that enrollment in plans receiving federal financial assistance constitutes a very small part of Cigna's current business, but under the proposed rule would expose all of its other business to increased costs, uncertainty and liability, Cigna's most prudent course of action would be to divest or discontinue those affected plans.

Thus, finalizing the proposed rule in its current form can reasonably be expected to trigger a reorganization of the private health insurance industry into two distinct segments; insurers that are covered entities and insurers that are not. That in turn has implications for market competition and coverage availability.

To illustrate further, the following table provides data on19 Blue Cross and Blue Shield carriers that currently offer QHPs in 30 states where they are a BCBS licensee, but for whom their plans receiving federal financial assistance account for less than one-quarter of their total enrollment.

[Bold: BCBS Licensees That Offer QHPs and Have Less Than One-Quarter of Their Total Enrollment in Plans Receiving Federal Assistance]

[See original comment for Table]

Source: Mark Farrah Associates (www.markfarrah.com), compiled using data from NAIC, CA-DMHC, CMS and other state government and private sources.

Notes:

* Enrollment figures are for comprehensive coverage plans only and do not include enrollment in supplement plans (dental, vision, etc.).

** Combined enrollment in individual market, Medicare Advantage and Medicaid managed care plans.

Furthermore, six of those carriers (collectively offering coverage in 11 states) are organized as member-owned mutual insurance companies. [Footnote 24: Blue Cross Blue Shield of Michigan Mutual Insurance Company, Blue Cross of Idaho Health Service, Inc., Health Care Service Corporation, Noridian Mutual Insurance Company, USAble Mutual Insurance Company, and Wellmark, Inc.] Unlike traditional non-profit Blues, they are not subject to "community benefit" requirements that could potentially complicate or impede their exiting a state or a line of business.

In fact, several of them previously avoided or exited the ACA exchange market due to unfavorable conditions. For instance, Wellmark has never offered exchange coverage in South Dakota and did not offer exchange coverage in Iowa until 2017, then exited in 2018, but returned in 2019. Similarly, Health Care Service Corporation withdrew its New Mexico Blue Cross subsidiary from that state's exchange in 2016, though it returned the following year. Blue Cross and Blue Shield of Nebraska exited the exchange in 2017 and has not returned. Currently, only two percent of that company's enrollees are receiving federal assistance (consisting of few than 7,000 individuals in Medicare Advantage plans). Blue Cross & Blue Shield of Mississippi is also a mutual insurer. It has never offered exchange coverage and has no Medicare Advantage or Medicaid manage care enrollees.

Any resulting insurer exits could also have significant localized effects. For instance, Blue Cross Blue Shield of Vermont is one of only two insurers offering coverage in that state's exchange.

The same holds true for both Noridian in North Dakota and Highmark in West Virginia. Also, Highmark is the only insurer offering exchange coverage in Delaware. Blue Cross and Blue Shield of Alabama is the only insurer offering exchange coverage in 63 of that state's 67 counties.

The above table is not exhaustive. There also are non-Blue Cross carriers with less than one-quarter of their enrollment in affected plans, as well as 30 insurers with between 25 percent and 50 percent of their total enrollment is in affected plans. Some of those insurers would likely also take action to avoid being covered entities.

Comment Number: HHS-OS-2022-0012-DRAFT-65765-0005
All Sections: 7.7.3, 7.7.2

(b)(5)

Organization: Genentech

Excerpt Text:
[underlined: Third], as discussed in detail above, AFM benefit designs, specifically, discriminate against patients with disabling health conditions. AFMs are a systematic denial of coverage for medically appropriate care for patients with a disabling disease that deny coverage or condition coverage for a medically necessary therapy on the patient attempting and failing to obtain their medicine from scarce CDP resources.
Furthermore, unlike certain utilization management techniques that may rely on evidence-based clinical guidelines, AFMs are used to categorically deny access to life-saving medications for the sole purpose of shifting costs away from health plans.

As noted above, AFMs delay and interrupt patient access to medically necessary care by forcing patients who have insurance to work through a vendor to access safety net CDPs intended for uninsured or underinsured patients. This additional administrative burden can cause unnecessary psychological distress and potential delays to or interruptions in therapy (or even abandonment of therapies that are working for the patient), resulting in worse health outcomes for patients. Moreover, as discussed above, AFMs may compromise patient safety by disrupting the care coordination infrastructure built into provider and insurance models and adding additional administrative requirements for pharmacists and/or providers to manage complex disabling health conditions.

In short, AFMs cause individuals living with serious health conditions that meet the "disability" under section 1557 and the proposed rule to undergo additional burdensome and stressful processes when coverage for a medically necessary treatment is denied for cost-saving reasons without any clinical justification, leading to delays and disruptions in therapy (assuming the patients ultimately receive their medication at all) and placing these patients at risk of disease progression and poorer health outcomes. For these reasons, AFMs constitute a benefit design that discriminates on the basis of disability, and are therefore prohibited under Section 92.207(b) and ACA 1557 when designed or administered by a covered entity.

[Italics/underlined: HHS Should Deem AFMs To Be a Presumptively Discriminatory Practice Under Section 1557]

As described above, AFMs constitute discriminatory benefit designs that disproportionately impact patients living with disabling health conditions who need specialty and high-cost medications.
Specifically, AFMs deny these patients access to life-saving and other critical therapies for reasons unrelated to clinical considerations, putting them at increased risk for poor health outcomes. [underlined: Accordingly, we urge HHS to specify explicitly in the final rule that AFMs are one example of a presumptively discriminatory benefit design under Section 1557. By doing so, HHS may help ensure that covered entities do not use AFMs to seek cost-savings at the expense of vulnerable patients with disabling health conditions and thereby curb the growth of this disturbing discriminatory practice.]

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0051
All Sections: 7.7.3
(b)(5)

Organization: Justice in Aging

Excerpt Text:
Nondiscrimination in 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

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Comment Number: HHS-OS-2022-0012-DRAFT-68050-0006
All Sections: 7.7.3
(b)(5)

(b)(5)

Organization: AFLAC

Excerpt Text:

II. Should the Department nevertheless attempt to apply 1557 to any excepted benefits, it must do so through a separate notice and comment process

The text of the proposed rule itself does not mention excepted benefits. There are, however, some references to excepted benefits in the preamble. Specifically, on page 47875, at the end of the section on [Italics: Benefit Design], the preamble states that:

[Indented: As discussed in detail later in this section [superscript: 484], we propose to apply this part to all the operations of a covered entity that is principally engaged in the provision or administration of health programs or activities as described in paragraph (a) of the proposed definition of ''health program or activity,'' including a health insurance issuer's excepted benefits and short-term limited duration insurance products. Given the unique nature of these products, which are generally exempt from complying with any of the ACA's market reforms, we provide further analysis on how OCR proposes to investigate potential claims of discrimination challenging benefit design features in these products. OCR will consider the nature, scope, and contours of the specific plan at issue, and will evaluate on a case-by-case basis an alleged discriminatory design feature in light of the entity's stated coverage parameters.]

Footnote number 484 in the above-quoted paragraph refers the reader to the immediately following section of the preamble, headed "Scope of Application and Application to Excepted Benefits and Short-Term Limited Duration Insurance". That section, on page 47876, includes the following:

[Indented: [B]ecause the Department believes commenters' concerns about the application of Section 1557 to excepted benefits and short-term limited duration insurance warranted further consideration, we have provided additional discussion on how OCR proposes to analyze allegations of discrimination in such products in the preceding discussion on benefit design.]

These vague, general statements do not provide any detail to allow insurers to discern the analysis or instances of discrimination that the Department might consider with respect to the various types of excepted benefits. Rather than providing detail on what the Department's approach will be, the Department includes a request for comments on page 47878 "on the anticipated impact of the proposed application to excepted benefits". This request for comments suggests that the Department may be unsure as to how 1557 would apply. More detail is needed to fully respond to this request for comments.

Comment Number: HHS-OS-2022-0012-DRAFT-43609-0007
All Sections: 7.7.3, 7.7.2
Classification: Substantive

(b)(5)

Organization: Endocrine Society

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68050-0007
All Sections: 7.7.3

(b)(5)

Organization: AFLAC

Excerpt Text:
Given that the proposed rule is silent on the issue, the preamble's vague references to excepted benefits are not sufficient notice to implement such a requirement in the final rule. For notice to be sufficient, it must be specific enough for interested parties to anticipate what the requirements of the final rule might be, so that they can submit objections during the comment period. [Footnote 11: See Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin., 626 F.3d 84, 94-95 (D.C. Cir. 2010).] In situations like this, in which there are only "'ambiguous comments and weak signals from the agency'" in the proposal, notice is insufficient, because it does not give commenters the "'opportunity to anticipate and criticize the rule [ ] or to offer alternatives.'" [Footnote 12: Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin., 407 F.3d 1250, 1261 (D.C. Cir. 2005) quoting Shell Oil Co. v. EPA, 950 F.2d 741, 751 (D.C. Cir. 1991).]

Here, although there are statements indicative of the intent to apply the rule to excepted benefits, there is no detail on how the rule would apply and no information whatsoever as to how the Department will reconcile any application of 1557 with statutory exceptions from ACA requirements or take into account the fact that excepted benefits are significantly different from major medical products. Rather, the reference to an investigative process on a case-by- case basis seems to indicate a regulation-by-audit scheme.

Specific notice on how the rule would apply to excepted benefits, taking into account the specific nature and legal structure of such products, as repeatedly reaffirmed by Congress, is needed. That notice is lacking in the proposed rule. Thus, while we believe that excepted benefits should be outside the scope of section 1557, if the Department wishes the rule to be applied to excepted benefits, the agency must issue a new proposed rule with comment period that explains how.

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0009
All Sections: 7.7.3, 7.7.2, 7.7.5

(b)(5)

Organization: National Health Council

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-67996-0009
All Sections: 7.7.3, 7.7.2, 7.7.6

(b)(5)

Organization: The Alabama Disabilities Advocacy Program

Excerpt Text:

ADAP strongly supports the proposed restoration of broad language prohibiting benefit design discrimination on the basis of disability or any other protected basis. People with disabilities have historically endured discrimination in health insurance, ranging from outright denial of coverage to exorbitant premiums to exclusions, coverage caps, and "special" co-pays, higher co-insurance, and arbitrary exemptions that don't count toward a deductible, all triggered by the mere fact of having a disability or chronic condition [Hyperlink: https://scholarship.law.nd.edu/ndjlepp/vol25/iss2/16/].

Insurers were not required to share actuarial calculations justifying denials or imposing greater costs on people with disabilities, nor did they have to undertake any kind of individualized assessment of any applicant's health. While the ACA prohibited some of the worst discriminatory insurance behavior, such as outright denial of coverage or dropping people with disabilities from coverage, it did impose new benefit design prohibitions on top of existing discriminatory practices that had already endured for decades. We have an existing discriminatory insurance system being slowly dragged into the light, not a requirement to issue new insurance policies that have been scrubbed of discriminatory language, practice, and reimbursement policies.

For example, just looking at the small area of durable medical equipment coverage, private insurers place unique annual coverage caps on items such as wheelchairs, commonly fail to provide any coverage for items such as hearing aids for adults, and place stringent utilization management controls on medications that are primarily used by people with specific chronic conditions such as AIDS/HIV. People with disabilities bear the brunt of these kinds of benefit design decisions or omissions, and they also bear the burden of factually establishing discrimination when data either doesn't exist at all or the issuer holds the data on details of coverage, denial rates, reasons for denial, and the presence or total absence of "a legitimate, nondiscriminatory reason for determining that such health service fails to meet applicable coverage requirements in any given individual case," as detailed in § 92.07(c).

Section 7.7.4 - Gender identify/gender transition/gender-affirming care provisions (§92.207(b)(3) through (5))

Comment Number: HHS-OS-2022-0012-DRAFT-64680-0001
All Sections: 7.7.4

(b)(5)

Organization: Kansas Catholic Conference

Excerpt Text:
We applaud 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66854-0001
All Sections: 6.2.3, 7.7.4, 7.1.3
(b)(5)
Organization: Wisconsin Primary Health Care Association

Excerpt Text:
WPHCA 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. WPHCA recommends also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0010
All Sections: 7.7.4
(b)(5)
Organization: 38 Members of Congress

Excerpt Text:
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 imposed to "normalize" a child's variations in sex characteristics in accordance with the presumed 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0011
All Sections: 7.6.6, 7.6.7, 7.7.4

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:
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)(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, birth-assigned, or recorded gender.

Comment Number: HHS-OS-2022-0012-DRAFT-44558-0011
All Sections: 7.7.4

(b)(5)

Organization: Equitas Health

Excerpt Text:
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 Section 1557 do apply to insurance plans and coverage.Consistent with our recommendations above, we strongly suggest adding "transgender status" to section 92.207(b)(3):

"A covered entity must not, in providing or administering health insurance coverage or other health- related coverage: … (3) 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, [italic, bold: transgender status], or gender otherwise recorded."

Additionally, 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 currently drafted, it could be misconstrued to [italic: only] apply if an insurer excludes "all" health services related to gender transition or other gender affirming care services; however, we believe the true intent is to proscribe exclusions of "any" such services.

To clarify this language and to protect access to gender affirming care, we strongly 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 [strikethrough: all] health services related to gender transition or other gender-affirming care:"

Furthermore, Section 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."

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0012
All Sections: 7.7.4
(b)(5)
Organization: Concerned Women for America

Excerpt Text:
[Underline: Peddles "gender affirmation" ideology and is a direct threat to youth struggling with identity]

Section 92.207 mandates a broad class of new health care coverage obligations based on a person's "gender identity" with no identification or reporting of documented associated risks and no limitation regarding age. So-called "standards of care" in this field are based on non-empirical self-reporting surveys and are highly controversial. Calls for review have been silenced by complicit medical associations like in the American Academy of Pediatrics. 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-fdasadverse-event-reporting-system-faers/january- march-2017-potential-signals-serious-risksnew-safetyinformation-identified-fda-adverse). Recently, the FDA added warnings about the potential harmful effects of puberty blocking drugs, including brain swelling and vision loss (see https://www.formularywatch.com/view/study-jak-inhibitors-may-have- different-side-effects).

A new review in the Journal of Sex and Marital Therapy evaluating the "Dutch protocol," which has been used to defend the use of puberty-blocking drugs and more severe forms of treatment on youth, cannot be ignored (see

https://www.tandfonline.com/doi/full/10.1080/0092623X.2022.2121238). The Department must be able to answer these questions: What evidence underlies the requirements for treating minors under "gender affirming care"? Are there any age limitations on treatment? Who determines this?

The Rule cannot ignore the evidence of bodily and psychological harm that use of unapproved drugs cause, especially for young people, yet that is what the Rule requires by defining any withholding of "gender affirming" treatment an act of discrimination. Gender transition regret is only growing which will substantially add to costs of repairing physical and mental health. What long-term scientific research and objective evidence exists to fully justify the safety and use of puberty blockers for purpose of gender exploration? What proof that these interventions "do no harm" exists to justify mandating coverage as a matter of "nondiscrimination"?

Here's what Garrett from Baton Rouge told Lesley Stahl on 60 Minutes (May 22, 2021): "I didn't get enough pushback on transition. I went for two appointments, and after the second one I had my letter to go get on cross-sex hormones." In just 3 months, Garrett went from taking hormones to getting his testicles removed. He later got a breast augmentation but instead of feeling better he felt worse. "I had never really been suicidal before until I had my breast augmentation and about a week afterwards I wanted to, like, actually kill myself. I had a plan and I was actually going to do it but I just kept thinking about my family to stop myself."

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0013
All Sections: 7.7.3, 7.7.2, 7.7.1, 6.1, 7.7.4

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
2. In section 92.101(a)(1) we recommend adopting the following change: "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, [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), (b)(2), and (b)(3). Utilizing this language will strengthen the rule by clarifying that discrimination motivated by multiple characteristics is prohibited.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0016
All Sections: 7.7.4

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:

Additionally, we support proposed Section 92.207's prohibition of discrimination in the coverage of gender-affirming and transition-related care. Transgender and gender diverse people face significant barriers to health care access, such as coverage exclusions, waiting periods, high cost sharing, lack of access to providers, and determinations that gender-affirming care is cosmetic or not medically necessary. These barriers to care are further heightened for Black, Indigenous, and other transgender people of color, as well as transgender people with disabilities. The proposed rule aims to protect transgender, nonbinary, intersex, and gender diverse people from discriminatory benefit design and other practices by insurers that are contrary to well-established standards of care, and realigns regulatory protections with the medical standards of care put forth by major medical associations.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0016
All Sections: 7.7.4

(b)(5)

Organization: Colors+

Excerpt Text:
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)(3):

"A covered entity must not, in providing or administering health insurance coverage or other health-related coverage: … (3) 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, underline: 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 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 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 a[bold: ll] health services related to gender transition or other gender-affirming care:"

Section 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."

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0016
All Sections: 7.7.4

(b)(5)

Organization: Concerned Women for America

Excerpt Text:
What long-term scientific research and objective evidence is available that justifies the use and safety of puberty blockers, cross sex hormones, and "gender confirming" surgeries for the purpose of gender transition of minors? What proof that these interventions "do no harm" exists to justify mandating coverage as a matter of "non-discrimination"?

Mandating coverage for "gender affirming care" for a teen girl wanting to remove her breasts is tantamount to requiring liposuction for an anorexic. Cosmetic reconstruction and hormone treatments will never make a female/woman a male/man. The idea that children could be "born in the wrong body" is unscientific - as scientifically preposterous as saying the earth is flat. To affirm a child's view of himself as "her" and call irreversible sex reassignment "health care" is insidious deception. Mutilating a youth's body for "gender exploration," causing long-term health risks, including loss of IQ, decrease in bone density, increased risk of cancer, vision impairment, and sterilization, is nothing short of child abuse. No ethical medical practice should be engaged in such practice, and no insurer forced to cover the evolving "queer" and "gender fluid" ideology that would give anyone a claim to such medical services and fuel an insatiable market diverting scarce medical resources for cosmetic claims to "affirm" a person's physical appearance.

Does the Rule's nondiscrimination requirement allow for health services and insurance coverage related to sexual attraction fluidity exploration in therapy (SAFE-T) and other sexual orientation change efforts? Does the Rule's nondiscrimination requirement forbid discriminating against SAFE-T health care? Is SAFE-T part of the full spectrum of health care options related to a person's sexual orientation? If not, why not, especially in light of the empirical research cited in this study of sexuality attraction fluidity and well-being in the [Italics: Journal of Human Sexuality]:
https://www.journalofhumansexuality.com/_files/ugd/ec16e9_d0708a0dc82e4da78e0258eb96dc1467. pdf?

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0016
All Sections: 7.7.4

(b)(5)

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
5. In section 92.207(b)(4), which bars categorical coverage exclusions of services related to gender transition or other gender-affirming care, we recommend a small but important change. As drafted, the language 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 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 [Strikethrough: all] health services related to gender transition or other gender-affirming care:"

6. In section 92.207(b)(5), we recommend the following change to provide better clarity: "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 [Strikethrough: if such denial, limitation, or restriction results in discrimination on the basis of sex.]"

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0017
All Sections: 7.7.4

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Bold: Scope of Section 1557]

Section 1557 is expanding its scope to include health 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, "Section 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." Ibid., 54190 and 54220] Although the Department claimed that the proposed regulations would not "affirmatively require" [Footnote 42: Ibid., 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 will evaluate the extent of the plan's coverage of hysterectomies under other circumstances. [Footnote 43: Ibid.]

A provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to perform the procedure on transgender individuals in the same manner it provides the procedure for other individuals. [Footnote 44: Ibid., 54204.]

Under these guidelines, if a covered physician administered treatments or performed surgeries that [Italics: could] further gender transitions, that physician would [Italics: have to] provide them for gender transitions on the same terms, and insurance had to cover it, regardless of the independent medical judgment of the physician. [Footnote 45: According to the Department, "if a provider is not accepting new patients, the provider does not have to accept a new patient request from a transgender person." Ibid., 54205. However, all existing patients must be treated in a "nondiscriminatory" manner, and it was unclear whether a physician could stop taking new patients in response to the regulations or if the Department would consider that illegal discrimination as well.] Furthermore, the Department proposed no religious accommodation or exemption to its gender identity mandate or any other aspect of its proposed regulations.

Thus, the regulation, once finalized, would have forced many physicians, hospitals, and other health care providers to participate in "gender-reassignment" surgeries and treatments, even if it violated their religious beliefs or their best medical judgment. Moreover, because it applied so broadly, the regulation proposed could also force employers, individuals, and taxpayers to fund coverage for such procedures even if doing so conflicted with their sincere beliefs. However, those conflicts were averted by the revisions made in the subsequent 2020 Rule.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0017
All Sections: 7.7.4

(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
[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)(3):

"A covered entity must not, in providing or administering health insurance coverage or other health-related coverage: … (3) 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 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 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 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 [Bold/struck through: all] health services related to gender transition or other gender-affirming care:"

Section 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

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0017
All Sections: 7.6.10, 7.6.7, 7.7.4
(b)(5)
Organization: Center for Reproductive Rights

Excerpt Text:

Denials of access to and coverage for gender-affirming care are among the most common forms of discrimination against the LGBTQI+ communities. Therefore, the NPRM's proposal 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.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0019
All Sections: 6.2.1, 7.6.3, 7.6.7, 7.7.4, 7.6.4
(b)(5)
Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: C. The proposed rule should include transgender status as a protected 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 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).] 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; [Underline: 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 §156.1230 by the 2020 rule. However, because the proposed language of these protections differs from the language proposed under §92, we urge the Department to here, too, adopt language in the final rule consistent with the language in §92.101 to avoid confusion and ensure consistency of implementation.

Comment Number: HHS-OS-2022-0012-DRAFT-71242-0002
All Sections: 7.7.4

(b)(5)

Organization: National Alliance on Mental Illness

Excerpt Text:
Extending section 1557 protections to benefit design 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 higherv and the prospect of plan 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 fell considerably as the ACA was implemented,vi LGBTQ individuals continue to face considerable discrimination and poorer access to quality health care services.vii 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.viii Therefore, NAMI supports the clear prohibitions on discrimination in connection with health services related to medically necessary care, including gender-affirming care.

Comment Number: HHS-OS-2022-0012-DRAFT-65934-0002
All Sections: 9.1, 6.2.6, 7.7.4

(b)(5)

Organization: Sam & Devorah Foundation for Transgender Youth

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0002
All Sections: 7.6.3, 7.6.7, 7.7.4, 7.6.4

(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:
[Bold: TPCA recommends also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).]

Comment Number: HHS-OS-2022-0012-DRAFT-39933-0002
All Sections: 7.6.3, 7.6.7, 7.7.4, 7.6.4

(b)(5)

Organization: Minnesota Association of Community Health Centers

Excerpt Text:
[Bold: MNACHC recommends also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0022
All Sections: 7.7.4

(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
Consistent with our recommendations above, we suggest adding "transgender status" to section 92.207(b)(3):

"A covered entity must not, in providing or administering health insurance coverage or other health-related coverage: … (3) 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 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 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 [bold/strikethrough: all] health services related to gender transition or other gender-affirming care:"

Section 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 [strikethrough: if such denial, limitation, or restriction results in discrimination on the basis of sex."]

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0003
All Sections: 6.2.6, 7.6.3, 7.6.7, 7.7.4, 7.6.4, 6.2.5
(b)(5)

Organization: Health Care For All

Excerpt Text:
Protections against Discrimination on Basis of Sex

Sex discrimination disproportionately impacts women of color, LGBTQI+ 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 improper 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 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 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 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, therefore, recommend also including "transgender status" in § 92.206(b)(1), (b)(2) and (b)(4), and in §92.207(b)(3).

Comment Number: HHS-OS-2022-0012-DRAFT-74948-0003
All Sections: 7.7.4
(b)(5)
Organization: Center for Health and Welfare Policy, The Heritage Foundation

Excerpt Text:
[Bold: De facto regulation of medical practice and health insurance coverage]

A particularly controversial feature of the proposed rule is the Department's decision to reinterpret the Title IX prohibition of discrimination "on the basis of sex" to include "discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity." [Footnote 16: Ibid. proposed 45 CFR § 92.201(a)(2).]

Setting aside the issue of the legitimacy of that reinterpretation, the most significant implication for health insurers is that it provides the predicate for the Department to assert de facto authority over medical practice and over the relationship between health insurance and medical care under the pretext of implementing and enforcing Title IX and the other civil rights laws that are incorporated by reference in Section 1557. [Footnote 17: Pub. L. 111-148 § 1557, codified at 42 U.S.C. § 18116.]

Specifically, in its proposed § 92.206 the Department asserts authority to establish parameters for the practice of medicine by health care providers in connection with "gender transition or other gender-affirming care," and does the same with respect to insurer coverage and payment practices in its proposed § 92.207.

Furthermore, the Department categorically states in § 92.206(c) that "a provider's belief that gender transition or other gender-affirming care can never be beneficial for such individuals (or 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."

Similarly, the Department categorically states in § 92.207(b)(4) that an insurer must not, "have or implement a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care."

In discussing these provisions, the Department states that, "claims of medical necessity that are not based upon genuine medical judgments will be considered evidence of pretext for discrimination. For example, issuers have historically excluded services related to gender affirming care for transgender people as experimental or cosmetic (and therefore not medically necessary). Characterizing this care as experimental or cosmetic would be considered evidence of pretext because this characterization is not based on current standards of medical care." [Footnote 18: "Nondiscrimination in Health Programs and Activities," p. 47874.]

Thus, in the proposed rule the Department is explicitly asserting that it has authority under Section 1557 to regulate, in detail, the practice of medicine and the structure of health insurance coverage according to its own determination of what is "appropriate" and "non-discriminatory," along with authority to definitively determine what is, or is not, the "current standard of medical care."

While in the proposed rule the Department makes this assertion most explicitly with respect to "gender transition or other gender-affirming care," there is no limiting principle preventing the Department from, in the future, asserting and exercising the same, or similar, claims of authority with respect to other medical practices, standards of care, or health insurance coverages.

Indeed, the proposed § 92.207(d) states that, "The enumeration of specific forms of discrimination in paragraph (b) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section."

Given the overall structure of the proposed rule, the Department's stated intention to apply "disparate impact" analyses, and the fact that the proposed rule also incorporates a sweeping definition of "disability" under the Americans with Disabilities Act, it is largely a matter of when, not if, the Department will assert the same authority with respect to other medical conditions, practices, and health insurance coverages. [Footnote 19: Ibid. The definition of "disability" in the proposed 45 CFR § 92.4 states, "Disability means, with respect to a person, a physical or mental impairment that substantially limits one or more major life activities of such

person; a record of such an impairment; or being regarded as having such an impairment, as defined and construed in the Rehabilitation Act, 29 U.S.C. 705(9)(B), which incorporates the definition of disability in the ADA, 42 U.S.C. 12102, as amended and adopted at 28 CFR 35.108." The referenced 42 U.S.C. 12102 states in (2)(B) that, "a major life activity also includes the operation of a major bodily function, including but not limited to, functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions." The referenced 28 CFR 35.108 states in (c)(1)(ii) that, "The operation of a major bodily function, such as the functions of the immune system, special sense organs and skin, normal cell growth, and digestive, genitourinary, bowel, bladder, neurological, brain, respiratory, circulatory, cardiovascular, endocrine, hemic, lymphatic, musculoskeletal, and reproductive systems. The operation of a major bodily function includes the operation of an individual organ within a body system."]

Indeed, there are those who have advocated for years that the reference to the Americans with Disabilities Act in Section 1557 should be used as an avenue for regulating insurers with respect to numerous other medical conditions in the same fashion as the proposed rule would regulate them with respect to gender transition treatments. [Footnote 20: See: Douglas Jacobs, "The Section 1557 Regulation: What's Missing, And How We Can Include It," Health Affairs Blog, September 21, 2015, http://healthaffairs.org/blog/2015/09/21/the-section-1557-regulation-whats-missing-and-how-we-can-include-it/, and Douglas Jacobs and Wayne Turner, "Nondiscrimination And Chronic Conditions -- The Final Section 1557 Regulation," Health Affairs Blog, July 20, 2016, https://www.healthaffairs.org/do/10.1377/forefront.20160720.055888.]

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0036
All Sections: 4.3.1.2.5, 7.7.4

(b)(5)

Organization: Center for American Progress

Excerpt Text:

XII. Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage (§ 92.207)

a. Access to Coverage for Gender-Affirming Care and Other Health Care Services

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 Section 1557 do apply to insurance. We support the Proposed Rule's prohibition of nondiscrimination in the coverage of gender-affirming and transition-related care, which aims to protect individuals from discriminatory benefit design and other practices by insurers which are contrary to well-established standards of care. This section is

particularly important to help address the many challenges that transgender and nonbinary people encounter when seeking access to insurance coverage.

Although transgender people benefited from the adoption of the ACA, disparities persist in the uninsured rate for transgender people compared with cisgender people and transgender people who have insurance continue to be denied coverage for medically necessary services, including gender-affirming care [Footnote 80: Wyatt Koma and others, "Demographics, Insurance Coverage, and Access to Care Among Transgender Adults" (San Francisco: Kaiser Family Foundation, 2020), available at https://www.kff.org/health-reform/issue-brief/demographics-insurance-coverage-and-access-to-care-among-transgender-adults/] [Footnote 81: Matthew Bakko and Shanna K. Kattari. "Transgender-Related Insurance Denials as Barriers to Transgender Healthcare: Differences in Experience by Insurance Type," Journal of General Internal Medicine 35 (6) (2020): 1693–1700, available at https://pubmed.ncbi.nlm.nih.gov/32128693/]. For example, issuers continue to maintain internal coverage guidelines that exclude an array of medically necessary gender-affirming surgeries by designating these procedures as "cosmetic" or "not medically necessary" despite strong clinical evidence and standards of care that find these procedures medically necessary to provide gender-affirming care, including by treating gender dysphoria, improving mental health, and improving quality of life [Footnote 82: Connecticut Commission on Human Rights and Opportunities, "Declaratory Ruling on Petition Regarding Health Insurers' Categorization of Certain Gender-Confirming Procedures as Cosmetic" (Hartford, CT: 2020), pp. 10–12, available at https://www.glad.org/wp-content/uploads/2020/04/Dec-Rule_04152020.pdf].

New data from CAP's nationally representative survey emphasize the need to address discriminatory health insurance policies and to improve access to coverage for transgender and nonbinary people. Overall, 30 percent of transgender or nonbinary people, including 47 percent of transgender or nonbinary people of color, reported experiencing one form of denial by a health insurance company in the past year. These kinds of refusals can include a range of experiences when respondents reported barriers to access care both related to and unrelated to gender affirmation. For example, 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.

? 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.

? 15 percent of transgender or nonbinary respondents, including 33 percent of transgender or nonbinary respondents of color, reported that a health insurance company denied them coverage for gender-specific preventive care.

? 10 percent of transgender or nonbinary respondents, including 22 percent of transgender or nonbinary respondents of color, reported that a health insurance company denied them coverage for preventive care or screenings.

We strongly support this section and encourage the Department to adopt the following recommendations to strengthen this section. Consistent with our recommendations above, we suggest adding "transgender status" to § 92.207(b)(3). We also recommend a slight modification to § 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 proscribe exclusions of "any" such services. Thus, we propose deleting the word "all" from 2.207(b)(4):

"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 [strikethrough: all] health services related to gender transition or other gender-affirming care:"

As explained in more detail in the next section, we also believe that the terms "termination of pregnancy, contraception, fertility care, miscarriage management, pregnancy loss, maternity care, other reproductive and sexual health services, or any health services," should be added to § 92.207(b)(5).

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0042
All Sections: 7.7.4

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[Bold: Relevance of sex-based distinctions (and sex-based language):] The proposed rule's arbitrary excision from coverage determinations or service provision of sex-based language and sex-based clinical treatments puts patients in a precarious position. It also distorts 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 mammoplasty' 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 103: "For example, a health plan that excludes ''coverage for surgery, such as a vaginoplasty and mammoplasty'' 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 incudes a "general prohibition on the denial or limitation of health services, including those that are offered exclusively to individuals of one sex, to an individual based on the individual's sex assigned at birth, gender identity, or gender otherwise recorded." [Footnote 104: 87 Fed. Reg 47865.]

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0005
All Sections: 4.3.1.2.5, 7.7.2, 7.7.4, 4.3.1.2.3
(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
The Department's proposal to once again recognize Section 1557's application to private insurance continues this 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-lgbtqi-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.

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0008
All Sections: 7.7.1, 7.7.14, 7.7.4
(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:
III. [Bold: Sex Discrimination Coverage]

U.S. health insurance and other health-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 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 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_us-pdfmembers.pdf)] that providers do not take their fertility concerns seriously, instead "emphasiz[ing] 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 programs and contraceptive coverage mandates. This results in discrimination against people of color and people with low- incomes who face higher rates [embedded hyperlink text (https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception)] of unintended pregnancy and adverse reproductive health outcomes due to these barriers. Robust enforcement of Section 1557 is necessary to ensure health entities and providers do not perpetuate discriminatory policies against contraceptive care.

PRH agree 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. Thus, we strongly support HHS' restoration of and improvements to § 92.207, including its inclusion of specific forms of prohibited discrimination. However, as with proposed § 92.206, HHS must strengthen the text of proposed § 92.207 to address sex discrimination related to pregnancy or related conditions, such as discrimination related to abortion, fertility care, and contraception.

RECOMMENDATION: We urge HHS 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, [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, [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; or

(7) [Italics: 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 restriction results in discrimination on the basis of sex.]

In addition, we urge HHS to specify in the preamble that the health services addressed in our proposed § 92.207(b)(7) include both the full spectrum of reproductive and sexual health services and treatments and medications for patients that may prevent, complicate, or end fertility or pregnancies.

Comment Number: HHS-OS-2022-0012-DRAFT-43609-0008
All Sections: 7.7.4

(b)(5)

Organization: Endocrine Society

Excerpt Text:
Additionally, the proposed rule will prohibit covered entities from having or implementing a categorial coverage exclusion or limitation for all health services related to gender-affirming care. Currently, treatment for gender dysphoria/gender incongruence is often considered elective by insurance companies and many plans will not cover it. We support this provision because gender affirming care is both medically necessary and lifesaving [Footnote 4: Endocrine Society. Transgender Health. September 2017 https://www.endocrine.org/advocacy/priorities-andpositions/transgender-health]. Transgender individuals who have been denied care have an increased likelihood of dying by suicide and engaging in self-harm [Footnote 5: Davidge-Pitts C, Nippoldt TB, Danoff A, Radziejewski L, Natt N. Transgender Health in Endocrinology: Current Status of Endocrinology Fellowship Programs and Practicing Clinicians. J Clin Endocrinol Metab. Apr 1 2017;102(4):1286-1290. doi:10.1210/jc.2016-3007]. Prohibiting insurers from categorically excluding gender affirming care will improve mental health outcomes in transgender individuals.

Section 7.7.5 - Integrated setting; Olmstead v LC (§92.207(b)(6))

Comment Number: HHS-OS-2022-0012-DRAFT-36046-0001
All Sections: 7.7.5

(b)(5)

Organization: Pulmonary Fibrosis Foundation

Excerpt Text:
These comments will address the addition of § 92.207(b)(6). We commend HHS and OCR for the addition of this provision. We appreciate that this provision explicitly states that health insurance coverage and health-related coverage must include the provision or administration of

that coverage in the most integrated setting appropriate to the needs of covered individuals with disabilities, as it acknowledges a fundamental tenet of disability rights law and the pivotal 1999 Supreme Court decision in Olmstead v. Zimring. By explicitly incorporating this requirement into Section 1557, people with disabilities and disability advocates can use it to point out an increased risk of isolation, unmet health care needs, and lost functional capacity they experience when state Medicaid agencies, Medicare plans or private insurance policies place arbitrary distinctions on when and where services or treatments can be provided.

This new provision provides a standard against which unreasonable coverage restrictions found in Medicare Advantage and Exchange plans can be assessed. For example, a "use-in- the-home" policy that is applied to determine when an insurer will cover the provision of medically necessary supplemental oxygen for Medicare beneficiaries potentially runs afoul of this provision if the policy is used to deny oxygen equipment or services that an individual needs to access the broader community outside their home. Most patients with PF will need to use supplemental oxygen as their disease progresses. Patients with PF who use oxygen report being prevented from receiving the types of oxygen systems and amount of oxygen supplies that they would need for activities in the community. Any policy that only considers covering an individual's supplemental oxygen equipment and services if the supplemental oxygen is strictly needed for activities of daily living (e.g., toileting, grooming, eating) within the house, irrespective of the individual's need for oxygen to travel any distance outside of the home or undertake desired activities within the community such as attending a doctor's appointment, shopping, getting to work, attending worship services, or sharing a meal with a friend, is potentially discriminatory because it is an administration of health insurance benefits that denies the most integrated setting appropriate to the individual.

A home in the community may be less restrictive than an institutional placement but making medical benefits conditional on their exclusive use within one's home effectively serves to imprison a beneficiary within that home when beneficiaries fail to receive coverage of medically needed services, treatments, and items that enable them to function independently and safely in the community at large. The positive obligation to use benefit designs that provide coverage "in the most integrated setting appropriate to the needs" is particularly needed [underline: as states increasingly turn to managed care plans to administer Medicaid]. Large plans that administer a range or employer, private small group and individual plans, as well as public Medicare and Medicaid plans, could easily default to unified coverage policies for things like oxygen, wheelchairs, and other durable medical equipment that contradict a stated desire to emphasize community integration and rebalancing.

Comment Number: HHS-OS-2022-0012-DRAFT-67996-0010
All Sections: 7.7.5

(b)(5)

Organization: The Alabama Disabilities Advocacy Program

Excerpt Text:

We also want to applaud the addition of § 92.207(b)(6). The explicit requirement that health insurance coverage and health-related coverage must include the provision or administration of that coverage in the most integrated setting appropriate to the needs of covered individuals with disabilities acknowledges a fundamental tenet of disability rights law and the pivotal 1999 Supreme Court decision in Olmstead v. L.C. ex rel. Zimring. By explicitly incorporating this requirement into Section 1557, people with disabilities and disability advocates can use it to point out an increased risk of isolation, unmet health care needs, and lost functional capacity they experience when state Medicaid agencies, Medicare plans or private insurance policies place arbitrary distinctions on when and where services or treatments can be provided. For example, coverage of treatments needed by people with a range of chronic conditions such as podiatric care or diabetes management or physical therapy, or even home vaccinations needed by people with significant mobility disabilities during a pandemic, cannot be made available only to members/beneficiaries who are in institutional care if those who reside in the community have the same medical need for the treatment. The fact that it might be more convenient or less expensive to administer those treatments to institutional residents who are gathered in one location is not a factor that is relevant to clinical or medical standards of care.

ADAP has numerous, recent experiences involving clients who faced institutionalization in order to receive the care that they need. The first client facing this difficult circumstance was C.R. A thirty-one-year-old woman who both has an intellectual disability and is ventilator-dependent, C.R. had been receiving care in the community under Alabama's HCBS Waiver for Persons with Intellectual Disability (ID Waiver). The personal care and skilled nursing/respite were being provided by a third-party provider. This provider notified C.R.'s father, J.R., that her services would be terminated effective October 31, 2021. The provider gave no reason for the termination in their written notice, but through J.R.'s phone conversations, he figured out it was due to a lack of workers which the provider blamed on the state's lower reimbursement rates.

ADAP resolved this issue with the state through litigation, with the state moving C.R. to the state's Technology Assisted (TA) HCBS Waiver, which had more provider availability and a higher reimbursement rate. While the outcome in this case was ultimately positive, a robust interpretation of Section 1557 would surely have assisted C.R. in receiving services. Her risk of institutionalization under the Olmstead framework would result in the provider discriminating against her under this 1557 interpretation, which would have given her another avenue to redress the issue.

Another series of clients that ADAP is currently advocating for involve several children throughout the state who are ventilator dependent. All of them are co-enrolled in Alabama Medicaid's EPSDT program and the state's HCBS Waiver for the Elderly and Disabled (E&D Waiver). Further, under this waiver, all of the clients are approved for various amounts of personal care and/or skilled/unskilled respite care. However, none of them have received the entirety of the hours of care which they are approved for. For many opting to use the traditional provider method of care delivery (as opposed to the self- directed option), this lack of hours comes down to lack of provider capacity to handle the hours. Again, while the larger issue is with the state's administration of waiver program, ensuring protections from provider discrimination is equally necessary in these situations, and 1557 would again act as a stopgap to prevent provider discrimination from the start.

At the same time, the new provision also provides a standard against which unreasonable coverage restrictions found in Medicare Advantage and Exchange plans can be assessed. For example, an "use-in-the-home" policy that is applied to determine when an insurer will cover the provision of medically necessary wheelchairs for Medicare beneficiaries potentially runs afoul of this provision if the policy is used to deny a wheelchair that an individual needs to access the broader community outside their home. Any policy that only considers covering an individual's wheelchair and ancillary equipment and services if the wheelchair is strictly needed for activities of daily living (e.g., toileting, grooming, eating) within the house, irrespective of the individual's need for a wheelchair to travel any distance outside of the home or undertake desired activities within the community such as shopping, getting to work, attending worship services, or sharing a meal with a friend, is potentially discriminatory because it is an administration of health insurance benefits that denies the most integrated setting appropriate to the individual. A home in the community may be less restrictive than an institutional placement but making medical benefits conditional on their exclusive use within one's home effectively serves to imprison a beneficiary within that home when beneficiaries fail to receive coverage of medically needed services, treatments, and items that enable them to function independently and safely in the community at large. The positive obligation to use benefit designs that provide coverage "in the most integrated setting appropriate to the needs" is particularly needed as states increasingly turn to managed care plans to administer Medicaid [Hyperlink: https://www.macpac.gov/subtopic/enrollment-and-spending-on-medicaid-managed-care/]. Large plans that administer a range or employer, private small group and individual plans, as well as public Medicare and Medicaid plans, could easily default to unified coverage policies for things like wheelchairs and other durable medical equipment that contradict a stated desire to emphasize community integration and rebalancing.

Comment Number: HHS-OS-2022-0012-DRAFT-70479-0011
All Sections: 7.7.5

(b)(5)

Organization: National Disability Rights Network

Excerpt Text:
[Bold: § 92.207 - Nondiscrimination in health insurance coverage and other health-related coverage]

We strongly support the addition in this proposed regulation of an explicit provision detailing the integration mandate which will ensure that this provision is correctly understood and interpreted.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0011
All Sections: 7.7.5

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
We also support the inclusion of Section 92.207(b)(6), i.e. the "integration mandate" that requires "services, programs, and activities [be administered] in the most integrated setting appropriate to the needs of qualified individuals with disabilities." It is necessary for the rule to specifically address the integration mandate given its role in ensuring disabled people are not segregated in health care settings. Far too often hospital systems and providers have pushed people with disabilities into long-term institutionalization due to their dependency on certain services, going against the rights given to disabled people in the Americans with Disabilities Act and the Olmstead decision. [Footnote 9: Olmstead v. Lois Curtis, 527 U.S. 581 (1999).] and thus necessitating HHS to explicitly add the integration mandate in Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-40175-0011
All Sections: 7.7.5
(b)(5)

Organization: California Department of Health Care Services

Excerpt Text:
[Underlined: Integration mandate in Medicaid benefit design]: The NPRM would prohibit state Medicaid programs from having or implementing a benefit design that does not provide coverage in the most integrated setting appropriate to the needs of an individual with disabilities. This would not only apply to direct benefit design features, but also to an open-ended range of indirect mechanisms that "affect" implementation of such designs including reimbursement rates and incentive structures, utilization management policies, contracting relationships, and quality assessments. While we recognize that Medicaid programs are already subject to the integration mandate stemming from Section 504 of the Rehabilitation Act, the proposed regulatory text makes no mention of the longstanding limiting principle that states are not required to make fundamental alterations to their programs as a result of this command. This stands in contrast to other provisions in the rule which strike a more appropriate balance by expressly recognizing that modifications cannot impose undue fiscal or administrative burdens upon states or fundamentally alter a program or activity (see, for example, proposed Sections 92.204 and 92.205). If finalized, DHCS believes it is imperative that these same exceptions are sufficiently incorporated into the language of Section 92.207(b)(6).

Comment Number: HHS-OS-2022-0012-DRAFT-64284-0011
All Sections: 7.7.5
(b)(5)

Organization: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Excerpt Text:

4. The MRCT Center suggests that OCR clarify that health benefits should not be compromised by complying with the integration mandate of Title II of the ADA. The same coverage, for example, of home health services should be provided for people cared for in institutions, living in congregate structures, or living in community-based settings.

Comment Number: HHS-OS-2022-0012-DRAFT-67996-0011
All Sections: 7.7.2, 7.7.5

(b)(5)

Organization: The Alabama Disabilities Advocacy Program

Excerpt Text:
While ADAP's experience with Medicare Part C and Exchange plans is admittedly limited, we have seen barriers to accessing health care through the state's Medicaid program, both in the managed and traditional context. Alabama has started operating a managed Medicaid system through a 1915(b) waiver [Hyperlink: https://medicaid.alabama.gov/content/5.0_Managed_Care/default.aspx]. Called the Alabama Coordinated Health Networks (ACHN), the goal of the delivery system is to be "a more flexible and cost- efficient effort." While the specifics of this delivery method have yet to borne out in specific issues, it is likely that the ACHN will continue and potentially increase the barriers of access to care in the traditional Medicaid sphere.

A specific ad hoc policy that has pervaded the Medicaid delivery space is barriers in accessing durable medical equipment (DME). ADAP has two recent examples regarding these hurdles. In both cases, the client was trying to receive a wheelchair, and both clients qualified under the DME conditions enumerated in the Medicaid Provider Manual's DME section [Hyperlink: https://medicaid.alabama.gov/content/Gated/7.6.1G_Provider_Manuals/7.6.1.4G_Oct2022/Oct22_14.pdf]. However, in both cases, the state's agencies were recalcitrant to providing the needed wheelchair.

First, T.C. is an adult in her sixties who had diabetic complications resulting in the amputation of her leg. A recipient of general Medicaid, she tried to obtain a prior authorization to receive her wheelchair. The first request was denied, and the reason given was unrelated to any of the criteria Medicaid lists in its coverage requirements, but rather related to the cost of the wheelchair by a specific provider. Eventually, we were able to discuss the issue with both the provider in question and the state agency, leading to T.C. being fitted for and receiving the wheelchair she needed.

Second. K.G. is a child who has the diagnoses of acute flaccid myelitis, chronic respiratory failure (resulting in her being dependent on a ventilator), quadriplegia, dysphagia, hypertension, gaseous abdominal distention, idiopathic constipation, dysmotility, osteoporosis, generalized anxiety disorder with panic attacks, bilateral dry eye syndrome, Postural Tachycardia Syndrome (POTS), recurrent vertigo, and autonomic dysfunction. She needed a wheelchair both to be involved in her community and to make it to the numerous appointments related to her diagnoses. Despite being 11 years-old and having grown a fair bit, she was relying on a

wheelchair provided for her when she was five. Again, her situation met the criteria spelled out in the DME section of the provider manual (and arguably should have been covered through EPSDT's "medical necessity" provision), but her request took months to be processed. The timeline was so lengthy that it functioned as an effective denial. When the agency finally reached out, they insisted that she has to be fitted for the wheelchair and that would include her passing a usability test (something not present in the manual at all). The insistence that she pass this test to receive the wheelchair was arbitrary, and constituted discrimination of the basis of her disability, leaving her at great risk of institutionalization.

Comment Number: HHS-OS-2022-0012-DRAFT-70479-0013
All Sections: 7.7.5
(b)(5)
Organization: National Disability Rights Network

Excerpt Text:
[Bold: §92.207(b)(6) - Integration Mandate]

We strongly support HHS clarification of the application of the provisions of Section 504 and the Americans with Disabilities Act known as the integration mandate. We are supportive of the addition of explicit regulatory text addressing this issue. Section 1557 explicitly references Section 504, which has regulatory requirements to provide services and programs in the most integrated setting appropriate to the needs of individuals with disabilities and has consistently been interpreted as requiring those receiving federal financial assistance to not segregate individuals with disabilities from their communities. [Footnote 1: 45 C.F.R § 84.4(b)(2) ("aids, benefits, and services . . . [must afford equal opportunity] . . . in the most integrated setting appropriate to the person's needs."); Olmstead v. L.C. ex rel. Zimring, 527 U.S. 581 (1999); see, e.g., Pashby v. Delia, 709 F.3d 307, 321 (4th Cir. 2013) (both Section 504 and the ADA contain the same integration requirements and the claims may be considered together); Am. Council of the Blind v. Paulson, 525 F.3d 1256, 1266 (D.C. Cir. 2008); Henrietta D. v. Bloomberg, 331 F. 3d 261, 272 (2d Cir. 2003); see also Townsend v. Quasim, 328 F.3d 511, 517 (9th Cir. 2003) (where the issue is the location of services provided -- institution versus community -- rather than whether services should be provided, Olmstead controls). Although the Court in Olmstead noted that Section 504 does not contain the same express recognition that isolation or segregation of persons with disabilities is form of segregation, the regulations make such a recognition and case law enforcing the community integration mandate have consistently found violations of 504 due to segregation of people with disabilities and not providing services in the most integrated setting appropriate to their needs. See, e.g., Day v. D.C., 894 F. Supp. 2d 1, 4 (D.D.C. 2012) (noting the lack of express recognition but relying on the regulations); Steimel v. Wernert, 823 F.3d 902, 911 (7th Circ. 2016) (finding integration mandate violations because the Defendant's service system design, planning, funding choices, and service implementation promoted or relied on segregation of people with disabilities); Waskul v. Washtenaw Cnty. Cmty. Mental Health, 979 F.3d 426, 462 (6th Cir. 2020) (policies limiting plaintiffs' access to the community and activities violated the integration mandated).]

Importantly, Section 504 also prohibits covered entities from utilizing criteria or methods of administration that "have the purpose of or effect defeating or substantially impairing accomplishment of the objectives of the recipient's program or activity" or otherwise discriminates against people with disabilities. [Footnote 2: 45 C.F.R. 84.4(b)(4).] Therefore, covered entities under Section 1557 are prohibited from providing health programs and services in settings that are more segregated than are appropriate to the needs of people with disabilities, and from employing coverage policies, benefit design, coverage decisions, and other criteria and methods of administration that will do the same.

People with disabilities were historically segregated in institutional settings due to ablism and misconceptions about ability; this systemic discrimination continues today and is built into many of health care systems and processes. [Footnote 3: National Council on Disability, Olmstead: Reclaiming Institutionalized Lives (Sept. 29, 2003), https://ncd.gov/publications/2003/aug192003.] This needless segregation of individuals with disabilities identified clearly in [Italics: Olmstead v. L.C.], 527 U.S. 581 (1999), continues through the structure and processes of health care today. The ACA dramatically shifted what discrimination in health care and health-related services looks like, especially for non-public health plans. [Footnote 4: See Amicus Brief of Nat'l Health L. Program et al. in Doe v. CVS, available at https://healthlaw.org/resource/amicus-brief-from-national-health-law-program-in-cvs-v-doe/ (discussing history of disability discrimination in health coverage and how the ACA changed the landscape, but did so in a way that allows insurers to have nondiscriminatory limitations on coverage and services); Schmitt v. Kaiser, 965 F.3d 945, 954-59 (discussing how Section 504 may not have prohibited discriminatory benefit design, but the ACA and Section 1557 does).] While Section 504 allowed various insurance policies that discriminated against people with disabilities, the ACA – and the incorporation of Section 504 in Section 1557 -- explicitly prohibited many of these same policies. [Footnote 5: Id.]

We are extremely glad that the HHS has provided an explicit mention in the regulatory text and extensive discussion in the proposed rule about the details of this discrimination. We strongly support the proposal's specific mention of "utilization management practices, provider reimbursement, contracting out to third party- contractors such as pharmacy benefit managers, and quality measurement and incentive systems" as areas where covered entities should pay careful attention. We also agree with HHS's examples of plans requiring prior authorization or step therapy or other utilization management when individuals are accessing a medication in the community, but not using these tools when individuals are institutions would count as discrimination. A further example is the prohibition on retroactive coverage of HCBS and the fact that HCBS will not be covered for any date preceding the date on which a Medicaid HCBS service plan is approved. [Footnote 6: Centers for Medicare & Medicaid Services, Application for a § 1915(c) Home and Community-Based Waiver; Instructions, Technical Guide and Review Criteria, at 52, 73 (Appendix B), 190 (Appendix D-1):] This is not the case for nursing facilities, where retroactivity is possible.

As mentioned earlier, we strongly disagree with the language in the preamble that a covered entity like a state Medicaid program would generally not be required to provide a new benefit because that would fundamentally alter the program. [Footnote 7: 87 Fed. Reg. 47873.] This language, although it includes the qualifier of "generally", is not entirely consistent with case law

and could lead to arguments that would unjustly be relied upon by covered entities to limit access to non-discriminatory, integrated care. [Footnote 8: See, e.g., Townsend, 328 F.3d at 516-521; Hampe v. Hamos, 917 F.Supp.2d 805 (N.D. Ill. 2013); Lane v. Kitzhaber, 283 F.R.D. 587 (D. Or. 2012).] We ask that HHS correct this language in the publishing of the final rule. Although a covered entity may be able to use a fundamental alteration defense to establish that creation of a new service would fundamentally alter their services or otherwise be unreasonable, they may sometimes be required to create a new service to avoid discrimination.
For example, a covered entity that provides for services in an institutional setting may have to create those services in the community where they have not existed before, including creating coverage policies, provider networks, and other functionalities to ensure that people with disabilities are not forced to go to more segregated settings than are appropriate for their needs to receive the service. In one practical example, an insurer that only provides for residential treatment for certain SUD conditions and does not provide coverage of such services in community-based settings that are clinically appropriate may need to "create" a new benefit in that they have not offered that benefit in the community before, it may go under a different name with different clinical standards, etc. In addition, an entity may have to cover a service that it may want to term as "new" in order to not be discriminatory in coverage even though the service sought is within the existing services being provided. [Footnote 9: Plans already deny services based on coverage discriminatory coverage exclusions that would push needed services into being considered outside of coverage of the plan or potentially "new" to the plan. See, e.g., Schmitt v. Kaiser, 965 F.3d 945 (discussing coverage exclusion of certain hearing services); N.R. Raytheon, 24 F.4th 740 (1st Cir. 2022) (discussing exclusions based on Autism diagnosis); Duncan v. Jack Henry & Assocs., Inc., No. 6:21-CV-03280-RK, 2022 WL 2975072 (W.D. Mo. July 27, 2022) (discussing exclusions for gender affirming surgery compared to other covered surgeries). Furthering the idea or presumption of not having to cover "new" or "services outside the plan" would likely lead to more discriminatory denials.]

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0015
All Sections: 7.7.5

(b)(5)

Organization: American Academy of Family Physicians

Excerpt Text:
HHS is also proposing to require health insurance coverage to provide the most integrated setting appropriate to the needs of individuals with disabilities. The AAFP strongly supports this proposal because health insurance and payment should not interfere with a patient's equitable access to medically necessary, evidence-based clinical care [Hyperlink: https://www.aafp.org/about/policies/all/health-care-for-all.html].

Comment Number: HHS-OS-2022-0012-DRAFT-66437-0020
All Sections: 7.7.3, 7.7.5

(b)(5)

(b)(5)

Organization: Center for Elder Law & Justice

Excerpt Text:

[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 dissuading 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 $18,000 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0024

All Sections: 7.7.5

(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:

14. Nondiscrimination in health insurance and other health-related coverage (§92.207): This 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 su bsection 92.101(b)(1), also incorporates existing Section 504 regulations at 45 CFR Part 84, including 45 CFR 84.4(b)(2).)

Recommendation: BCBSA 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
(i) modifying the benefit design would fundamentally alter the nature of the health insurance coverage or other health-related coverage, or
(ii) 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 non-discriminatory 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 ach ievement 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 person's needs."

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0029
All Sections: 7.7.5
(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
We also strongly support the proposed rule's § 92.207(b)(6), which rightly 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. Zimring] [Footnote 121: Olmstead v. L.C. ex rel. Zimring, 527 U.S. 581 (1999).] and allows patients with disabilities and disability advocates to highlight their increased risk of isolation, unmet health care needs, and lost functional capacity when public and private insurance providers and policies place arbitrary distinctions on when and where services or treatments may be provided.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0039
All Sections: 7.7.5
(b)(5)

Organization: Center for American Progress

Excerpt Text:

c. Integration Mandate

We strongly support the addition of the integration mandate to the proposed rule, as this can apply to a variety of services and treatments that unjustly isolate disabled people from their communities. We encourage the application of the integration mandate across a range of health services, including mental health and behavioral health services.

We also encourage the Department to apply the integration mandate to state Medicaid programs, Medicare plans, and private insurance providers given the institutional bias in long-term supports and services that often results in the segregation and institutionalization of older people and people with disabilities [Footnote 87: Amber Christ and Natalie Kean, "Medicaid Home and Community-based Services for Older Adults with Disabilities: A Primer" (Washington: Justice in Aging, 2021), available at https://justiceinaging.org/wp-content/uploads/2021/04/HCBS-Primer.pdf]. This can occur when access to treatments or services is only covered for individuals in institutional care. Access to home and community-based services (HCBS) can be essential to community living and health outcomes, but waiting lists for such services indicate widespread unmet need [Footnote 88: Natalie Chong and others, "The relationship between unmet need for home and community-based services and health and community living outcomes," Disability and Health Journal 15 (2) (2022), available at https://www.sciencedirect.com/science/article/abs/pii/S1936657421001953?fr=RR-2&ref=pdf_download&rr=74b427f4cc3dc44a]. In 2018, about 820,000 people were on a waiting list for HCBS; however, half of states spent twice as much on institutional care compared to HCBS for older and disabled people [Footnote 89: Amber Christ and Natalie Kean, "Medicaid Home and Community-based Services for Older Adults with Disabilities: A Primer" (Washington: Justice in Aging, 2021), available at https://justiceinaging.org/wp-content/uploads/2021/04/HCBS-Primer.pdf].

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0004

All Sections: 7.7.5

(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:

[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 48% 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 discrimination 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 wipe 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.

Comment Number: HHS-OS-2022-0012-DRAFT-39933-0004
All Sections: 7.7.5

(b)(5)

Organization: Minnesota Association of Community Health Centers

Excerpt Text:
[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 48% 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 discrimination 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 wipe 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0052
All Sections: 7.7.5

(b)(5)

Organization: Justice in Aging

Excerpt Text:
[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 in rooting out the deeply imbedded institutional biases in our health care and LTSS systems.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0053
All Sections: 7.7.5

(b)(5)

Organization: Justice in Aging

Excerpt Text:
We agree 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. 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 (despite 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 outpatient visit 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 "encounters" 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 (NEMT) and onerous pre-authorization processes are another barrier. For many people with disabilities living in the community, NEMT is essential to get any health services at all and should be easily accessible. Requiring a person needing dialysis, for example, to get pre-authorization for each and every NEMT ride effectively imposes an additional pre-authorization on the dialysis service itself that does not exist in an institutional setting.
- Lack of access to dental care can be a barrier to community living for older adults and people with disabilities because untreated oral health conditions are detrimental to overall health. [Footnote 45: See Justice in Aging, Adding a Dental Benefit to Medicare: Addressing Oral Health Inequity Based on Disability (Oct. 2020), https://justiceinaging.org/wp-content/uploads/2020/10/Adding-a-Dental-Benefit-to-Medicare- Disability.pdf (noting that 62% of individuals with disabilities under 65 report that they have not seen a dentist in the last year and that lack of accessibility and training contributes to oral health disparities for people with disabilities).] Federal skilled nursing regulations mandate that dental services be made available in nursing facilities. There is no similar Medicaid mandate for HCBS. Although some HCBS waivers (typically for I/DD populations) include dental, most older adults and other people with disabilities in the community are on their own for dental care.

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0006
All Sections: 7.7.1, 7.7.5
(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:
[Bold: TPCA 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.

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: Thus TPCA strongly supports HHS' restoration of and improvements to § 92.207, including its inclusion of specific forms of prohibited discrimination.]

Comment Number: HHS-OS-2022-0012-DRAFT-66245-0007
All Sections: 7.7.5
(b)(5)

Organization: Institute for Exceptional Care

Excerpt Text:
[Bold: Design features of insurance or plan benefits that result in segregation or institutionalization of individuals with disabilities or place them at serious risk of institutionalization or segregation]
IEC 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-1499?rskey=rKVI3G&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 mid1950s, 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 human body waste remains. Sexual and physical abuse and disease were common.

Comment Number: HHS-OS-2022-0012-DRAFT-66245-0008
All Sections: 7.7.5
(b)(5)

(b)(5)

Organization: Institute for Exceptional Care

Excerpt Text:

[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&currentTimeframe=0&selectedDistributions=idd&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D], 810,300 people with IDD 1915(c) waiver participants, comprising 42.59 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&currentTimeframe=0&selectedDistributions=total-waiting-list-enrollment&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%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&currentTimeframe=0&selectedDistributions=total-waiting-list-enrollment&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D], 464,398 people with IDD represent 70.00 percent of the total 665,015 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0009
All Sections: 7.7.3, 7.7.2, 7.7.5

(b)(5)

Organization: National Health Council

Excerpt Text:

[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.

Section 7.7.6 - Applicable coverage requirements; medical necessity; utilization/medical management techniques (§92.207(c))

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0011
All Sections: 7.7.6

(b)(5)

Organization: National Health Council

Excerpt Text:
As described in the proposed rule's preamble, 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 their costs 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, nondiscriminatory reason, based on clinical evidence, for the practice."]

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0012
All Sections: 7.6.10, 7.7.6

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:
[Bold: 1. HHS should clarify the distinction between sex-based discrimination and nondiscriminatory 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 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 (or 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; that the use of the phrase "legitimate, nondiscriminatory reason" in these sections should not be construed in any way to limit the method of proof for any Section 1557 claim to the [Italics: McDonnell-Douglas] burden-shifting framework; and that this method cannot be used to defend an express sex-based classification that causes injury.

Comment Number: HHS-OS-2022-0012-DRAFT-67996-0009
All Sections: 7.7.3, 7.7.2, 7.7.6
(b)(5)

Organization: The Alabama Disabilities Advocacy Program

Excerpt Text:
ADAP strongly supports the proposed restoration of broad language prohibiting benefit design discrimination on the basis of disability or any other protected basis. People with disabilities have historically endured discrimination in health insurance, ranging from outright denial of

coverage to exorbitant premiums to exclusions, coverage caps, and "special" co-pays, higher co-insurance, and arbitrary exemptions that don't count toward a deductible, all triggered by the mere fact of having a disability or chronic condition [Hyperlink: https://scholarship.law.nd.edu/ndjlepp/vol25/iss2/16/].

Insurers were not required to share actuarial calculations justifying denials or imposing greater costs on people with disabilities, nor did they have to undertake any kind of individualized assessment of any applicant's health. While the ACA prohibited some of the worst discriminatory insurance behavior, such as outright denial of coverage or dropping people with disabilities from coverage, it did impose new benefit design prohibitions on top of existing discriminatory practices that had already endured for decades. We have an existing discriminatory insurance system being slowly dragged into the light, not a requirement to issue new insurance policies that have been scrubbed of discriminatory language, practice, and reimbursement policies.

For example, just looking at the small area of durable medical equipment coverage, private insurers place unique annual coverage caps on items such as wheelchairs, commonly fail to provide any coverage for items such as hearing aids for adults, and place stringent utilization management controls on medications that are primarily used by people with specific chronic conditions such as AIDS/HIV. People with disabilities bear the brunt of these kinds of benefit design decisions or omissions, and they also bear the burden of factually establishing discrimination when data either doesn't exist at all or the issuer holds the data on details of coverage, denial rates, reasons for denial, and the presence or total absence of "a legitimate, nondiscriminatory reason for determining that such health service fails to meet applicable coverage requirements in any given individual case," as detailed in § 92.07(c).

Section 7.7.7 - Excepted benefits, short-term limited duration insurance (STLDI)

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0010
All Sections: 7.7.7
(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:
Recommendation 2:

BCBSA recommends that excepted benefits be excluded from 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 TPAs, 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 could 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 on-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.

Comment Number: HHS-OS-2022-0012-DRAFT-68050-0008
All Sections: 7.7.7
(b)(5)
Organization: AFLAC

Excerpt Text:
III. Excepted benefits should not be confused with Short-Term Limited Duration Insurance (STLDI) plans

In the [Italics: Benefit Design and Scope of Application and Application to Excepted Benefits and Short- Term Limited Duration Insurance] section, as excerpted in above, the Department's repeated, joint reference to excepted benefits and STLDI implies that the Department views them as similar products. However, they are very different products both under the statute and in the market. The Department should consider them separately (not similarly) when considering imposing section 1557 requirements (or other regulatory requirements).

While both STLDI and excepted benefits are exempt from the ACA and other federal insurance mandates, there are no other similarities between them. STLDI plans operate like comprehensive medical insurance plans in that they are expense-based and compensate or reimburse medical providers, including doctors and hospitals, for services rendered. STLDI plans are marketed and sold as primary health insurance. In contrast, excepted benefits are not intended as primary health insurance or a substitute for such insurance, which is why they are often referred to in the marketplace as supplemental benefits. STLDI plans are only offered in the individual market, whereas excepted benefits are offered in both group and individual markets.

Unlike excepted benefits statutory requirements, there no federal law statutory requirements for STLDI plans to be exempt from federal health mandates; rather, the law requires only that a policy be "short-term". In contrast, federal law contains four separate categories of excepted benefits, each with their own purpose and detailed requirements. Some excepted benefits, including accident and disability benefits, are always "excepted" without any additional requirements, whereas other benefits, such has health fixed indemnity benefits and specified disease, are subject to additional statutory restrictions. Each class of excepted benefits has different characteristics, which is the reason for different requirements. For example, vision and dental plans typically reimburse individuals for specific provider expenses incurred. Health indemnity excepted benefits [Footnote 13: Health indemnity products are in Code § 9832(c)(3), ERISA § 733(c)(3), and PHS Act § 2791(c)(3).] provide a cash benefit to the policyholder as an extra layer of financial protection in the event of illness or injury. No type of excepted benefit is intended as primary health coverage.

STLDI and excepted benefits policies are also subject to regulation at the state level. States recognize the differences in these products.

STLDI, intended as primary coverage, creates very different issues than excepted benefits, including fixed indemnity health excepted benefits, and should be evaluated separately. We are aware of the concerns that some plans purporting to qualify as excepted benefits are being marketed as primary medical insurance. We support additional scrutiny of these marketing practices. However, we do not believe such marketing practices warrant treating excepted benefit plans like STLDI plans for purposes of section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-35383-0009
All Sections: 7.7.7

(b)(5)

Organization: American Dental Association

Excerpt Text:
Scope of Application and Application 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 standard as dental offices.

Section 7.7.8 - Third party administrators

Comment Number: HHS-OS-2022-0012-DRAFT-72212-0001
All Sections: 5.2.2, 5.2.3, 7.7.3, 7.7.8

(b)(5)

Organization: Senate Democrats

Excerpt Text:
The Proposed Rule Clarifies and Expands 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 like 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)].

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0002
All Sections: 7.7.8
(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:
• 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 an Administrative Services Only (ASO) or State Drug Assistance Program (SDAP) contracts administered by a covered entity as it would create an incentive for certain purchase rs to cease doing business with a covered entity.

Comment Number: HHS-OS-2022-0012-DRAFT-67830-0006
All Sections: 7.7.8
(b)(5)

Organization: U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Excerpt Text:
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 all individuals can access health care without unnecessary barriers.

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0009
All Sections: 5.2.1, 7.7.8
(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:
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 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.

Section 7.7.9 - Employer-sponsored group health plans

Comment Number: HHS-OS-2022-0012-DRAFT-66235-0001
All Sections: 7.7.9, 5.2.1
(b)(5)

(b)(5)

Organization: National Association of Health Underwriters

Excerpt Text:
[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. It also explicitly indicates 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66235-0002
All Sections: 7.7.9

(b)(5)

Organization: National Association of Health Underwriters

Excerpt Text:
As part of this clarification, our association 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, thereby 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, retention tax credits, paid leave credits, COBRA subsidies, etc.). Would these tax credits and subsidies qualify as indirect funding?

Section 7.7.10 - Federal Employees Health Benefits (FEHB) Program; Federal Employees Dental and Visions Insurance Program (FEDVIP); Federal Long Term Care Insurance Program (FLTCIP)

No comments are associated with this issue

Section 7.7.11 - Network adequacy

Comment Number: HHS-OS-2022-0012-DRAFT-70479-0014
All Sections: 7.7.11

(b)(5)

Organization: National Disability Rights Network

Excerpt Text:
[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, but many managed care systems are based on the premise of funding the most commonly accessed medical services, which infrequently includes specialists. Thus, states need to strengthen their network adequacy provisions to ensure they are also covering the medical services of a wide spectrum of specialists.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0015
All Sections: 7.7.11, 7.7.13

(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
The Final Rule must prohibit race discrimination in narrow networks

The Proposed 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 their 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 academic hospitals had lower mortality risk compared to those treated at nonteaching hospitals. Other studies have found that cancer treatment centers are regularly excluded from insurance plans on exchange networks and that these centers are often underutilized by Hispanic and Asian groups, despite better treatment outcomes. As a result, people of color, who are likely to be overrepresented in patient populations insured under a plan with a narrow network, may have less access to a range of specialized providers and treatments that can result in life-saving care.

Ultimately, the Final Rule must address the ways in which narrow networks impact patients of color and ensure health insurance plans do not exclude hospitals that treat higher proportions of patients of color or that provide a wider range of specialized health care options.

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0016
All Sections: 7.7.11
(b)(5)
Organization: American Academy of Family Physicians

Excerpt Text:
OCR is also seeking comment on how section 1557 might apply to provider networks and network adequacy, particularly as it relates to individuals with disabilities.

The AAFP provided detailed comments for the 2023 Notice of Benefit and Payment Parameters, which included the AAFP's suggestions for improving network adequacy standards, such as by implementing time and distance standards and incorporating wait time data [Hyperlink: https://www.aafp.org/dam/AAFP/documents/advocacy/coverage/aca/LT-HHS-2023NBPP-012722.pdf]. The AAFP agrees that network adequacy should take into account accessible medical equipment for individuals with disabilities, as well as language and translation accessibility for LEP individuals and individuals with disabilities. HHS should require that plans

take reasonable steps to make accessible care available within established time, distance, and wait time standards.

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0022
All Sections: 7.7.11

(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:
12. Network Adequacy (Preamble): The Preamble recognizes that network adequacy is regulated by other HHS regulations and that it is outside 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:

BCBS 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.

Comment Number: HHS-OS-2022-0012-DRAFT-73220-0042
All Sections: 7.7.11

(b)(5)

Organization: National Immigration Law Center

Excerpt Text:
Network Adequacy

We encourage OCR to state that issuers 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 trained 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0005
All Sections: 7.7.11
(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:
• 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68054-0005
All Sections: 7.7.11, 7.7.15
(b)(5)

Organization: Washington Health Benefit Exchange

Excerpt Text:
WAHBE supports addressing these topics along with questions of network adequacy and value assessment methodologies to assure practices do not unfairly limit access to care and coverage while assuring that coverage provides the best value possible.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0054
All Sections: 7.7.11
(b)(5)

Organization: Justice in Aging

Excerpt Text:
[Italics: Network Adequacy]

We agree with HHS that narrow provider networks 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 is contracting with existing providers reflective of 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 their 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 in a better position 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 looks like me, who can relate to me, who knows what it's like to almost 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 Latinx 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), https://www.healthaffairs.org/do/10.1377/forefront.20211207.962085/full/.] Another factor should be adequate access to specialists who treat conditions that disproportionately affect communities of color, such as Alzheimer's and dementia.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0055
All Sections: 7.7.11

(b)(5)

Organization: Justice in Aging

Excerpt Text:
HHS 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.

Section 7.7.12 - OCR framework for analyzing complaints; legitimate, nondiscriminatory reason; pretext

No comments are associated with this issue

Section 7.7.13 - Disparate impact (related to health insurance benefit design)

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0015
All Sections: 7.7.11, 7.7.13

(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
The Final Rule must prohibit race discrimination in narrow networks

The Proposed 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 their 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 academic hospitals had lower mortality risk compared to those treated at nonteaching hospitals. Other studies have found that cancer treatment centers are

regularly excluded from insurance plans on exchange networks and that these centers are often underutilized by Hispanic and Asian groups, despite better treatment outcomes. As a result, people of color, who are likely to be overrepresented in patient populations insured under a plan with a narrow network, may have less access to a range of specialized providers and treatments that can result in life-saving care.

Ultimately, the Final Rule must address the ways in which narrow networks impact patients of color and ensure health insurance plans do not exclude hospitals that treat higher proportions of patients of color or that provide a wider range of specialized health care options.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0009
All Sections: 7.7.13
(b)(5)

Organization: Health Care For All

Excerpt Text:
Insurance Plan Benefit Design

Despite 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 surgeries 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.20170817.061561/full/]. Regardless of benefit design, more Black and Latinx 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.

Section 7.7.14 - Case law discussion

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0008
All Sections: 7.7.1, 7.7.14, 7.7.4

(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:

III. [Bold: Sex Discrimination Coverage]

U.S. health insurance and other health-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 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 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_us-pdfmembers.pdf)] that providers do not take their fertility concerns seriously, instead "emphasiz[ing] 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 programs and contraceptive coverage mandates. This results in discrimination against people of color and people with low- incomes who face higher rates [embedded hyperlink text (https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception)] of unintended pregnancy and adverse reproductive health outcomes due to these barriers. Robust enforcement of Section 1557 is necessary to ensure health entities and providers do not perpetuate discriminatory policies against contraceptive care.

PRH agree 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. Thus, we strongly support

HHS' restoration of and improvements to § 92.207, including its inclusion of specific forms of prohibited discrimination. However, as with proposed § 92.206, HHS must strengthen the text of proposed §
92.207 to address sex discrimination related to pregnancy or related conditions, such as discrimination related to abortion, fertility care, and contraception.

RECOMMENDATION: We urge HHS 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, [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, [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; or

(7) [Italics: 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 restriction results in discrimination on the basis of sex.]

In addition, we urge HHS to specify in the preamble that the health services addressed in our proposed § 92.207(b)(7) include both the full spectrum of reproductive and sexual health services and treatments and medications for patients that may prevent, complicate, or end fertility or pregnancies.

Section 7.7.15 - Value assessment methodologies

Comment Number: HHS-OS-2022-0012-DRAFT-67899-0001
All Sections: 7.7.15
(b)(5)

Organization: Institute for Gene Therapies (IGT)

Excerpt Text:
Our comments mainly respond to the Department's request for feedback on the extent, scope, and nature of value assessment methods that discriminate on the grounds prohibited by Section 1557 of the Affordable Care Act (ACA).

Discriminatory Implications of the QALY Indicator

It is well documented in literature that value assessments derived from the quality-adjusted life year (QALY) may lead to unfair discrimination against individuals with less than perfect health. The QALY framework relies on a system of numeric utility to quantify the value of various health states wherein the highest possible utility for a health state is 1, representing "perfect health," and 0 which is an arbitrary value for death. The central criticism to the use of the QALY framework is that QALYs place greater value on years lived in full health, or on interventions that prevent loss of perfect health while discounting gains in health for individuals with chronic conditions or disabilities. Within the QALY framework, individuals with chronic conditions and disabilities experience a lower maximum baseline in health than their non-disabled counterparts. As a result, a treatment that improves their quality of life may result in fewer QALYs gained than a similar treatment for individuals who are not disabled. These individuals are thus at a serious disadvantage as the framework favors those with greater potential for health.

The QALY was originally developed for use in academic population-level assessments. However, use of QALYs has expanded over time in the Unites States to determine the economic value of health care interventions for the purposes of guiding coverage and reimbursement decisions, though not without objection. Notably, in 1992, HHS found that Oregon's efforts to use a QALY-based cost-effectiveness standard in the state's Medicaid program violated the Americans with Disabilities Act (ADA) by systematically disadvantaging individuals with pre-existing disabilities [Footnote 2: Pear R. White House Expected to Back Oregon's Health-Care Rationing, New York Times (Mar. 1993)]. The ACA also explicitly prohibits the Patient-Centered Outcomes Research Institute (PCORI) from using the cost-per-QALY as a threshold to establish what type of health care is cost effective or recommended [Footnote 3: 42 U.S.C. §1320e-1(e)]. The ACA further restricts the use of QALYs by precluding their use as a threshold to determine coverage, reimbursement, or incentive programs in Medicare [Footnote 4: Id]. Moreover, the National Council on Disability (NCD), an independent federal agency, has found sufficient evidence of the discriminatory effects of QALYs to warrant concern, including concerns raised by bioethicists, patient rights groups, and disability rights advocates [Footnote 5: NATIONAL COUNCIL ON DISABILITY, Quality-adjusted life years and the devaluation of life with disability (Nov. 2019)]. Finally, the recently-enacted Inflation Reduction Act (IRA) of 2022 expressly prohibits HHS from considering "evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill" when negotiating drug prices under the new Drug Price Negotiation Program [Footnote 6: Inflation Reduction Act (IRA) of 2022, Pub. L. No. 117-169, adding new Social Security Act § 1194(e)(2)(D)].

Other Value Elements That Must Be Given Weight

A separate critique of the QALY framework is that it does not represent how society actually views health or value. QALYs capture only a subset of benefits that may be produced by a health care intervention while ignoring additional considerations of value. IGT is leading the effort to educate policymakers and stakeholders about what constitutes value and identify additional elements of value that warrant consideration in health care interventions. We believe value cannot be limited to one or two elements, such as a QALY or direct medical costs. For patients, families, and society, value must include patient preferences with respect to a treatment, the

impact of a treatment on the patient's family and caregivers, a treatment's ability to advance health equity and address unmet needs, and societal impact. In the gene therapy space in particular, a value assessment must include the lifetime impact or durability of a treatment, a treatment's effects (both short- and long-term), and the rarity or severity of disease. It is our unwavering assertion that to the extent that every vital measure or element of value that is not included in a value assessment, such assessment is not complete and must not be used for coverage or payment decisions. To restrict coverage and access to any health intervention based on an incomplete or inaccurate depiction of value amounts to discrimination in violation of federal law.

Comment Number: HHS-OS-2022-0012-DRAFT-67996-0014
All Sections: 7.7.15

(b)(5)

Organization: The Alabama Disabilities Advocacy Program

Excerpt Text:

V. Value-Based Assessment and Purchasing Methodologies Related to Medication Access

We appreciate the request for comment on value-based assessment and purchasing methodologies for drug treatments [Hyperlink: https://www.federalregister.gov/d/2022-16217/p-938]. As people with disabilities and disability advocates, we support a movement that tries to place a fair, appropriate, and sustainable value on drug treatments according to how much they benefit patients. Our concern is with certain value assessment methods that automatically begin with the premise that the benefits or life extension that a treatment brings to the lives of people with disabilities is worth less than benefits or life extension for people without disabilities.

One prime example of such a biased value assessment method is the "Quality Adjusted Life Year" (QALY). The QALY focuses on evaluating how a drug or therapy extends or improves the quality of a person's life as a way to determine the economic worth of any given treatment. Health insurers and the third party administrators such as Pharmacy Benefit Managers (PBMs) that contract with insurers and health plans use QALY evaluations to decide if they should include a drug among a plan's covered benefits, and to figure out the conditions that must be met for an insured beneficiary to get access to the drug. Unfortunately, the QALY bases its assessment of quality-of-life improvements and life values on subjective general public assessments on quality of life, and these assessments are deeply influenced by implicit bias and stereotypes about what it's like to live with a disability. The actual lived experience of people with disabilities is given no account. Not surprisingly, QALY's assign lower values to the improvements that a treatment can bring to the length and quality of life of people with disabilities, making it more likely that drugs that help disabled people to maintain their function, quality of life, and independence will "not make the cut" for being included in an insurer's formulary, or that access to the drug will involve layers of utilization management. Disability Rights Education and Defense Fund (DREDF) has a legal brief that examines how QALYs potentially violate federal disability rights law; to the extent that any state's existing laws have

incorporated federal disability rights law, the analysis may also be relevant to a state's use of QALYs [Hyperlink: https://dredf.org/2021/09/23/pharmaceutical-analyses-based-on-the-qaly-violate-disability-nondiscrimination-law/].

Under the ACA, the use of QALY's to assess treatment value in Medicare and by the Patient-Centered Outcomes Research Institute (PCORI) is already restricted [Hyperlink: https://r20.rs6.net/tn.jsp?f=001pvc29sIt4l-LJ7yjDupaqDmyk8tOgBBvRk8NEcOtbc5nqFlQ6Ztla83y9w0OiOBKH58GMAMhbe_tZ1uxACuZ8-5b1dsQs861Pqsd8wA0DGQ9x7H9xBjFt2mL_ATtHuPCLqfKTZmM-6hodKoUQkv8Wd9IuDtOdYWi&c=13F6U57C51yBhwzHnapUiBFsJAGRX-DKf5HF2u5wadW5CocXqY8n-g%3D%3D&ch=DURMCQcP-WTPP4us2mt0mqiRKOiCZ-0gAQ1c8XJqcIURJUv4inaM5Q%3D%3D]. States, however, continue to consider use of QALYs for coverage decisions in state Medicaid programs [Hyperlink: https://r20.rs6.net/tn.jsp?f=001pvc29sIt4l-LJ7yjDupaqDmyk8tOgBBvRk8NEcOtbc5nqFlQ6Ztla83y9w0OiOBKH58GMAMhbe_tZ1uxACuZ8-5b1dsQs861Pqsd8wA0DGQ9x7H9xBjFt2mL_ATtHuPCLqfKTZmM-6hodKoUQkv8Wd9IuDtOdYWi&c=13F6U57C51yBhwzHnapUiBFsJAGRX-DKf5HF2u5wadW5CocXqY8n-g%3D%3D&ch=DURMCQcP-WTPP4us2mt0mqiRKOiCZ-0gAQ1c8XJqcIURJUv4inaM5Q%3D%3D]. Private insurers, as well as the PBMs they contract with, also are likely using QALYs in their coverage and benefit design decisions, without necessarily being transparent about that fact. The National Council on Disability has recommended an unequivocal ban on the use of QALYs and any value-based methodology that assigns lower values to the lives of people with disabilities and the treatments used by people with disabilities [Hyperlink: https://ncd.gov/publications/2021/ncd-letter-qaly-ban].

D.A., another client ADAP tried to assist, has numerous diagnoses that result in her being prescribed 18 medications. She is also a recipient on the state's E&D HCBS Waiver, meaning she was at risk of institutionalization if she did not receive the care she needed in her home and community. Despite this risk, she was only allowed to fill five of her prescriptions per month, per an Alabama Medicaid policy. This resulted in her picking and choosing which prescriptions to fill based on necessity, often meaning she had to forgo medications that were vitally important to her continued care. The arbitrary nature of these policies results in discrimination across the board, regardless of the source for coverage. Shoring up the protections under § 92.207 would ensure greater access to medications and would result in far fewer situations where individuals have to pick and choose prescriptions or resort to rationing.

Comment Number: HHS-OS-2022-0012-DRAFT-70479-0015
All Sections: 7.7.15
(b)(5)
Organization: National Disability Rights Network

Excerpt Text:
Bold: Value Assessment]

We appreciate the Department's recognition of concerns 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) produced a series of reports in 2019 regarding bioethics and the ways in which the lives of people with disabilities are undervalued in the health care system. NCD recommended that OCR, 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 do not include the input of people with disabilities and chronic illnesses." [Footnote 10: National Council on Disability, Quality-Adjusted Life Years and the devaluation of Life with Disability (Nov. 2019), at 15..
https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.] We support these recommendations. We also support the NCD recommendation that federal programs, including Medicaid, should not rely on cost-effectiveness research or reports that gather input from the public on health preferences that do not include the input of people with disabilities and chronic illnesses.

We would be similarly concerned about value assessment methods and metrics that measure the cost effectiveness of treatments relative to health outcomes in a way that discriminates on the basis of race, color, national origin, sex, or age. For example, older people are expected to live fewer years than younger people; value assessment metrics that value the years of life a treatment adds may discriminate based on age. Some health care treatments may work less effectively in someone with co-morbid conditions and many racial and ethnic minorities experience health disparities and multiple chronic conditions; a value assessment that measures outcomes of a specific treatment may determine that it is not cost-effective to cover a treatment for racial and ethnic minorities. Such value assessments would be discriminatory and should not be allowed in any health program or activity that receives federal financial assistance. When

making life or death health care decisions, the government should not rely on instruments that are based on surveys of the general public. These instruments will reinforce the devaluation and discrimination that Congress has intended to address through civil rights and antidiscrimination statutes.

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0018
All Sections: 7.7.15

(b)(5)

Organization: National Health Council

Excerpt Text:
[Bold: Value Assessment Methodologies]

The NHC appreciates that CMS is using 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, or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill.

Comment Number: HHS-OS-2022-0012-DRAFT-68054-0005
All Sections: 7.7.11, 7.7.15

(b)(5)

Organization: Washington Health Benefit Exchange

Excerpt Text:
WAHBE supports addressing these topics along with questions of network adequacy and value assessment methodologies to assure practices do not unfairly limit access to care and coverage while assuring that coverage provides the best value possible.

Section 7.8 - Marital, Parental, or Family Status - Sex Discrimination (§92.208)

No comments are associated with this issue

Section 7.8.1 - Generally

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0020
All Sections: 7.8.1
(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: III. Sex discrimination in the context of marital, parental, or family status 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 77: 87 Fed. Reg. 149, p.47918 (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 OSF 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 couple[s] of opposite sex spouses." [Footnote 78: Shira Stein, Hospital Chain Blocks Fertility Coverage for Its LGBTQ Employees, BLOOMBERG LAW (July 18, 2022), https://www.bgov.com/core/news_articles/RF7N4HT0G1LX.] 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 this 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 IUD placement or hysterectomies to patients who are unmarried, childless, or are not in the presence of their spouse, even where they would otherwise provide that care. [Footnote 79: See, e.g., Cate Charron, Many Struggle to Find a Doctor to Tie Their Tubes. Roe's Overturn May Make it Harder, THE HERALD TIMES (July 12, 2022), https://www.heraldtimesonline.com/story/news/local/2022/07/12/roes-overturn- may-make-harder-those-who-want-get-tubes-tied/7765626001/ ; Meena Venkataramanan, Post-Roe, More

Americans Want Their Tubes Tied. It Isn't Easy, WASHINGTON POST (Aug. 17, 2022), https://www.washingtonpost.com/health/2022/08/15/roe-tubal-sterilizations-barriers/.]

We urge the Department to clarify in the final rule that any conduct that denies access to or coverage for health care by considering the patient's sex in combination with marital, parental, or family status is prohibited sex discrimination under Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0027
All Sections: 7.8.1, 7.7.1, 7.6.1
(b)(5)
Organization: Center for American Progress

Excerpt Text:
iii. The Department should make clear the scope of Section 1557's protections against discrimination on the basis of pregnancy or related conditions, including termination of pregnancy.

In the Proposed Rule's discussion of § 92.208, the Department asks whether there should be a provision to "specifically address discrimination on the basis of pregnancy-related conditions" [Footnote 47: Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824, 47878 (proposed August 4, 2022) (to be codified at 45 C.F.R. pt. 92)]. We are concerned that including such a provision under § 92.208 could cause policies that are biased against people seeking abortions. In our comments below, we recommend that HHS add new provisions on discrimination related to pregnancy or related conditions, including termination of pregnancy, under § 92.206 and § 92.207 instead. Further, we would support the Department's decision to include an additional provision elsewhere in the Final Rule to "specifically address discrimination on the basis of pregnancy-related conditions" and the broad scope of protected services that fall under this form of care.

Comment Number: HHS-OS-2022-0012-DRAFT-46192-0003
All Sections: 7.8.1, 6.2.1
(b)(5)
Organization: American Nurses Association

Excerpt Text:
3) HHS should work closely with nurses while implementing Section 1557 provisions relating to discrimination on the basis of sex.

HHS is proposing to ensure equal access to health care programs on 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. 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/~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 unique barriers to care, including LGQTQ+ 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 communicates 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 LGBTQ+ patients based on sex-stereotyping.

This crucial work complements ANA's focus on educating nurses on their biases and prejudices for indications of discriminatory actions. ANA stands ready to work with HHS to build on this work to ensure that covered entities have the right resources and support to educate staff on combatting sex discrimination in the provision of health care services. [Bold: As such, ANA urges HHS to work closely with nurses to support covered entities coming into compliance with Section 1557 sex discrimination provisions].

Section 7.8.2 - Include pregnancy-related conditions

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0010
All Sections: 7.8.5, 7.8.2

(b)(5)

Organization: The Century Foundation

Excerpt Text:
[Bold: Explicitly including pregnancy status in protections from sex discrimination 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 name pregnancy termination in its definition of sex discrimination. Many communities could not access abortion care prior to the Dobbs decision, and marginalized 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-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 Intersection of Abortion Access and Black Maternal Health," The Century Foundation, June 22, 2022, https://tcf.org/content/facts/the-intersection-of-abortion-access-and-black-maternal-health/].

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0011
All Sections: 6.2.4, 7.8.2

(b)(5)

Organization: The Century Foundation

Excerpt Text:
This explicit protection should be present in at least two areas of the finalized 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."

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0012
All Sections: 7.8.3, 7.8.2

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Italics: Title IX's definition of sex as it relates to pregnancy is largely derived from Title VII]

Title IX's abortion neutrality, and longstanding definition of pregnancy, is not an isolated ruling. Title VII's Pregnancy Discrimination Act addresses the limits of compelled 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 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." [Footnote 31: Ibid.] 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 a company is 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 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; (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 32: 87 Federal Register 41390]

In this, #2 and #3 follows the logic of Title VII as it relates to abortion: namely, categorizing abortion as a subsequent medical condition that warrants medically directed accommodations; providing necessary periods of recovery without discrimination or penalty. The first definition, however, breaks with Title VII's definition of sex and changes Title IX's current definition of pregnancy.

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0014
All Sections: 7.8.2
(b)(5)

(b)(5)

Organization: The Century Foundation

Excerpt Text:
[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 still 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.

Comment Number: HHS-OS-2022-0012-DRAFT-67830-0017
All Sections: 7.8.2

(b)(5)

Organization: U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Excerpt Text:
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 13: 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 LGBTQI+ 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).]

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0017
All Sections: 7.8.2

(b)(5)

Organization: American Academy of Family Physicians

Excerpt Text:
Prohibition on Sex Discrimination Related to Marital, Parental, or Family Status (§ 92.208)

HHS is proposing to align 1557 protections with Title IX protections, which prohibit discrimination on the basis of sex with respect to an individual's marital, parental, or family status. OCR is considering including a provision on the basis of pregnancy-related conditions and how to do so.

The AAFP strongly supports HHS clarifying that discrimination related to marital, parental, or family status includes pregnancy-related conditions, including the decision to terminate a pregnancy.

Comment Number: HHS-OS-2022-0012-DRAFT-66750-0002
All Sections: 6.2.4, 7.8.2

(b)(5)

Organization: Jacobs Institute of Women's Health

Excerpt Text:
To improve equity in care for those who are or could become pregnant, the Jacobs Institute of Women's Health recommends the following revisions to the rule:

- Explicitly name "termination of pregnancy" in any text where "pregnancy or related conditions" is defined as part of sex discrimination.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0020
All Sections: 7.8.2

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
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 provision 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. Entities writing policies will have clearer guidance if the department includes discrimination based on obtaining an abortion outside of Section 92.208.

Comment Number: HHS-OS-2022-0012-DRAFT-43142-0003
All Sections: 6.2.4, 7.8.2

(b)(5)

Organization: American Psychological Association

Excerpt Text:

2) Reproductive Healthcare. The NPRM clarifies the scope of Section 1557's 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, including 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, Chibber KS, Gould H, Rocca CH, Foster DG. Risk of violence from the man involved in the pregnancy after receiving or being denied an abortion. September 2014. BMC Medicine, 12:144].

The ability to control childbearing and to take advantage of educational and employment opportunities are often inextricably linked. Therefore, discrimination in access to all forms of reproductive health care can have devastating consequences across the lifespan, including worsening and/or leading to disparities in behavioral health outcomes. Restricting access to reproductive health care undermines the ability of women to attain the related rights of health, equality, and nondiscrimination in other sectors.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0040
All Sections: 7.8.2

(b)(5)

Organization: Center for American Progress

Excerpt Text:
XIII. Prohibition on Sex Discrimination Related to Marital, Parental, or Family Status (§ 92.208)

a. Placement of Pregnancy or Related Conditions Discrimination in the Final Rule

We appreciate HHS' request for comment on if pregnancy or related conditions discrimination should be addressed in § 92.208, in a separate stand-alone provision, or elsewhere in the Final Rule. We do not believe that § 92.208 is the appropriate place to do so. Instead, HHS should address these issues in § 92.206 and § 92.207 as discussed above. In addition to those recommendations, we would support a separate stand-alone provision.

Primarily addressing the prohibition on discrimination of "pregnancy or related conditions, including termination of pregnancy" under § 92.208 could cause policies that are biased against single people experiencing discrimination based on obtaining or having obtained an abortion. While this provision is welcome for ensuring robust enforcement against sex being used to determine eligibility for a health program in specific instances, primarily including discrimination on the basis of abortion in this context could cause confusion that a person facing discrimination because they have had an abortion only occurs in a marital, parental, or family context. Entities writing policies will have clearer guidance by including discrimination based on obtaining an abortion in the broader definition of § 92.101(a)(2) with examples listed in § 92.206(b) and § 92.207(b).

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0005
All Sections: 7.8.3, 7.8.2

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: B. The final rule should be clear that Section 1557 prohibits discrimination against patients in the treatment of pregnancy emergencies and complications, including termination of pregnancy, miscarriage management, and other pregnancy outcomes.]

[Italics: I. The final rule should clarify that EMTALA and 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 36: 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-medical-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 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 CFR 457, 42 CFR 460, 45 CFR 80, 45 CFR 84, 45 CFR 86, 45 CFR 91, 45 CFR 92, 45 CFR 147, 45 CFR 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 employ a more restrictive definition of an emergency medical condition. [Footnote 38: 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-medical-care-letter- to-health-care-providers.pdf.] In the July guidance, the Department clarified 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." [Footnote 39: Id.]

Despite the July guidance, health care providers need clarity as to when they may treat patients. Each day, physicians across the country seek guidance from the American College of Obstetricians and Gynecologists and share fears that they cannot make the best health care decisions for their patients following [Italics: Dobbs]. [Footnote 40: A Post Roe America: The Legal Consequences of the Dobbs Decision Before the Sen. Comm. on the Judiciary, 117th Cong. (2022) (oral testimony of Collen P. McNicholas, Chief Medical Officer, Planned

Parenthood of the St. Louis Region and Southwest Missouri) https://www.judiciary.senate.gov/meetings/a-post-roe-america-the-legal- consequences-of-the-dobbs-decision (sharing her experience as a leader in the American College of Obstetricians and Gynecologists).] Providers urgently need clarity on when they may treat the patients who rely on them for care. [Footnote 41: Id.] Providers have been placed in an impossible situation, where providing the health care their patients need – even emergency care – could potentially expose them to prosecution and civil suit in states that ban abortion. [Footnote 42: Reese Oxner & María Méndez, Texas Hospitals are Putting Pregnant Patients at Risk by Denying Care Out of Fear of Abortion Laws, Medical Gro Says, TEXAS TRIBUNE (July 15, 2022), https://www.texastribune.org/2022/07/15/texas-hospitals-abortion-laws/; AP, Letter Says Texas Hospitals Reportedly Refusing Abortion Care, NBC DFW (Jul. 15, 2022), https://www.nbcdfw.com/news/local/texas- news/letter-says-texas-hospitals-reportedly-refusing-abortion-care/3015545/. Reese Oxner & María Méndez, Texas Hospitals are Putting Pregnant Patients at Risk by Denying Care Out of Fear of Abortion Laws, Medical Gro Says, TEXAS TRIBUNE (July 15, 2022), https://www.texastribune.org/2022/07/15/texas-hospitals-abortion-laws/; AP, Letter Says Texas Hospitals Reportedly Refusing Abortion Care, NBC DFW (Jul. 15, 2022), https://www.nbcdfw.com/news/local/texas- news/letter-says-texas-hospitals-reportedly-refusing-abortion-care/3015545/.]

We also recommend that the final rule clarify that denying an abortion in an emergency situation due to personal or institutional opposition to abortion violates Section 1557, because it is per se discrimination on the basis of sex. This is true regardless of any state laws that purport to ban abortion entirely. The final rule should put health care providers on notice that a failure to stabilize a patient for any reason having to do with the condition of pregnancy – including refusing to or delaying termination of pregnancy – is a violation of federal law under both EMTALA and Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-66244-0006
All Sections: 7.8.5, 7.8.2

(b)(5)

Organization: Association of American Medical Colleges (AAMC)

Excerpt Text:
[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 regulation.] 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 this 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.

Comment Number: HHS-OS-2022-0012-DRAFT-40175-0007
All Sections: 7.8.3, 7.8.5, 7.8.2
(b)(5)
Organization: California Department of Health Care Services

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0078
All Sections: 7.8.2
(b)(5)
Organization: Ethics & Public Policy Center

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0080
All Sections: 15.2, 7.8.2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 woman's); 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 lies 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0083
All Sections: 7.8.2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[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.

Section 7.8.3 - Abortion Title IX abortion neutrality

Comment Number: HHS-OS-2022-0012-DRAFT-10445-0001
All Sections: 7.8.3
(b)(5)

Organization:

Excerpt Text:
In 1986, the Emergency Medical Treatment & Labor Act (EMTALA) was enacted 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 the dignity of

both mother and child. They will evaluate and treat both the mother and child as the clinical situation requires while upholding the highest medical and ethical standards. Those who respect life at all stages will continue to provide exemplary care for all those they encounter, regardless of how EMTALA is manipulated to achieve partisan political ends.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0001
All Sections: 7.8.3
(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: I. The final rule should explicitly affirm Section 1557's nondiscrimination 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 Zawn Villines, Effects of Gender Discrimination on Health, MEDICAL NEWS TODAY, (Jun. 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 P'SHIP FOR WOMEN & FAMS, BAD MEDICINE: HOW POLITICAL AGENDA IS UNDERMINING ABORTION CARE AND ACCESS IN OKLAHOMA (2019), https://www.nationalpartnership.org/our-work/repro/reports/bad-medicine- oklahoma.html.] 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 opposed to); expected to biologically desire to birth children and fulfill traditional roles of homemaker and child caretaker within the nuclear family structure. Alison Norris et al., Abortion Stigma: A Reconceptualization of Constituents, Causes, and Consequences, 21 WOMEN'S HEALTH ISSUES 1, 6 (2011), https://www.guttmacher.org/ sites/default/files/pdfs/pubs/journals/Abortion-Stigma.pdf;

Anuradha Kumar et al., Conceptualising Abortion Stigma, 11 CULTURE, HEALTH & SEXUALITY 625, 628–29 (2009).]—or discrimination against a person seeking an abortion—is experienced by the majority of people seeking abortion [Footnote 4: See Paula Abrams, The Scarlet Letter: The Supreme Court and the Language of Abortion Stigma, 19 MICH. J. GENDER & L. 293, 328–29 (2013); M. Antonia Bigg et al., Perceived Abortion Stigma and Psychological Well- Being Over Five Years After Receiving or Being Denied an Abortion, 15 PLOS ONE 1, 2 (2020) https://journals. plos.org/plosone/article?id=10.1371/journal.pone.0226417 (finding that most people considering abortion perceive some stigma related to their decision).] and perpetuates a wide variety of discriminatory sex-based tropes, [Footnote 5: See Alanna Vagianos, Women Aren't the Only People Who Get Abortions, THE HUFFINGTON POST (June 6, 2019), https://www.huffpost.com/entry/women-arent-the-only-people-whoget-abortions_n_5cf55540e4b0e346ce8286d3 (describing how people capable of pregnancy who identify at non-binary or transgender are also impacted by abortion restrictions).] which may vary in impact depending, in part, on the intersecting identities of the individual seeking care. [Footnote 6: Id.] Discrimination based on abortion is per se sex discrimination, because it discriminates against patients based on their pregnancy and pregnancy-related care, which are protected under Section 1557.

There are serious physical and socioeconomic consequences for patients who experience discrimination when seeking abortion care, particularly for those who are denied a wanted abortion. A groundbreaking study found that participants who were denied wanted abortions and forced to give birth had statistically poorer long-term health outcomes than those who accessed abortions. [Footnote 7: See Lauren J. Ralph et al., Self-reported Physical Health of Women Who Did and Did Not Terminate Pregnancy After Seeking Abortion Services: A Cohort Study, 171 ANNALS OF INTERNAL MED. 238, 238-247 (2019) https://annals.org/aim/article-abstract/2735869/self-reported-physical-health-women-who-did-did-terminate- pregnancy (finding that 27% of women who gave birth reported fair or poor health compared with 20% of women who had first-trimester abortion and 21% who had second-trimester abortion).] Participants denied abortion services were more likely to experience serious complications that generally occur at the end of pregnancy, including eclampsia and death; more likely to stay tethered to abusive partners; more likely to suffer anxiety and loss of self-esteem in the short term; and less likely to have aspirational life plans for the coming year. [Footnote 8: Turnaway Study, ADVANCING NEW STANDARDS IN REPROD. HEALTH, https://www.ansirh.org/research/turnaway- study (last visited Oct. 1, 2022).] In contrast, study participants who received a wanted abortion were not only less likely to experience serious health problems than those denied a wanted abortion, but were also 50 percent more likely to set an aspirational plan and achieve it—such as finishing their education, getting a better job, giving a good life to their children, and being more financially stable—compared to participants who were denied a wanted abortion. [Footnote 9: Ushma Upadhyay et al., The Effect of Abortion on Having and Achieving Aspirational One-year Plans, 15 BMC WOMEN'S HEALTH 1, 1-10 (2015), https://bmcwomenshealth.biomedcentral.com/articles/10.1186/s12905-015-0259-]

There are also serious consequences for patients who face delays in obtaining an abortion; as delays increase, the logistical and financial burdens multiply. For example, when a patient is turned away from a doctor's office or a hospital without a referral, they must find a willing

provider to access the health care they need. This costs patients significant time researching other available providers and additional time off from work for a new appointment. In areas with a limited number of health care providers, or in states that have implemented an abortion ban following the Supreme Court's overturn of [Italics: Roe v. Wade], a patient may need to travel long distances in order to access care, requiring expenses for travel, overnight stays and childcare. The additional time and expense fall most heavily on low-income individuals and those without the job flexibility to take paid sick time.

Delays also have the effect of increasing the cost of an abortion. Abortion in the first trimester is substantially less expensive than in the second trimester: the median price of a surgical abortion at ten weeks is $508, while the cost rises to $1,195 at week 20. [Footnote 10: Rachel K. Jones et al., Differences in Abortion Service Delivery in Hostile, Middle-Ground and Supportive States in 2014, 28 WOMEN'S HEALTH ISSUES 212, 212-218 (2018), http://www.whijournal.com/article/S1049- 3867(17)30536-4/abstract.] The rising cost of abortion as gestational age increases poses a profound challenge to the affordability of the procedure for lower-income people. As one Utah woman explained: "I knew the longer it took, the more money it would cost . . . We are living paycheck to paycheck as it is, and if I [had] gone one week sooner, it would have been $100 less." [Footnote 11: Sarah C.M. Roberts et al., Utah's 72-Hour Waiting Period for Abortion: Experiences Among a Clinic-Based Sample of Women, 48 PERSPS. ON SEXUAL & REPROD. HEALTH 179, 184 (2016).] Moreover, delays raise the cost of each step of obtaining an abortion—not just the cost of the procedure. For example, one recent study found that Utah's mandatory waiting period caused 47 percent of patients having an abortion to miss an extra day of work. [Footnote 12: Jessica N. Sanders et al., The Longest Wait: Examining the Impact of Utah's 72-Hour Waiting Period for Abortion, 26 WOMEN'S HEALTH ISSUES 483, 485 (2016).] More than 60 percent were negatively affected in other ways, including increased transportation costs, lost wages by a family member or friend, or being required to disclose the abortion to someone whom they otherwise would not have told. [Footnote 13: Id.; Deborah Karasek et al., Abortion Patients' Experience and Perceptions of Waiting Periods: Survey Evidence Before Arizona's Two-Visit 24-hour Mandatory Waiting Period Law, 26 WOMEN'S HEALTH ISSUES 60, 60-66 (2016).] And because many clinics do not offer second-trimester abortions, a person who has been delayed into the second trimester will typically be required to travel farther to obtain an abortion, thereby incurring additional travel and related costs, such as lost wages and costs for childcare. [Footnote 14: Rachel K. Jones & Jenna Jerman, How Far Did US Women Travel for Abortion Services in 2008?, 22 J. WOMEN'S HEALTH 706, 706-13 (2013).] As a result, health care denials that result in a delay in care can significantly drive up the cost of care for a person seeking abortion care or make it impossible altogether.

In another example, a patient who has a cesarean section birth and wishes to have a post-partum tubal ligation immediately following delivery cannot do so at a Catholic hospital, [Footnote 15: Catholic hospitals must comply with the Ethical and Religious Directives for Catholic Health Care Services, which prohibit abortion, contraception (including sterilization) and IVF. U.S. CONF. OF CATH. BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR THE CATHOLIC HEALTH CARE SERVICES, SIXTH ED. (2016), https://www.usccb.org/about/doctrine/ethical-and-religious-directives/upload/ethical-religious-directives-catholic-health-service-sixth- edition-2016-06.pdf.] even though having the procedure

at that time is medically recommended, presents fewer risks to the patient, and is more cost-effective than delaying the procedure to a later time. If the patient cannot have the procedure immediately following delivery, they must first recover from the cesarean surgery and then schedule the tubal ligation at least six weeks later when they are busy caring for their newborn. They will be required to go to another hospital and possibly a different doctor, transfer their medical records, and endure another invasive procedure and recovery. [Footnote 16: NAT'L WOMEN'S LAW CTR., When Health Care Providers Refuse: The Impact on Patients of Providers' Religious and Moral Objections to Give Medical Care, Information or Referrals (Apr. 2009), https://www.nwlc.org/wp- content/uploads/2015/08/April2009RefusalFactsheet.pdf; See also, Debra B. Stulberg et al., Tubal Ligation in Catholic Hospitals: A Qualitative Study of Ob-Gyns' Experiences, 90 CONTRACEPTION 422, 422-28 (2014) ("Cesarean delivery in Catholic hospitals raised frustration for obstetrician-gynecologists when the hospital prohibited a simultaneous tubal ligation and, thus, sent the patient for an unnecessary subsequent surgery. [. . .] Some obstetrician-gynecologists reported that Catholic policy posed greater barriers for low-income patients and those with insurance restrictions.").]

Reproductive health care is at a crisis point in this country. Since 2011, states have passed more than 500 laws restricting access to reproductive health care, closing clinics and creating a shortage of abortion providers. Following the Supreme Court's overturn of [Italics: Roe v. Wade] in [Italics: Dobbs v. Jackson Women's Health Organization], many states began banning abortion outright. Large swaths of the country no longer have access to abortion care.

As a result, patients who are denied abortion care may find it difficult or even impossible to find a willing and available provider in a reasonable timeframe. Even prior to the Supreme Court's decision to overturn the constitutional right to abortion in [Italics: Dobbs], eighty-nine percent of counties in the United States did not have a single abortion clinic, and some counties that had a clinic only provided abortion services on certain days. [Footnote 17: NAT'L P'SHIP FOR WOMEN & FAMS., BAD MEDICINE: HOW POLITICAL AGENDA IS UNDERMINING ABORTION CARE AND ACCESS IN OKLAHOMA (2019), https://www.nationalpartnership.org/our-work/repro/reports/bad-medicine- oklahoma.html.] Since then, many more clinics have shuttered. Abortion bans in the U.S. have left over 78 million people across 13 states without access to abortion. [Footnote 18: Calculated using the 2020 U.S. Census Apportionment Population numbers.] Thirteen states are enforcing total bans, two states are enforcing six-week bans, and six other states have tried to prohibit abortion, but are blocked by court orders as of the end of September 2022. [Footnote 19: CTR. FOR REPROD. RIGHTS, AFTER ROE FELL: ABORTION LAWS BY STATE, accessed 30 Sep. 2022.https://reproductiverights.org/after-roe-fell-abortion-laws-by-state/.] As a result, many patients must travel long distances at great expense to access care, if they are able to access care at all. [Footnote 20: CTR. FOR REPROD. RIGHTS, AFTER ROE FELL: ABORTION LAWS BY STATE, accessed 30 Sep. 2022. https://reproductiverights.org/after-roe-fell-abortion-laws-by-state/.] In addition, in some areas, the increased demand resulting from patients traveling from states that prohibit abortion results in significantly increased wait times [Footnote 21: Margot Sanger-Katz, Claire Cain Miller & Josh Katz, Interstate Abortion Travel Is Already Straining Parts of the System, N.Y. TIMES, (Sept. 19, 2022), https://www.nytimes.com/2022/07/23/upshot/abortion-interstate-travel- appointments.html.] and, in some cases, patients may be turned away altogether. [Footnote 22: Marty Schladen,

Affidavits: More Pregnant Minors Who Were Raped Denied Ohio Abortions, OHIO CAPITAL JOURNAL, (Sept. 22, 2022), https://ohiocapitaljournal.com/2022/09/22/affidavits-more-pregnant-minors-who-were- raped-denied-ohio-abortions/ (quoting Allegra Pierce, a medical assistant at Preterm-Cleveland, saying that "[e]ven those patients who are able to travel out of state often have a hard time getting an appointment due to increasingly long wait times at clinics in states where abortion is still legal."); Laura Hancock, Hamilton County Judge Immediately Halts Enforcement of Ohio's Fetal 'Heartbeat' Abortion Law for 14 Days; Abortion Now Legal Until 22 Weeks, CLEVELAND.COM (Sept. 14, 2022), https://www.cleveland.com/news/2022/09/ohio-judge-halts- enforcement-of-fetal-heartbeat-abortion-law-for-14-days.html.] Abortion opponents emboldened by these recent developments may be more likely to deny appropriate medical care to pregnant patients. In addition, state bans and restrictions that conflict with federal law mean that patients and providers are mired in uncertainty as to their rights and obligations with regards to abortion care. The final rule will be an important tool to ensure patients are not subject to discrimination on the basis of their pregnancy-related choices, particularly following the [Italics: Dobbs] decision, which has exacerbated this already pervasive form of discrimination.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0011
All Sections: 7.8.3

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Italics: Title IX's Abortion Neutrality Clause]

Title IX's statute includes an abortion neutrality provision which states that "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." [Footnote 28: 20 U.S.C. § 1681(a)] Additionally, Title IX ensures that institutions and individuals have access to strong religious liberty protections in the form of exemptions.

Relying on HHS' "applies by extension argument," the department fails to provide an explanation for why Section 1557's proposed rule [Italics/Bold: 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 doesn't follow for HHS to abandon the longstanding abortion neutrality clause.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0012
All Sections: 7.8.3, 7.8.2
(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Italics: Title IX's definition of sex as it relates to pregnancy is largely derived from Title VII]

Title IX's abortion neutrality, and longstanding definition of pregnancy, is not an isolated ruling. Title VII's Pregnancy Discrimination Act addresses the limits of compelled 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 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." [Footnote 31: Ibid.] 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 a company is 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 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; (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 32: 87 Federal Register 41390]

In this, #2 and #3 follows the logic of Title VII as it relates to abortion: namely, categorizing abortion as a subsequent medical condition that warrants medically directed accommodations; providing necessary periods of recovery without discrimination or penalty. The first definition,

however, breaks with Title VII's definition of sex and changes Title IX's current definition of pregnancy.

Comment Number: HHS-OS-2022-0012-DRAFT-75461-0002
All Sections: 7.8.3, 8.2

(b)(5)

Organization: Charlotte Lozier Institute

Excerpt Text:
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 protect 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://lozierinstitute.org/the- equality-act-threatening-life-and-equality/ detailing the history and purpose of Title IX's religious exception and abortion-neutrality provision.)

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0002
All Sections: 4.3.1.2.1, 7.8.3

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
Diminished trust in health care providers is likely to increase in the wake of [Italics: Dobbs]. We expect a stark increase in prosecution for self-managed abortion; likely, 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 Criminalization 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 (Jul. 3, 2022), https://www.npr.org/2022/07/03/1109015302/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/ (citing 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 Dirks, Criminalization of Pregnancy has Already Been Happening to the Poor and Women of Color, NPR (Aug. 3, 2022), https://www.npr.org/2022/08/03/1114181472/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: This has already occurred while the protections of Roe were intact. Pregnant people have been investigated, penalized, and even incarcerated where there is suspicion that a person was responsible for the termination of their pregnancy. See Brief for If/When/How: Lawyering for Reproductive Justice et al. as Amici Curiae Supporting Petitioners, June Medical Services L.L.C v. Russo, 140 S. Ct. 2103 (2020) (No. 18-1323), at 3, https://www.if whenhow.org/resources/amicus-brief-june-v-gee/.] This growing health crisis has exacerbated unjustifiable dangers to pregnant people, as the criminalization of pregnancy outcomes harms the health and wellbeing of patients and violates their civil and human rights. [Footnote 27: Brief for Experts, Researchers, and Advocates Opposing the Criminalization of People Who Have Abortions, as Amici Curiae Supporting Respondents, Dobbs v. Jackson Women's Health Organization, et al., 142 S.Ct. 2228 (2022) (No. 19-1392 at ii).]

The burden of abortion bans falls disproportionately on people of color and others at the intersection of marginalized identities, who already face disproportionate discrimination within the health care system as well as higher rates of poverty and policing. [Footnote 28: Brief for If/When/How: Lawyering for Reproductive Justice et al. as Amici Curiae Supporting Petitioners, June Medical Services L.L.C v. Russo, 140 S. Ct. 2103 (2020) (No. 18-1323), at 3, https://www.ifwhenhow.org/resources/ amicus-brief-june-v-gee/; A Post Roe America: The Legal Consequences of the Dobbs Decision Before the Sen. Comm. on the Judiciary, 117th Cong. 11-12 (2022) (statement of Kharia M. Bridges, Professor of Law, UC Berkeley School of Law) https://www.judiciary.senate.gov/meetings/a-post-roe-america-the-legal-consequences-of-the- dobbs-decision.] Even prior to the overturn of Roe, people of color, especially Black pregnant people, were prosecuted for the outcomes of their pregnancies at disproportionate rates, including by using fetal assault laws, or policies that punish or penalize pregnant people for substance use during pregnancy. [Footnote 29: In one instance, a South Carolina hospital serving a predominantly Black and low-income community engaged in targeted searches of pregnant women for narcotics and assisted the arrests, prosecution, and incarceration of pregnant Black women and those who recently gave birth; women were removed from their hospital beds in handcuffs and shackles. Ferguson v. Charleston, 532 U.S. 67 (2001).] Often this prosecution occurred with the assistance of the pregnant person's health care provider. A study of 413 cases in which pregnant women were arrested or otherwise deprived of their liberty on the basis of harm or perceived harm to a fetus found that 58 percent were reported by hospital personnel. [Footnote 30: See Lynn M. Paltrow & Jeanne 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 Pol., Pol'y & L. 299, 311 tbl. 1 (2013).] In particular, Black pregnant people who suffered from stillbirths, miscarriages, or simply alerted their doctors to substance use, irrespective of pregnancy outcomes, have been and continue to be incarcerated with the assistance of the health care system. [Footnote 31: Sandhya Dirks, Criminalization of Pregnancy Has Already Been Happening to the Poor and Women of Color, NPR (Aug. 3, 2022) https://www.npr.org/2022/08/03/1114181472/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); Cortney Loller, Criminalizing Pregnancy, 92 Indiana Law Journal 947 (2017).] With the rapid increase of states criminalizing abortion post-[Italics: Roe], patients will question whether they can trust their providers with

their full medical history, or trust them with their pregnancy-related care at all. [Footnote 32: Making Abortion a Crime (Again), IF/WHEN/HOW (2022), https://www.ifwhenhow.org/resources/making- abortion-a-crime-again/.]

Comment Number: HHS-OS-2022-0012-DRAFT-66818-0002
All Sections: 7.8.3

(b)(5)

Organization: NCPA

Excerpt Text:
[Bold: Abortion Neutrality Provision]
The proposed rule states that HHS OCR's 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.''] into 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 also notes 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 [Italics: Dobbs v. Jackson Women's Health Organization] decision, 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 by regulatory and enforcement bodies. This includes many questions about how broadly state laws will be interpreted and the impact of these actions on pharmacists' ability to serve the needs of their patients. Pharmacists need clear guidance from HHS OCR to support the prescribing and dispensing of medically necessary medications that may be affected by this new legal and regulatory paradigm. Without such guidance, we are deeply concerned that our patients will lose access to care and suffer irreparable harm.

In the wake of the [Italics: Dobbs] decision, over half of U.S. states have severely restricted or are expected to soon restrict access to abortion services, including medications that induce abortions. In many states, these laws prohibit prescribing and dispensing an "abortion-inducing

drug," or contain other comparable terms. This language is vague, and it is unclear whether it prohibits certain medications only when prescribed to induce abortion or whether a medication is prohibited entirely if it has the potential to induce abortion regardless of the condition for which it was prescribed. Namely, as stated above, methotrexate can be used off-label for the termination of intrauterine pregnancy and is also approved and used off-label for numerous indications such as cancer and ectopic pregnancy along with being commonly prescribed as the first-line treatment of inflammatory diseases such as arthritis. Similarly, mifepristone is indicated for the termination of pregnancy but is also prescribed in a medical emergency to treat ectopic pregnancy, preeclampsia, and other emergent medical presentations during labor and delivery and for the medical management of a miscarriage.

Patients who rely on these medications for reasons unrelated to pregnancy termination report new challenges in accessing these and other medications, and it is placing our patients' health at risk. Many health care professionals, including pharmacists, are uncertain of their legal liability related to prescribing and/or dispensing these medications regardless of whether they are being used for an abortion or another indication.

Without access to medications proven to be safe and effective, our patients' health is at risk. As pharmacists, we view patient wellbeing as paramount and are deeply troubled that continuity of care is being disrupted. [Bold: We call on HHS OCR to ensure through this regulation that patient care is not disrupted and that pharmacists shall be free to continue to practice without fear of professional sanction or liability. We strongly urge HHS OCR to act to help ensure that our patients retain continuity of care and that our members clearly understand their legal obligations.]

Comment Number: HHS-OS-2022-0012-DRAFT-69700-0002
All Sections: 7.8.3, 3.1.4, 7.8.4
(b)(5)
Organization: Senator Kirsten Gillibrand

Excerpt Text:
While the Biden administration has recently signed an executive order protecting 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 13: DOBBS, STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH, ET AL. v. JACKSON WOMEN'S HEALTH ORGANIZATION ET AL. [2022] §41–41–191 19-1392 (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 a 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 14: Rosman, K. (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- accessibility-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 issuing guidance to the nation's retail pharmacies, and we know further explicit regulatory action to restore the patient-physician relationship can help our nation take great strides forward to help people with disabilities make health care decisions in a non-coercive environment, in which their lives will be rightfully valued on an equal basis [Footnote 16: U.S. Department of Health And Human Services, 2022. Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services. Office for Civil Rights, pp.1-4]. We urge you to clearly outline: specific guidance surrounding medical professionals 'ability to prescribe life-saving medications to people with disabilities without delay and to include protections for providers who terminate pregnancies with dangerous complications. We urge you to include: specific guidance surrounding medical professionals 'ability to prescribe life-saving medications to people with disabilities without delay in the final rule to implement Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0021
All Sections: 7.8.3

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[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 education 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 individual or 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 Siljander 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0028
All Sections: 7.8.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:
Finally, the Final Rule should make clear that Section 1557 prohibits discrimination relating to treating pregnancy emergencies and complications, including termination of pregnancy, miscarriage management, and other pregnancy outcomes. Patients needing emergency abortion care or miscarriage management face discrimination from health professionals who object to such care; examples abound of individuals who present with emergency pregnancy complications only to be denied critical, time sensitive, and often life-saving medical care because a provider considers this care to be abortion [Footnote 65: Tamesha Means v. United States Conference of Catholic Bishops, ACLU, https://www.aclu.org/cases/tamesha-means-v-united-states-conference-catholic-bishops (last visited September 8, 2022)] [Footnote 66: Brief of Amici Curiae Rachael Lorenzo, Mindy Swank And Meghan Eagen In Support of Appellees and for Affirmance, New York et al. v. Dept' Health & Human Servs., No. 19-4254, Doc. 323, 7–20 (3d Cir. Aug. 3, 2020) (collecting stories of individuals denied life-saving care to treat emergency pregnancy complications)]. These tragic circumstances have occurred both before and after passage of the ACA, and have been increasingly documented since the Dobbs decision. The Department should make clear that such behavior constitutes discrimination on the basis of pregnancy or related conditions, including termination of pregnancy, under Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0029
All Sections: 7.8.3, 7.11.1
(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
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, 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 Decision Impact on Telemedicine & Privacy (July 2022), https://mailchi.mp/cchpca/telehealth-policy-heats-up-with-abortion-decision-plus- telehealth-sud-recommendations-from-white-house-more (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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0030
All Sections: 7.8.3
(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
The Proposed Rule does not expressly define sex discrimination or pregnancy-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 a Title IX regulation prohibiting discrimination on the basis of "pregnancy, childbirth, false pregnancy, termination of 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 31,387-88.

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 more 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 need 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] decision, people capable of becoming pregnant face numerous logistical and legal barriers to accessing care, particularly in the context of miscarriage management or pregnancy loss where there is a very real threat of arrest and prosecution as states seek to criminalize self-managed abortions. [Footnote 46: See National Advocates for Pregnant Women, Confronting Pregnancy Criminalization: A Practical Guide for Healthcare Providers, Lawyers, Medical Examiners, Child Welfare Workers, and Policymakers 9-11 (June 23, 2022), https://www.nationaladvocatesforpregnantwomen.org/wp-content/uploads/2022/06/1.Confronting-Pregnancy-Criminalization_6.22.23-1.pdf.] Furthermore, there are many documented instances of providers refusing to provide care or engaging in other punitive measures against pregnant patients for behavior perceived as harming the fetus. For example, a provider may not report a non-pregnant patient for substance use disorder, but would report a pregnant person for similar conduct. A standalone provision could protect patients from experiencing discrimination from healthcare providers on the basis of a past termination of pregnancy when accessing a broad range of healthcare services in states that now ban abortion. For example, without clarification that sex discrimination includes past pregnancy, a provider could turn away a potential patient after reviewing their medical history—even if the termination was years prior or if the patient is seeking unrelated medical services. It is therefore essential that the Final Rule expressly identify this conduct as prohibited sex discrimination.

Providing clear direction that discrimination on the basis of sex includes pregnancy- related medical conditions such as past pregnancy and the termination of pregnancy further bolsters other HHS guidance to covered entities. Indeed, much of HHS's recent guidance to retail pharmacies made clear that discrimination based on adverse pregnancy outcomes could constitute a violation of the Proposed Rule. For example, if a pharmacy regularly fills contraceptive prescriptions but refuses to provide emergency contraceptives because they could prevent ovulation or block fertilization, this could constitute sex discrimination in violation of Section 1557. [Footnote 47: U.S. Dep't of Health & Human Servs., Guidance to Nation's Retail Pharmacies: Obligations Under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services (Jul. 14, 2022), https://www.hhs.gov/civil-rights/for-

individuals/special-topics/reproductive- healthcare/pharmacies-guidance/index.html.] Providing clear language to covered entities is invaluable in ensuring that patient care is not delayed or denied due to sex discrimination. 87 Fed. Reg. at 47,833.

Furthermore, a standalone provision would make clear to covered entities that pregnant persons are entitled to the same level of information about their medical condition and needs as any other non-pregnant person. Indeed, current federal conscience laws do not exempt healthcare providers from a responsibility to provide [Italics: information] about abortion. See, e.g., Consolidated Appropriations Act of 2022, Pub. L. No. 117-103, § 507(d)(1), 136 Stat. 49, 496 (Weldon Amendment) (prohibiting discrimination against healthcare providers who refuse to "provide, pay for, provide coverage of, or refer for abortions"); 42 U.S.C. § 300a-7(b)(2)(A) (2012) (Church Amendment) (permitting religious healthcare entities to avoid "participat[ing] or assist[ing]" or "mak[ing] facilities available" for abortion). Under the Proposed Rule, healthcare providers, regardless of their religious exemption status, could not withhold information to patients on a discriminatory basis. [Footnote 48: Moreover, the Proposed Rule would preclude the exercise of broader state conscience clauses that would allow healthcare providers to withhold information in a discriminatory manner. The preemption clause of the ACA makes clear that the ACA trumps conflicting state laws. See 42 U.S.C. § 18041(d) (2012). Moreover, while the ACA does not change federal conscience protection, it makes no similar proviso for state-level conscience laws. See id. § 18023(c)(2)(a)(i) (2012) ("Nothing in this Act shall be construed to have any effect on Federal laws regarding . . . conscience protection."). Indeed, while the statute does not preempt state laws regarding the "coverage, funding, or procedural requirements on abortions, including parental notification or consent" it omits "conscience protection." Id. § 18023(c)(1)-(2).]

Comment Number: HHS-OS-2022-0012-DRAFT-75461-0004
All Sections: 7.8.3, 8.2

(b)(5)

Organization: Charlotte Lozier Institute

Excerpt Text:

II.) The NPRM Incorrectly Interprets Section 1557 To Exclude Title IX's 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) [italic: 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 inconsistent 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 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 jurisprudence. CLI queries how the Department's proposed interpretation can be reconciled with Franciscan Alliance's clear rejection of the similar 2016 regulation.

Comment Number: HHS-OS-2022-0012-DRAFT-0636-0005
All Sections: 7.8.3

(b)(5)

Organization:

Excerpt Text:
Also outrageous is 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. This would be laughable if it were not seriously proposed by bureaucrats in positions of power.

Comment Number: HHS-OS-2022-0012-DRAFT-43142-0005
All Sections: 6.2.4, 5.9.1, 7.8.3

(b)(5)

Organization: American Psychological Association

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0005
All Sections: 7.8.3, 7.8.2

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: B. The final rule should be clear that Section 1557 prohibits discrimination against patients in the treatment of pregnancy emergencies and complications, including termination of pregnancy, miscarriage management, and other pregnancy outcomes.]

[Italics: I. The final rule should clarify that EMTALA and 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 36: 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-medical-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 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 CFR 457, 42 CFR 460, 45 CFR 80, 45 CFR 84, 45 CFR 86, 45 CFR 91, 45 CFR 92, 45 CFR 147, 45 CFR 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 employ a more restrictive definition of an emergency medical condition. [Footnote 38: 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-medical-care-letter- to-health-care-providers.pdf.] In the July guidance, the Department clarified 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." [Footnote 39: Id.]

Despite the July guidance, health care providers need clarity as to when they may treat patients. Each day, physicians across the country seek guidance from the American College of Obstetricians and Gynecologists and share fears that they cannot make the best health care decisions for their patients following [Italics: Dobbs]. [Footnote 40: A Post Roe America: The Legal Consequences of the Dobbs Decision Before the Sen. Comm. on the Judiciary, 117th Cong. (2022) (oral testimony of Collen P. McNicholas, Chief Medical Officer, Planned Parenthood of the St. Louis Region and Southwest Missouri) https://www.judiciary.senate.gov/meetings/a-post-roe-america-the-legal- consequences-of-the-dobbs-decision (sharing her experience as a leader in the American College of Obstetricians and Gynecologists).] Providers urgently need clarity on when they may treat the patients who rely on them for care. [Footnote 41: Id.] Providers have been placed in an impossible situation, where providing the health care their patients need – even emergency care – could potentially expose them to prosecution and civil suit in states that ban abortion. [Footnote 42: Reese Oxner & María Méndez, Texas Hospitals are Putting Pregnant Patients at Risk by Denying Care Out of Fear of Abortion Laws, Medical Gro Says, TEXAS TRIBUNE (July 15, 2022), https://www.texastribune.org/2022/07/15/texas-hospitals-abortion-laws/; AP, Letter Says Texas Hospitals Reportedly Refusing Abortion Care, NBC DFW (Jul. 15, 2022), https://www.nbcdfw.com/news/local/texas- news/letter-says-texas-hospitals-reportedly-refusing-abortion-care/3015545/. Reese Oxner & María Méndez, Texas Hospitals are Putting Pregnant Patients at Risk by Denying Care Out of Fear of Abortion Laws, Medical Gro Says, TEXAS TRIBUNE (July 15, 2022), https://www.texastribune.org/2022/07/15/texas-hospitals-abortion-laws/; AP, Letter Says Texas Hospitals Reportedly Refusing Abortion Care, NBC DFW (Jul. 15, 2022), https://www.nbcdfw.com/news/local/texas- news/letter-says-texas-hospitals-reportedly-refusing-abortion-care/3015545/.]

We also recommend that the final rule clarify that denying an abortion in an emergency situation due to personal or institutional opposition to abortion violates Section 1557, because it is per se discrimination on the basis of sex. This is true regardless of any state laws that purport to ban abortion entirely. The final rule should put health care providers on notice that a failure to stabilize a patient for any reason having to do with the condition of pregnancy – including refusing to or delaying termination of pregnancy – is a violation of federal law under both EMTALA and Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0005
All Sections: 7.8.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:
Especially in the case of urgent or emergency care, a patient often does not have 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 London & 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]. 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 or 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 guidance") makes clear that the EMTALA statute preempts any state laws or mandates that employ a more restrictive definition of an emergency medical condition [Footnote 6: 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-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 & Hum. Servs., HHS Secretary Letter to Health Care Providers About Emergency Medical Care (Jul. 11, 2022), https://www.hhs.gov/sites/default/files/emergency-medical-care-letter-to-health-care-providers.pdf. 42 U.S.C. 18116(a)]. Additionally, the Department should be clear that EMTALA and Section 1557 provide reinforcing protections to patients needing emergency care, especially when it comes to termination of pregnancy.

The Final Rule should make clear that Section 1557 incorporates a provision in Section 1303 barring refusals of abortion care in emergency situations. As discussed in the following part, Section 1303 of the ACA incorporates specific provisions related to religious refusals, requiring covered entities provide care "except as otherwise provided for [under Title I of the ACA]" [Footnote 8: 42 U.S.C. 18116(a)]. Among other provisions, Section 1303 incorporates harmful federal laws that allow certain health care entities to refuse to provide abortion care, including

the Weldon, Church, and Coats-Snowe Amendments [Footnote 9: See 42 U.S.C. § 18023(c)(2)]. Notably, the Section 1303 refusal provisions do not apply to miscarriage management, nor do they permit refusals of abortion care in emergency situations, as these statutes yield to EMTALA [Footnote 10: New York v. United States Dep't of Health & Hum. Servs., 414 F. Supp. 3d 475, 538 (S.D.N.Y. 2019)]. Section 1303 itself clarifies that its application of refusal laws excludes emergency care [Footnote 11: 42 U.S.C. § 18023(d) ("Nothing in this Act shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law")]. The Final Rule must make clear that Section 1557 protects against discrimination in emergency situations for abortion or miscarriage management and requires covered entities—that otherwise offer comprehensive or comparable care—to provide such emergency care to the patient. This requirement remains unless a statutory exception applies. Because no such exception permits refusal of such care in emergency situations, Section 1557 requires such care.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0006
All Sections: 7.8.3

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: C. The proposed rule correctly declined to incorporate the Danforth 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 congressional 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, 31379-80 (May 18, 2016).] Section 1557

incorporates the bases of discrimination prohibited by Title IX; it does not incorporate the Title IX exemptions. Any conflicting interpretation runs contrary to congressional intent and would undermine the purpose of Section 1557 by prioritizing the beliefs of health care entities over the health care needs of patients.

Comment Number: HHS-OS-2022-0012-DRAFT-66750-0006
All Sections: 7.8.3

(b)(5)

Organization: Jacobs Institute of Women's Health

Excerpt Text:
- Incorporate into the discussion of EMTALA the clarification from the July 11, 2022 guidance 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." [Footnote 14: U.S. Department of Health and Human Services. 2022. 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]
- Prohibit refusing to provide information, resources, or referrals about abortion care and reproductive health care.

Comment Number: HHS-OS-2022-0012-DRAFT-40175-0007
All Sections: 7.8.3, 7.8.5, 7.8.2

(b)(5)

Organization: California Department of Health Care Services

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-75461-0007
All Sections: 7.8.3
(b)(5)

Organization: Charlotte Lozier Institute

Excerpt Text:
III. The NPRM Relies On An Erroneous Interpretation Of EMTALA To Justify Excluding Title IX's Abortion Neutrality Provision From Section 1557.

The Department's claim that the abortion-neutral 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 its definitions or operative provisions, can be construed to require involvement in abortion. This amendment straightforwardly clarified and effectively narrowed [italic: 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 in 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 mandate 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 CLI 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)(i); see also "Pro-Life Laws Protect Mom and Baby: Pregnant Women's Lives are Protected in All States," available at https://lozierinstitute.org/pro-life-laws-protect-mom-and-baby-pregnant-womens-lives-are-protected-in-all-states/.) The Department's interpretation has been rejected by at least one district court. (See State of Texas v. Becerra et al, No. 5:2022cv00185 - Document 73 (N.D. Tex. 2022).) CLI asks the Department to explain its intended interpretation of EMTALA in light of ongoing litigation, and to clarify whether healthcare providers that provide life-saving care to mothers, but not direct abortions, will be subject to enforcement actions under Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0079
All Sections: 7.8.3, 7.8.5
(b)(5)

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 exemption for health insurance benefits for abortion. [Footnote 234: Id.] once again demonstrating Congress chooses neutrality when it comes to abortion. Unless or until [Italics: Gilbert] is overruled, it is contrary to law 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0008
All Sections: 6.2.4, 7.8.3, 7.8.5

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[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 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 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]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0081
All Sections: 7.8.3

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[Bold: 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 237: 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.] Thus, "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 [Italics: et seq.]," [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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0082
All Sections: 15.2, 7.8.3

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0087
All Sections: 7.8.3

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[Bold: G. EMTALA does not require provision of elective abortions or preempt 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 an 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—(i) 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—[Italics: 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/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/reinforcement-emtala-obligations-specific- patients-who-are-pregnant-or-are-experiencing-pregnancy-0.]

But no state abortion law prohibits a hospital from taking necessary steps to save a mother's life or properly treat ectopic pregnancy or miscarriage. An abortion with the intended outcome of the death of the child is never necessary to save the life of the mother. Indeed, if a hospital performs an emergency abortion that results in the mother and child surviving, it is considered a failed abortion.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0009
All Sections: 7.8.3
(b)(5)
Organization: The Heritage Foundation

Excerpt Text:
[Italics: Applies by extension, or by convenience?]

The Department of Health and Human Services, per their own admission, 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 unaccountably 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 bans the use of its funds going toward an abortion outright. What right or basis does Section 1557 have to include 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75461-0009
All Sections: 7.8.3, 8.2
(b)(5)

Organization: Charlotte Lozier Institute

Excerpt Text:
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 unfettered access to abortion - at the expense of those healthcare providers that have genuine religious or moral objections.

Section 7.8.4 - Pharmacies providing abortion-related medication (OCR guidance and resulting litigation)

Comment Number: HHS-OS-2022-0012-DRAFT-69700-0002
All Sections: 7.8.3, 3.1.4, 7.8.4
(b)(5)

(b)(5)

Organization: Senator Kirsten Gillibrand

Excerpt Text:

While the Biden administration has recently signed an executive order protecting 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 13: DOBBS, STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH, ET AL. v. JACKSON WOMEN'S HEALTH ORGANIZATION ET AL. [2022] §41–41–191 19-1392 (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 a 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 14: Rosman, K. (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- accessibility-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 issuing guidance to the nation's retail pharmacies, and we know further explicit regulatory action to restore the patient-physician relationship can help our nation take great strides forward to help people with disabilities make health care decisions in a non-coercive environment, in which their lives will be rightfully valued on an equal basis [Footnote 16: U.S. Department of Health And Human Services, 2022. Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services. Office for Civil Rights, pp.1-4]. We urge you to clearly outline: specific guidance surrounding medical professionals 'ability to prescribe life-saving medications to people with disabilities without delay and to include protections for providers who terminate pregnancies with dangerous complications. We urge you to include: specific guidance surrounding medical professionals 'ability to prescribe life-saving medications to people with disabilities without delay in the final rule to implement Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-66750-0003
All Sections: 7.6.1, 7.8.4

(b)(5)

Organization: Jacobs Institute of Women's Health

Excerpt Text:
- Explicitly indicate that prohibited forms of discrimination include fertility care, contraception, mistreatment in maternity care, and sex discrimination in access to medications and treatments for disabilities and emergency medical conditions.
- Include in the rule descriptions of discrimination that can affect access to contraception in the retail pharmacy setting, using language from the July 13, 2022 guidance. [Footnote 13: U.S. Department of Health and Human Services. (2022). Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services, Jul. 13, 2022. https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html]
- Include explicit clarification of other types of discrimination against those seeking contraception, such as a state program that otherwise provides coverage of contraceptives but excludes a specific contraceptive because of an assertion that the contraception causes an abortion or a provider network that would only include facilities that refuse to perform female sterilization procedures.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0033
All Sections: 6.2.8, 7.8.4

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Bold: Title IX and Chemical Abortion Pills]

The abortion procedure itself has changed significantly since 1972. Given the rules' ambiguity and the change in terminology in "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 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 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 pills, does the department believe the existing federal law protects conscience rights for clinic employees who do not wish to be party to an abortion procedure? Or does the department believe that such an employee could find themselves accused of Title IX discrimination for opting out of assisting students in aborting their unborn children?

The chemical abortion process is often bloody and painful; abortion providers routinely downplay the significance of the physical process. Under new protocols, failure to evaluate women in-person means that more women will take abortion pills past the 10-week cutoff, at which point the risk of complications exponentially increases. Women who order pills online without undergoing an ultrasound may take the pills despite the fact that she may have an undiagnosed ectopic pregnancy (which, in turn, can be a fatal complication).
If the department envisions the proposed rule being used to bolster access to abortion pills in campus health clinics, the department must provide an estimate of the cost increase to campus health centers and address how they will respond to an increase in harmful side effects experienced with chemical abortion pills.

Does the department believe campus health centers are equipped to handle women experiencing post-abortion physical and mental health complications?
Can the department provide a cost estimate for the increased toll on health and counseling centers caring for post-abortive women – and/or her roommate(s) – who were traumatized and experience adverse mental health consequences after undergoing a dorm room abortion?

Section 7.8.5 - Case law discussion - Dobbs

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0010
All Sections: 7.8.5, 7.8.2

(b)(5)

Organization: The Century Foundation

Excerpt Text:
[Bold: Explicitly including pregnancy status in protections from sex discrimination 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 name pregnancy termination in its definition of sex discrimination. Many communities could not access abortion care prior to the Dobbs decision, and marginalized 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-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 Intersection of Abortion Access and Black Maternal Health," The Century Foundation, June 22, 2022, https://tcf.org/content/facts/the-intersection-of-abortion-access-and-black-maternal-health/].

Comment Number: HHS-OS-2022-0012-DRAFT-67830-0018
All Sections: 7.8.5

(b)(5)

Organization: U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0019
All Sections: 7.8.5

(b)(5)

Organization: National Health Council

Excerpt Text:
[Bold: Implications of the Dobb's 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: (1) https://www.latimes.com/california/story/2022-07-11/post-roe-many-autoimmune-patients-lose-access-to-gold- standard-drug (2) https://www.pharmacytimes.com/view/hhs-guidance-for-pharmacists-following-supreme-court-abortion- decision-creates-confusion (3) https://www.nola.com/news/healthcare_hospitals/article_238af184-ff02-11ec-9bce-dfd660a21ce1.html] detail 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 halting 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0028
All Sections: 6.2.8, 7.8.5

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[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 comment humbly requests similar explanations and definitions from the department related to abortion and Title IX.

Comment Number: HHS-OS-2022-0012-DRAFT-66235-0006
All Sections: 6.2.4, 7.8.5
(b)(5)

Organization: National Association of Health Underwriters

Excerpt Text:
[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 it 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66244-0006
All Sections: 7.8.5, 7.8.2
(b)(5)

Organization: Association of American Medical Colleges (AAMC)

Excerpt Text:
[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 regulation.] 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 this 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.

Comment Number: HHS-OS-2022-0012-DRAFT-40175-0007
All Sections: 7.8.3, 7.8.5, 7.8.2
(b)(5)

Organization: California Department of Health Care Services

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0079
All Sections: 7.8.3, 7.8.5
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 exemption for health insurance benefits for abortion. [Footnote 234: Id.] once again demonstrating Congress chooses neutrality when it comes to abortion. Unless or until [Italics: Gilbert] is overruled, it is contrary to law 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0008
All Sections: 6.2.4, 7.8.3, 7.8.5
(b)(5)
Organization: The Heritage Foundation

Excerpt Text:
[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 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 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]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0084
All Sections: 7.8.5

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[Bold: D. After [Italics: Dobbs], HHS has no compelling interest in promoting abortion.]

HHS also seeks comment 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."" [Footnote 240: 87 Fed. Reg. 47879.] [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).] Post-[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)).] Thus, as [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.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0085
All Sections: 7.8.5

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[Bold: E. 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 a proposed rule and give states and the American public proper 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 think 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.

Section 7.10 - Clinical Algorithms in Decision-Making (§92.210)

No comments are associated with this issue

Section 7.10.1 - Generally

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0001
All Sections: 7.10.1, 7.11.1, 5.1.1

(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-65981-0001
All Sections: 7.10.1

(b)(5)

Organization: Medical Imaging & Technology Alliance (MITA)

Excerpt Text:
AI products—in alignment with the Quintuple [Footnote 1: https://jamanetwork.com/journals/jama/article-abstract/2788483] Aim—promise to achieve

greater efficiency and effectiveness in the delivery of healthcare by (1) improving population health, (2) enhancing patient experiences, (3) avoiding unnecessary costs and driving cost efficiency, (4) improving the experiences of clinicians 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 implement policies that enable patient access to these technologies, while also fostering trust in their accuracy and reliability.

Bias Identification and Mitigation vs Elimination

In this proposed rule, HHS proposes to establish § 92.210 that states that a covered entity must not discriminate against any individual on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision-making. HHS is taking this action because it believes it is critical to address this issue given recent research demonstrating the prevalence of clinical algorithms that may result in discrimination. The HHS Office of Civil Rights (OCR) believes that proposed § 92.210 would put covered entities on notice that they cannot use discriminatory clinical algorithms and may need to make reasonable modifications in their use of the algorithms, unless doing so would cause a fundamental alteration to their health program or activity.

A fundamental assumption throughout this proposed rule is elimination of bias in clinical algorithms is possible and preferable and that use of these products always results in harmful discriminatory care. MITA member companies go to great lengths to mitigate bias inherent in clinical algorithms and provide transparency into how these technologies are developed. Medical imaging algorithm developers have extensive experience balancing the risks and benefits provided by a product to provide a safe, effective device. Risk management processes, quality management systems, and intensive training programs all reflect a commitment to products which improve patient care. Regulatory oversight by FDA offers further confirmation that the products are safe and effective.

Comment Number: HHS-OS-2022-0012-DRAFT-46192-0001
All Sections: 5.2.2, 7.10.1, 5.2.1, 7.11.1, 6.1
(b)(5)

Organization: American Nurses Association

Excerpt Text:
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 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 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. [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].

Comment Number: HHS-OS-2022-0012-DRAFT-67206-0001
All Sections: 7.10.1

(b)(5)

Organization: American College of Cardiology

Excerpt Text:
The ACC also believes clinical algorithms are a tool that supplement medical decision-making. 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 influence clinical decisions and are only one in a variety of factors leading to a decision for treatment. The starting point for such decisions must always be the individual patient. [Bold: Tools can help 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 together how to manage that person's health].

Clinical algorithms are developed using the best information available in the medical literature and should make every effort to guard against biases by using representative and inclusive data sets. The inclusion of diverse patient samples relative to race and ethnicity has been a goal of clinical researchers for decades; however, researchers have not always achieved this goal. Inaccurate or incomplete data that might lead to flawed algorithms is the responsibility of the

entire system of care, not just covered entities, including but not limited to federal funding agencies such as the Food and Drug Administration (FDA), the NIH National Heart, Lung, and Blood Institute (NHLBI), the Patient-Centered Outcomes Research Institute (PCORI), and the Agency for Healthcare Research and Quality (AHRQ). The ACC believes there should be continued support for coordination across all federal agencies to better understand bias in our health systems, how these biases may impact clinical algorithm development, and development of methods to create more accurate and inclusive algorithms that better serve patient needs and guard against adverse outcomes, including discrimination.

Clinical algorithms vary in nature, complexity, and utilization, and it is important that all federal agencies not only appropriately monitor and regulate against adverse outcomes such as incorrect clinical outputs or discriminatory recommendations but also guard against unintended consequences that stifle innovation and inadvertently hold clinicians and other covered entities accountable for actions outside of their control. In comments below, the ACC will provide OCR with background and context into how the ACC is working to use clinical guidelines and algorithms to improve heart health, provide clinical examples where protected class demographic information such as gender, age, or race influence the medical decision making process, and offer comments and recommendations on ways to ensure that Section 1557 regulations more precisely utilize terms such as "clinical algorithm" and provide additional and sufficient guidance and information to ensure covered entities understand their liability and responsibilities to ensure discrimination does not take place with clinical algorithms in the decision- making process.

Comment Number: HHS-OS-2022-0012-DRAFT-64284-0001
All Sections: 6.2.1, 5.2.2, 5.2.3, 5.10.2, 5.7.1, 7.10.1, 5.8.1, 10.1, 7.11.1, 8.1

(b)(5)

Organization: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-68913-0001
All Sections: 7.10.1, 7.10.7, 7.10.5

(b)(5)

Organization: Multistakeholder consensus group of organizations

Excerpt Text:
In its proposed rule, HHS proposes to 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, and requests input on the appropriate scope and specificity of such a requirement. While we share HHS' goal of advancing the use of beneficial algorithms by covered entities, share concerns with potential discriminatory outcomes resulting from the use of health AI tools and services, and further support the intent of the 1557 rule as a whole, HHS' proposal target AI in its rules raises numerous concerns:

- HHS' evaluation of various use cases demonstrating its concerns with health AI-related discriminatory outcomes does not adequately differentiate root causes for the outcomes it then seeks to avoid.

- HHS' proposal to explicitly address an emerging technology area (AI) raises the risk of technology terms and capabilities evolving more quickly than regulations can be updated.

- Our community is working to develop a consensus standard on how to validate that biases are being identified and appropriately mitigated, and to establish an adequate

infrastructure of test beds for making such standards operational. For example, providers, technology developers, governments, and others continue to address how to make AI data sets appropriately representative of the populations/communities AI tools are intended to serve and benefit.

- HHS' proposal appears to omit that providers rely on a health AI manufacturer's intended uses, whether the AI meets the definition of a medical device or not, and that its proposal would force covered entities to police their own supply chains for AI tools and services, despite realities that would make such efforts impracticable (for example, it is often infeasible to require a covered entity to audit AI and/or the datasets used to train AI they purchase). Further, the additional steps that covered entities would need to take to comply with HHS' proposed requirement are very likely to contribute to providers' already strained workload and further contribute to burnout.

- HHS' proposed rule does not account for the fact that some algorithms are specifically designed to identify and/or consider specific patient characteristics when assisting decision-making (e.g., an algorithm intended to identify certain groups of patients susceptible to a condition or that may benefit from a particular therapy).

- HHS' proposals impacting the use of AI do not adequately consider the role of transparent communication of intended uses and related risks, and of patient consent, with respect to the appropriate use of AI tools and services by covered entities.

- Under HHS' proposal, covered entities could face liability for discriminatory outcomes realized after using an AI tool for some time, presenting a significant incentive to avoid using AI tools altogether, which may not align with health AI-related liability distributions for other risks (e.g., patient safety).

- Machine translation tools are widely relied upon by providers, and serve as a critical tool in providing timely and efficacious care (particularly in the real-time communication context), and continue to be improved upon. HHS proposes to require a covered entity that uses machine translation to have translated materials reviewed by a qualified human translator when the underlying text is 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, non-literal, or technical language. HHS' rationale for such a proposal lacks a sufficient evidence base of machine translation tools being blanket categorized as not fit for purpose and could effectively force any covered entity using machine translation tools to have to further provide for a human translator's review in all circumstances.

- Implementing the proposed 1557 regulations for AI will require significant efforts to build capacity within HHS to appropriately conduct fact-specific analyses of allegations of discrimination, and to work with the covered entity to achieve compliance.

Comment Number: HHS-OS-2022-0012-DRAFT-67206-0010
All Sections: 7.10.1

(b)(5)

Organization: American College of Cardiology

Excerpt Text:
Covered Entity Responsibility for Understanding Clinical Algorithms

In the 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 it is ideal a clinician trust and 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 with the resources made available today]. 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 all 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 ACC 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 underlying biases built into a tool should fall solely on clinicians]. It is vital that OCR work closely with all stakeholders, including the FDA, device manufacturers, clinicians, patients, and others to ensure information is accessible and easily understandable so they can make informed decisions on standards of care together.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0011
All Sections: 7.10.1, 7.7.1, 6.1

(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
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 antidiscrimination 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0015
All Sections: 7.10.1

(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
[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 there be language in the final rule that compels users of these algorithms to demonstrate benefit or at 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, can 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 xxxvi: Joseph L. Wright, Wendy S. Davis, Madeline M. Joseph, Angela M. Ellison, Nia J. Heard-Garris, Tiffani L. Johnson, the AAP Board Committee on Equity; Eliminating Race-Based Medicine. Pediatrics July 2022; 150 (1): e2022057998.10.1542/peds.2022-057998]

Comment Number: HHS-OS-2022-0012-DRAFT-70479-0017
All Sections: 7.10.1

(b)(5)

Organization: National Disability Rights Network

Excerpt Text:
[Bold: § 92.210 - 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 reliance 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, prognosis, 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-46426-0017
All Sections: 7.10.1

(b)(5)

Organization: Genesee County Legal Aid Society dba Center for Civil Justice

Excerpt Text:
Use of Clinical Algorithms in Decision-Making

CCJ supports the addition of this new provision 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.

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0019
All Sections: 7.10.4, 7.10.1

(b)(5)

Organization: American Academy of Family Physicians

Excerpt Text:
Use of Clinical Algorithms in Decision-Making (§ 92.210)

HHS is proposing to prohibit discrimination under clinical algorithms by holding covered entities liable for any decision made when relying on a clinical algorithm if the intent or result is discriminatory. Covered entities would not be liable for the algorithm itself, only any decision and the impact of such decision.

[Bold: The AAFP supports OCR's proposal to prohibit discrimination using clinical algorithms and supports expanding this proposal beyond just clinical algorithms to include artificial intelligence and machine learning (AI/ML)]. While the AAFP believes that AI/ML have potential to improve outcomes for patients, we strongly support efforts to harness this technology and we recognize the limitations and pitfalls of this technology [Hyperlink: https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/equality/LT-OMB-EquityRFI-062321.pdf].

Recent studies indicate clinical guidance and existing algorithms for clinical decision making may be based on biased studies and exacerbate inequities [Footnote 13: Vyas DA, Eisenstein LG, Jones DS. Hidden in Plain Sight – Reconsidering the Use of Race Correction in Clinical Algorithms. N Engl J Med. 2020;383:874-882. Available at: https://www.nejm.org/doi/full/10.1056/NEJMms2004740]. One study found an algorithm used in hospitals systematically discriminated against Black patients [Footnote 14: Obermeyer Z, Powers B, Vogeli C, Mullainathan S. Dissecting racial bias in an algorithm used to manage the health of populations. Science. 2019. Available at: https://science.sciencemag.org/content/366/6464/447]. Experts also predict that rapid implementation of AI-solutions amid the COVID-19 pandemic may widen the already disparate impact of the virus [Footnote 15: Röösli E, Rice B, Hernandez-Boussard T. Bias at warp speed: how AI may contribute to the disparities gap in the time of COVID-19. Journal of the American Medical Informatics Association. 2020. Available at: https://doi.org/10.1093/jamia/ocaa210]. To improve trust in and equitability of AI/ML solutions, discriminatory outcomes must be addressed before successfully integrated AI/ML into clinical care. It is essential that AI-based technology augment decisions made by the user, not replace their clinical judgment or shared decision-making.

Comment Number: HHS-OS-2022-0012-DRAFT-20000-0002
All Sections: 7.10.1
(b)(5)

Organization: The Society of Thoracic Surgeons

Excerpt Text:
Subpart B—Nondiscrimination Provisions

Use of Clinical Algorithms in Decision-Making

[Italic: 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 their 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 3,800 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 Task

Force (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 recommendations on the subject of social risk (including SDS/SES status, race, and ethnicity). Although specific recommendations from various organizations and authors vary, several generally accepted principles include:

1. Direct and indirect causal pathways by which social risk might be associated with outcomes will be described, recognizing that for many if not most healthcare risk variables, the causal mechanism is incompletely understood.

2. If social risk variables are postulated to be associated with outcomes and are not included in risk models, the specific reasons for and potential effects of their omission will be discussed.

3. If racial and/or ethnic variables are included, risk model descriptions will acknowledge the substantial heterogeneity that exists within self-identified or even ancestry-based racial categories. Any race associations should be viewed "on average", which is also true of most other clinical or social risk variables. The rationale for inclusion of race or ethnicity variables will be explicitly discussed, as it has been in current STS risk model publications.

4. Available social risk variables (including missing %), will be described.

5. Exploratory analyses will be conducted with various combinations of social risk indicators (e.g., SDS/SES status, race, ethnicity), acknowledging that SDS/SES, as well as discrimination, may account for some of the apparent association of race with health outcomes. Any analyses of model performance, including but not limited to model calibration and discrimination, should be performed in the overall population and in the relevant SDS/SES, race, and ethnic populations (e.g., model performance in the estimation of stroke, overall and among

Black patients, with and without the inclusion of race, and with or without concomitant inclusion of other SDS/SES variables).

6. As they become generally available, more specific SES/SDS and genetic indicators for individual patients will be substituted, including those related to race and ethnicity (e.g., genetic polymorphisms or mutations that confer increased or decreased risk, and potentially actionable mutations such as those identified in various cancers). Continued inclusion of some current SDS/SES, race, or ethnicity variables may be unwarranted if their association with an outcome is fully explained by new and more specific risk factors with a more proximal and direct association.

7. Whether or not SDS/SES, race, or ethnicity variables are included in risk models, stratified analyses and feedback reports using these categories will be presented, which are more likely to explicitly demonstrate disparities in outcomes. Various approaches to stratification are available, and the most appropriate option(s) should be selected depending on the goal (e.g., within-provider stratification of outcomes by SDS/SES status or race; stratified between-provider differences in outcomes; or national outcomes stratified by SDS/SES, race, or ethnicity).

8. Language has been added to the STS risk calculator indicating that these estimates are only one of several sources of information to be used in cardiothoracic decision-making and patient counseling. Other sources include but are not limited to the clinical judgment of the surgeon, referring cardiologist, and PCP, and patient and family preferences. Most importantly, it states that risk calculators should not be used to exclude patients from surgery based on higher risks associated with any single clinical or social risk factor (e.g., BMI, kidney disease, sex, race, ethnicity, payer).

9. Potential unintended adverse consequences of including or excluding social risk factors in risk models will be explicitly discussed, and mechanisms implemented to monitor and mitigate them.

With careful attention to appropriate methodological principles, acknowledgment of limitations, and monitoring and mitigation of potential unintended negative consequences, STS will continue to judiciously and selectively incorporate social risk factors, including race and ethnicity, in its risk models to improve their predictive accuracy. This will optimize risk estimates for patient counseling and shared decision-making; quality improvement; detection and remediation of disparities; and provider performance classification. Updated and more specific social risk indicators will be substituted as they become available [Footnote 3: Shahian, David M., Vinay Badhwar, Sean M. O'Brien, Robert H. Habib, Jane Han, Donna E. McDonald, Mark S. Antman et al. "Social Risk Factors in Society of Thoracic Surgeons Risk Models Part 2: Review of Empirical Studies in Cardiac Surgery and Risk Model Recommendations." The Annals of Thoracic Surgery (2022)].

Comment Number: HHS-OS-2022-0012-DRAFT-37768-0002
All Sections: 7.10.1, 7.11.1

(b)(5)

Organization: Massachusetts Health Connector

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0021
All Sections: 7.10.1, 7.7.1, 4.3.1.1

(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-66437-0021
All Sections: 7.10.1

(b)(5)

Organization: Center for Elder Law & Justice

Excerpt Text:
[Bold: 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 dictate that Black patients must be more ill 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 motives 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/2021/02/FINAL-Intersectional-Guide-Crisis-Care-2-10-21.pdf]

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0021
All Sections: 7.10.1

(b)(5)

Organization: American Academy of Family Physicians

Excerpt Text:
[Bold: OCR should provide covered entities, specifically physician practices, with technical assistance and guidance to help integrate both clinical algorithms and improvements for these algorithms into existing clinical workflows to increase efficiency and minimize administrative burden]. This should include any required participation in governance, transparency, reporting, and impact assessments. OCR may consider working with ONC and the CMS Office of Burden Reduction and Health Informatics to accomplish this in a way that is efficient and sustainable for covered entities. OCR may consider providing template reporting structures or examples of how to continually evaluate algorithms and track their impacts on patients both during the process of use, immediate outcomes, and long-term outcomes for physician practices to use.

Comment Number: HHS-OS-2022-0012-DRAFT-69477-0024
All Sections: 7.10.1
(b)(5)

Organization: The Leadership Conference on Civil and Human Rights

Excerpt Text:
[Bold: B. The proposed rule would prohibit the discriminatory use of clinical algorithms and 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: Ibid. at 176-187.] Many clinical algorithms dictate that Black patients, for example, 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 reflected a 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 presumed 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0024
All Sections: 7.10.1
(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[Bold: E. Algorithm-Based Discrimination]

The States welcome HHS's proposed 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 47,918. 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 47,883, 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 into 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 Section 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 decision. [Footnote 62: See, e.g., Obermeyer et al., Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations, Science, 366, 447-453 (Oct. 25, 2019), https://pubmed.ncbi.nlm.nih.gov/31649194/ (noting that health program enrollment decisions "reflect how doctors respond to algorithmic predictions" in a way that reflects algorithmic bias).] HHS should clarify, and perhaps offer additional examples, explaining that merely adding an element of human clinical judgment on top of a discriminatory algorithm or system does not eliminate the covered entity's potential liability. Depending on the context, covered entities may need to implement policies and procedures in addition the use of individual judgment, in order to identify and eliminate bias resulting from use of a clinical algorithm.

Second, we agree with HHS's determination that this regulation does not represent a new prohibition, but a clarification and communication to covered entities of their responsibility regarding one specific form of discrimination. The field of algorithmic or computer-assisted decision making is fast-moving, and interacts in complicated ways with factors ranging from technology to payment policies. Accordingly, we suggest that HHS make clear in the preamble that despite the specificity of the (undefined) term "clinical algorithms in decision making," this regulation is exemplary, and does not represent the entire universe of algorithmic tools or automated decision making that may be used in a manner that violates Section 1557. Because Section 1557 applies to all "programs and activities" that could include pricing, financing, and other operational domains, it also reaches algorithms that may not be strictly "clinical" in nature, but that are used by providers, insurers, or other entities in non-clinical contexts that nonetheless

impact consumers' access to healthcare. [Footnote 63: For one example of a list of categories of algorithms that may pose risks of discrimination to healthcare consumers, see Letter from California Attorney General Rob Bonta to Hospital CEOs (Aug. 31, 2022), https://oag.ca.gov/system/files/attachments/press-docs/8-31-22%20HRA%20Letter.pdf.] For example, algorithms may be used to determine which patients get access to charity care or other financial support. [Footnote 64: See, e.g., Samuel Davis et al., Predicting a Need for Financial Assistance in Emergency Department Care, 9 Healthcare 2021 556 (May 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8150762/pdf/healthcare-09-00556.pdf.]

Third, in this or future rulemaking, HHS may wish to consider elaborating the ways in which varying scienter requirements for the non-discrimination statutes underlying Section 1557 relate to algorithmic bias. Algorithms that were not designed with affirmative animus or invidious intent may nonetheless contain subtle, facial discrimination (or a deprivation of meaningful access) based on protected characteristics (including as a "proxy" for protected characteristics, as HHS describes, 87 Fed. Reg. at 47,881), even in the absence of use of race as a variable. [Footnote 65: See Katie Palmer, 'It's Not Going to Work': Keeping Race Out of Machine Learning Isn't Enough to Avoid Bias, STAT (June 28, 2022), https://www.statnews.com/2022/06/28/health-algorithms- racial-bias-redacting/ (citing research that algorithms based on clinical notes can predict patients' self- identified race despite explicit redaction of race data).] HHS should note that disparate impact evidence, while not necessarily determinative, can be highly probative evidence of algorithmic decision making that violates Section 1557. Conversely, the States strongly welcome HHS's explanation that use of racial or ethnic variables may be appropriate and justified when used to "identify, evaluate, and address health disparities." 87 Fed. Reg. at 47,881. Indeed, covered entities may use these variables as part of a proactive effort to ensure equity and ameliorate effects of past discrimination in healthcare. [Footnote 66: See, e.g., Samorani et al., Overbooked and Overlooked: Machine Learning and Racial Bias in Medical Appointment Scheduling, Manufacturing & Service Operations Management (Aug. 18, 2021), https://www.scu.edu/media/leavey-school-of-business/isa/research/Machine-Learning-and-Racial-Bias- in-Medical-Appointment-Scheduling-SSRN-id3467047.pdf (describing "race aware" changes to algorithm to alleviate waiting room times for Black patients who were otherwise more likely to be overbooked).] HHS should make clear that Section 1557 does not interfere with such efforts.

Finally, the States urge HHS to make clear that its regulation addressing algorithmic discrimination by covered entities is intended to establish a floor, not a ceiling, for the protection of healthcare consumers. As HHS notes (87 Fed. Reg. at 47,884 n.578), several other federal agencies are examining this issue in detail, on varied timelines. State agencies can and will address issues of algorithmic bias in ways that are more specific or broader than HHS. [Footnote 67: See, e.g., California Civil Rights Council, Proposed Modifications to Employment Regulations Regarding Automated-Decision Systems (Ver. July 28, 2022), https://calcivilrights.ca.gov/wp- content/uploads/sites/32/2022/07/Attachment-G-Proposed-Modifications-to-Employment-Regulations- Regarding-Automated-Decision-Systems.pdf.] In some cases, States may decide to offer broader protection to vulnerable groups than federal law provides.

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0025
All Sections: 7.10.2, 7.10.1
(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:
15. Use of Clinical Algorithms in Decision-making (§ 92.210): This new provision 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 given 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 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, as none exist today. 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 identification of SDOH data sets necessary for addressing the needs of underserved communities in chronic disease management. The HL7 Gravity Project is developing a new SDOH data class for inclusion in the second version of the U.S. Core Data for Interoperability (USCDI V2) to create national stan dards
for representing SDOH-related data in Electronic Health Records (EHRs). At the federal level, discussions are under way including at includes the National Institute of Standards and Technology's (NIST) and the Office of the National Coordinator for Health Information (ONC) on mitigating risks and adverse biases in algorithms. Notable work at the federal level includes NIST AI Risk Management Framework [embedded hyperlink text (https://www.nist.gov/itl/ai-risk-management-framework)], which includes voluntary, industry-agnostic recommendations for mitigating risks across the lifecycle of algorithms, NIST's Managing Bias in AI [embedded

hyperlink text (https://www.nist.gov/artificial-intelligence/ai-fundamental-research-managing-ai-bias)]Guidance, and ONC convening of stakeholders [embedded hyperlink text (https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/getting-the-best-out-of-algorithms-in-health-care)] to discuss AI and healthcare data.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0025
All Sections: 7.10.1

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: VI. The inclusion of new provisions that address the changing health care landscape are important to further health equity.]

116 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 It, 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), https://www.who.int/publications/i/item/9789240029200; World Health Org., WHO Issues First Global Report on Artificial Intelligence (AI) in Health and Six Guiding Principles for Its Design and Use, WHO (Jun. 28, 2021), https://www.who.int/news/item/28-06-2021-who-issues-first-global-report-on-ai-in-health-and-six- guiding-principles-for-its-design-and-use.] Therefore, we support the Department's proposed provision on nondiscrimination in the use of clinical algorithms, and appreciate that proposed §92.210 makes 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.

Education will be critical to prevent further discrimination and harm as a result of biases in clinical algorithms. We urge the Department and the Biden-Harris Administration to collaborate with experts to help educate stakeholders, including insurers, health care system managers, clinicians, providers, and community health care workers, on the ways that algorithms inform decision-making processes. In addition to awareness of their liability for discriminatory use of these tools, this would ensure that entities can recognize and disrupt biases in those processes. The Department should also ensure that patients can easily access information about the use of these algorithms in the provision of their care. Finally, patients should also be made aware of any mechanism to file a complaint with the Office of Civil Rights to address and remedy discrimination they experience as a result of the use of a clinical algorithm.

Comment Number: HHS-OS-2022-0012-DRAFT-72212-0003
All Sections: 7.10.1

(b)(5)

Organization: Senate Democrats

Excerpt Text:
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 their clinical judgment [Footnote 7: 87 Fed. Reg. at 47880, 47918 (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 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/]. While complex and ever-changing, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-73220-0038
All Sections: 7.10.1

(b)(5)

Organization: National Immigration Law Center

Excerpt Text:
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 discrimination based on automatic decision-making tools and the implicit bias often built into such systems.

Comment Number: HHS-OS-2022-0012-DRAFT-65981-0004
All Sections: 7.10.1
(b)(5)
Organization: Medical Imaging & Technology Alliance (MITA)

Excerpt Text:
FDA-regulated vs Non-FDA-regulated Clinical Algorithms

Throughout 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 Algorithms

Finally, 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 clinical 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68054-0004
All Sections: 7.10.1, 7.11.1
(b)(5)
Organization: Washington Health Benefit Exchange

Excerpt Text:
The proposed rule also extends to clinical algorithms and telehealth, practices that can both improve health care and assist in addressing disparities, but can also perpetuate biases and health disparities if not well designed and implemented.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0042
All Sections: 7.10.1
(b)(5)
Organization: Center for American Progress

Excerpt Text:
XV. Nondiscrimination in the Use of Clinical Algorithms in Decision-Making (§ 92.210)

We support the multiple examples cited in the preamble to the 2022 Proposed Rule of bias from clinical algorithms. The indiscriminate use of race-based clinical algorithms has no place in health care. 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66235-0005
All Sections: 7.10.6, 7.10.1
(b)(5)
Organization: National Association of Health Underwriters

Excerpt Text:
[Bold: Algorithms and Nondiscrimination Requirements]
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, 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 individual 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0057
All Sections: 7.10.1

(b)(5)

Organization: Justice in Aging

Excerpt Text:
Nondiscrimination 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/FINAL- Intersectional-Guide-Crisis-Care-2-10-21.pdf.] However, we recommend that HHS broaden the prohibition to include any form of automated decision-making system as well as CSCs, which were often ranking systems or polices and 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 traumas 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-72260-0006
All Sections: 7.10.1

(b)(5)

Organization: Mayo Clinic

Excerpt Text:
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:

a) [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 decisions made in reliance on clinical algorithms."

b) "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."]

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0007
All Sections: 4.3.1.2.1, 7.10.1

(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
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 remain identical. [Footnote 21 Rae Ellen Bitchell & 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%20Daily%20Health%20Policy%20Report&utm_medium=email&_hsmi=13 2394588&_hsenc=p2ANqtz--4ODxarsKPHQSQeAfuOeyLJlAbaGTNgUoPyX4KJJqtvaQOUyan-ZRycCujUe8kMR623a6e7lV0KBUtZgGVacR1ynlazQ_Tte4IvXmfHP2n4J1zvI0&utm_content=132394588&utm_s ource=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 discrimination 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 Stare Vartan, Racial 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/.].

Comment Number: HHS-OS-2022-0012-DRAFT-66212-0007
All Sections: 7.10.1

(b)(5)

Organization: National Association of Chain Drug Stores

Excerpt Text:
[Bold and Underline: Use of Clinical Algorithms in Decision-Making (§ 92.210)]

NACDS 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 section that the agency consider the need for covered entities to take into account certain characteristics to provide optimal care. We believe that OCR's taking this type of reasonable approach would help covered entities provide even better care in the future to marginalized communities.

Comment Number: HHS-OS-2022-0012-DRAFT-69031-0008
All Sections: 7.10.1, 7.11.1
(b)(5)

Organization: Howard Brown Health

Excerpt Text:
[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 expansion 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: Apple DE, Lett E, Wood S, Freeman Baber K, Chuo J, Schwartz LA, Petsis D, Faust H, Dowshen 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.2020.0166]. 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.

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0009
All Sections: 7.10.1, 7.10.3
(b)(5)

Organization: Covered California

Excerpt Text:
Prohibiting discrimination in clinical decision-making algorithms, including telehealth services

Covered California supports HHS's efforts to mitigate the potential harm caused by valuable clinical algorithmic 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 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.

Section 7.10.2 - Definitions of clinical algorithm, artificial intelligence, machine learning, etc.

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0013
All Sections: 7.10.2, 7.10.6

(b)(5)

Organization: National Health Council

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0025
All Sections: 7.10.2, 7.10.1

(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:

15. Use of Clinical Algorithms in Decision-making (§ 92.210): This new provision 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 given 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 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, as none exist today. 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 identification of SDOH data sets necessary for addressing the needs of underserved communities in chronic disease management. The HL7 Gravity Project is developing a new SDOH data class for inclusion in the second version of the U.S. Core Data for Interoperability (USCDI V2) to create national stan dards
for representing SDOH-related data in Electronic Health Records (EHRs). At the federal level, discussions are under way including at includes the National Institute of Standards and Technology's (NIST) and the Office of the National Coordinator for Health Information (ONC) on mitigating risks and adverse biases in algorithms. Notable work at the federal level includes NIST AI Risk Management Framework [embedded hyperlink text (https://www.nist.gov/itl/ai-risk-management-framework)], which includes voluntary, industry-agnostic recommendations for mitigating risks across the lifecycle of algorithms, NIST's Managing Bias in AI [embedded hyperlink text (https://www.nist.gov/artificial-intelligence/ai-fundamental-research-managing-ai-bias)]Guidance, and ONC convening of stakeholders [embedded hyperlink text (https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/getting-the-best-out-of-algorithms-in-health-care)] to discuss AI and healthcare data.

Comment Number: HHS-OS-2022-0012-DRAFT-65981-0003
All Sections: 7.10.2

(b)(5)

Organization: Medical Imaging & Technology Alliance (MITA)

Excerpt Text:
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 in their use of the algorithms, unless doing so would cause a fundamental alteration to their 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 & procedure" [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 is 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 augmentative, an increasing number of autonomous products, with increasing levels of autonomy, will be introduced to the market in the coming years.

Comment Number: HHS-OS-2022-0012-DRAFT-72260-0004
All Sections: 7.10.2

(b)(5)

Organization: Mayo Clinic

Excerpt Text:
[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 in 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 labeling 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).

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0006
All Sections: 7.10.2, 7.10.7

(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:

• 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 user s of AI to safeguard against adverse bias and outcomes.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0006
All Sections: 7.10.4, 7.10.2, 7.10.3

(b)(5)

Organization: Health Care For All

Excerpt Text:

Discrimination in Clinical Algorithms

We support the multiple examples cited in 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/]. Nondiscrimination 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 matters because care management programs provide additional supports and navigation to patients that need it. In a state like Massachusetts, these programs have a large and growing impact given that the state's Medicaid program, private insurers, and health and hospital systems are all investing in them. If health systems are systematically excluding patients of color from participation, it adds additional discrimination on top of the underlying bias that is at the root of low utilization and cost for these patients to begin with [Footnote 5: Robert Pearl, New Study Blames Algorithm For Racial Discrimination, Ignores Physician Bias, Forbes (November 11 2019), https://www.forbes.com/sites/robertpearl/2019/11/11/algorithm/?sh=4f81bf77800f]. As algorithms and machine learning are increasingly used in the health care space, preventing this type of discrimination will become even more critical.

Section 7.10.3 - Expand to include artificial intelligence, machine learning, etc.

Comment Number: HHS-OS-2022-0012-DRAFT-70479-0019
All Sections: 7.10.3

(b)(5)

Organization: National Disability Rights Network

Excerpt Text:
We also request that HHS 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0043
All Sections: 7.10.3, 7.10.5

(b)(5)

Organization: Center for American Progress

Excerpt Text:
That said, we point to the numerous examples of bias, discrimination, and harm by covered entities by the ADS that may fall outside the term "clinical algorithm" [Footnote 91: Elizabeth Edwards and others, "NHeLP AHRQ Comments," (Washington: National Health Law Program, 2021), available at https://healthlaw.org/resource/nhelp-ahrq-comments/]. Such examples of harm 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, eligibility systems for Medicaid, CHIP, or Marketplace coverage that wrongfully deny or terminate coverage, "gender conflicts" in health decisions that lead to misdiagnoses and discrimination in health care settings, utilization review practices that are based on financial motives rather than generally accepted standards of care and deny necessary behavioral health services, and service utilization control methods and payment rates that violate mental health parity [Footnote 92: Elizabeth Edwards, "Preventing Harm from Automated Decision-Making Systems in Medicaid," (Washington: National Health Law Program, 2021), available at https://healthlaw.org/preventing-harm-from-automated-decision-making-systems-in-medicaid/] [Footnote 93: Skyler Rosellini, "Limited Data Collection for LGBTQI+ Health Promotes Bias," (Washington: National Health Law Program, 2021), available at https://healthlaw.org/limited-data-collection-for-lgbtqi-health-promotes-bias/] [Footnote 94: The Kennedy Forum, "A Breakdown of UnitedHealthcare's Recent Parity Settlements," August 24, 2021, available at https://www.thekennedyforum.org/blog/a-breakdown-of-unitedhealthcares-recent-parity-settlements/].

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. For example, some may consider the Crisis Standard of Care Plans cited in the preamble as not "clinical algorithms" under a narrow definition because many were policies or ranking systems rather than automated decisions.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0006
All Sections: 7.10.4, 7.10.2, 7.10.3

(b)(5)

Organization: Health Care For All

Excerpt Text:
Discrimination in Clinical Algorithms

We support the multiple examples cited in 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/]. Nondiscrimination 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 matters because care management programs provide additional supports and navigation to patients that need it. In a state like Massachusetts, these programs have a large and growing impact given that the state's Medicaid program, private insurers, and health and hospital systems are all investing in them. If health systems are systematically excluding patients of color from participation, it adds additional discrimination on top of the underlying bias that is at the root of low utilization and cost for these patients to begin with [Footnote 5: Robert Pearl, New Study Blames Algorithm For Racial Discrimination, Ignores Physician Bias, Forbes (November 11 2019), https://www.forbes.com/sites/robertpearl/2019/11/11/algorithm/?sh=4f81bf77800f]. As algorithms and machine learning are increasingly used in the health care space, preventing this type of discrimination will become even more critical.

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0009
All Sections: 7.10.1, 7.10.3

(b)(5)

Organization: Covered California

Excerpt Text:
Prohibiting discrimination in clinical decision-making algorithms, including telehealth services

Covered California supports HHS's efforts to mitigate the potential harm caused by valuable clinical algorithmic 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 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.

Section 7.10.4 - Types of clinical algorithms in use; examples of discriminatory practices

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0010
All Sections: 7.10.4, 7.10.6
(b)(5)

Organization: Covered California

Excerpt Text:
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 issuers, many of whom may not have the resources or technical knowledge to assess whether their tools are driving 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 could take – as well as providing technical assistance and guidance – would accelerate progress and reduce harm in this area.

Comment Number: HHS-OS-2022-0012-DRAFT-67830-0011
All Sections: 7.10.4, 7.10.7

(b)(5)

Organization: U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Excerpt Text:
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 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 Cong. (Oct. 14, 2021).] While race, ethnicity, and socioeconomic indicators can 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- 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.

Comment Number: HHS-OS-2022-0012-DRAFT-67996-0012
All Sections: 7.10.4

(b)(5)

Organization: The Alabama Disabilities Advocacy Program

Excerpt Text:
Formula- and algorithm-based discrimination in provision of care (§ 92.210)

States, health plans, and health care providers increasingly are using algorithms to support clinical decision making and establish clinical care standards. These tools are also widely used to support and inform population health management. Even as this evolving usage holds great promise for improving health care and health outcomes, it also can contribute to discrimination and amplify certain structural barriers and inequities that affect marginalized groups, including people with disabilities. Important work has been done that identifies how disability bias in algorithms negatively affects, for instance, employment decisions, determination of the need for Medicaid personal care services in the home, and the ability of autonomous vehicles to recognize pedestrian wheelchair users [Hyperlink: https://cdt.org/insights/report-challenging-the-use-of-algorithm-driven-decision-making-in-benefits-determinations-affecting-people-with-disabilities/]. Race and ethnicity bias in certain algorithmic tools also has been well documented [Hyperlink: https://sci-hub.tw/10.1126/science.aax2342]. Yet, very little work has been done to understand how bias in algorithms affects people with disability in health care even as it has the potential to profoundly affect health care decisions, services, and outcomes for this large population. Moreover, when disability intersects with other marginalized identities, algorithmic bias can further stigmatize patients, misdirect resources, and reinforce or ignore barriers to care rather than serving as a pathway to improving treatment and health outcomes.

For example, at the beginning of the COVID-19 pandemic, ADAP addressed the rationing of ventilators under the Alabama Department of Public Health's "Emergency Operations Plan," which ordered hospitals to "not offer mechanical ventilator support for patients" with "severe or profound mental retardation," "moderate to severe dementia," and "severe traumatic brain injury." As such, people with intellectual and cognitive disabilities were singled out for potential exclusion from life-saving medical care, in clear violation of federal nondiscrimination laws. Although federal law requires that decisions about how treatment should be allocated must be made based on individualized determinations, using current objective medical evidence, and not based on generalized assumptions about a person's disability, Alabama failed to uphold its responsibility to complete such individualized determinations and instead relied on formulaic assumptions about certain diagnoses as a justification for withholding care from individuals with disabilities.

ADAP filed an administrative complaint with the U.S. Department of Health and Human Services' Office for Civil Rights on March 23, 2020 to challenge this policy, and Alabama amended its policy on April 1, 2020. However, the amended policy did not make any specific references to ventilator triage, nor did it include specific provisions to ensure that people with disabilities would have equal access to life-saving treatment and that medical rationing would not be based on disability or other categories prohibited by law.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0014
All Sections: 7.10.4, 7.10.5

(b)(5)

Organization: Alliance of Multicultural Physicians

Excerpt Text:
The Proposed Rule would prohibit the discriminatory use of clinical algorithms 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 reflected a 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 de-prioritizing 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 indiscriminately 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). Alternatively, race IS a scientific category relative to being a meaningful factor in terms of predictive outcomes that includes the milieu of environmental economical sociological influencers on outcomes that individuals have. Where a so called race-based algorithm derives from an origin of understanding the population in 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.

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0019
All Sections: 7.10.4, 7.10.1
(b)(5)
Organization: American Academy of Family Physicians

Excerpt Text:
Use of Clinical Algorithms in Decision-Making (§ 92.210)

HHS is proposing to prohibit discrimination under clinical algorithms by holding covered entities liable for any decision made when relying on a clinical algorithm if the intent or result is discriminatory. Covered entities would not be liable for the algorithm itself, only any decision and the impact of such decision.

[Bold: The AAFP supports OCR's proposal to prohibit discrimination using clinical algorithms and supports expanding this proposal beyond just clinical algorithms to include artificial intelligence and machine learning (AI/ML)]. While the AAFP believes that AI/ML have potential to improve outcomes for patients, we strongly support efforts to harness this technology and we recognize the limitations and pitfalls of this technology [Hyperlink: https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/equality/LT-OMB-EquityRFI-062321.pdf].

Recent studies indicate clinical guidance and existing algorithms for clinical decision making may be based on biased studies and exacerbate inequities [Footnote 13: Vyas DA, Eisenstein LG, Jones DS. Hidden in Plain Sight – Reconsidering the Use of Race Correction in Clinical Algorithms. N Engl J Med. 2020;383:874-882. Available at: https://www.nejm.org/doi/full/10.1056/NEJMms2004740]. One study found an algorithm used in hospitals systematically discriminated against Black patients [Footnote 14: Obermeyer Z, Powers B, Vogeli C, Mullainathan S. Dissecting racial bias in an algorithm used to manage the health of populations. Science. 2019. Available at: https://science.sciencemag.org/content/366/6464/447]. Experts also predict that rapid implementation of AI-solutions amid the COVID-19 pandemic may widen the already disparate impact of the virus [Footnote 15: Röösli E, Rice B, Hernandez-Boussard T. Bias at warp speed: how AI may contribute to the disparities gap in the time of COVID-19. Journal of the American Medical Informatics Association. 2020. Available at: https://doi.org/10.1093/jamia/ocaa210]. To improve trust in and equitability of AI/ML solutions, discriminatory outcomes must be addressed before successfully integrated AI/ML into clinical care. It is essential that AI-based technology augment decisions made by the user, not replace their clinical judgment or shared decision-making.

Comment Number: HHS-OS-2022-0012-DRAFT-66790-0003
All Sections: 7.10.4

(b)(5)

Organization: The Arc of Pennsylvania

Excerpt Text:
3. 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 "utility" to a disability or chronic condition, automatically 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68873-0004
All Sections: 7.10.4, 7.10.6

(b)(5)

(b)(5)

Organization: Fenway Community Health Center

Excerpt Text:
Clinical Algorithms

The proposed rule states that a covered entity must not discriminate against any individual on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision-making. This provision is not intended to hinder the use of clinical algorithms; but to prevent discrimination given the recent increasing reliance on clinical algorithms in health care decision-making. This is an important provision, especially as more and more health care organizations collect and use sexual orientation and gender identity (SOGI) data to improve quality of care. The collection and use of SOGI data, along with anatomical inventory information, can inform clinical decision support, preventive screenings, and population health management [Footnote 32: Grasso C, Goldhammer H, Thompson J, Keuroghlian AS. Optimizing gender-affirming medical care through anatomical inventories, clinical decision support, and population health management in electronic health record systems. J Am Med Inform Assoc. 2021 Oct 12;28(11):2531-2535. doi: 10.1093/jamia/ocab080. PMID: 34151934; PMCID: PMC8510278]. It can also reduce the likelihood that a transgender, nonbinary, or intersex patient will experience culturally nonresponsive or even discriminatory treatment in health care. For example, an entry in the electronic medical record of simply "male" would likely lead a provider away from screening for cervical cancer or a breast exam, when it may be relevant to a patient whose sex assigned at birth was female. The collection and use of SOGI data in a culturally responsive, affirming way can prevent discrimination from influencing decision-making related to a TGD patient [Footnote 33: Grasso C, Goldhammer H, Brown RJ, Furness BW (2020). Using sexual orientation and gender identity data in electronic health records to assess for disparities in preventive health screening services. International Journal of Medical Informatics Volume 142, October 2020, 104245. https://doi.org/10.1016/j.ijmedinf.2020.104245].

Given the plethora of anti-transgender and anti-LGBT laws and policies being adopted by states across the U.S., it is especially important that SOGI data not be used to discriminate in health care or insurance coverage against LGBTQIA+ individuals [Footnote 34: Richgels C, Cahill S, Thompson J, Dunn M (2021). State bills restricting access of transgender youth to health care, school facilities, and school athletics threaten health and well-being. Boston: The Fenway Institute. https://fenwayhealth.org/wp- content/uploads/Anti-trans-legislation-policy-brief-FINAL.pdf]. Fear that SOGI data will be used in discriminatory ways may cause individual patients to not answer this question, or to not disclose their sexual or gender minority status. We support this provision.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0058
All Sections: 7.10.4

(b)(5)

Organization: Justice in Aging

Excerpt Text:
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, 9 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), Race, Research, & Pol'y Portal, https://rrapp.hks.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.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0006
All Sections: 7.10.4, 7.10.2, 7.10.3

(b)(5)

Organization: Health Care For All

Excerpt Text:
Discrimination in Clinical Algorithms

We support the multiple examples cited in 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/].
Nondiscrimination 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 matters because care management programs provide additional supports and navigation to patients that need it. In a state like Massachusetts, these programs have a large and growing impact given that the state's Medicaid program, private insurers, and health and hospital systems are all investing in them. If health systems are systematically excluding patients of color from participation, it adds additional discrimination on top of the underlying bias that is at the root of low utilization and cost for these patients to begin with [Footnote 5: Robert Pearl, New Study Blames Algorithm For Racial Discrimination, Ignores Physician Bias, Forbes (November 11 2019), https://www.forbes.com/sites/robertpearl/2019/11/11/algorithm/?sh=4f81bf77800f]. As algorithms and machine learning are increasingly used in the health care space, preventing this type of discrimination will become even more critical.

Comment Number: HHS-OS-2022-0012-DRAFT-67206-0009
All Sections: 7.10.4

(b)(5)

Organization: American College of Cardiology

Excerpt Text:
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 if 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 help covered entities. [Bold: 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 off 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].

Section 7.10.5 - Crisis Standards of Care, including racial inequities

Comment Number: HHS-OS-2022-0012-DRAFT-68913-0001
All Sections: 7.10.1, 7.10.7, 7.10.5
(b)(5)

Organization: Multistakeholder consensus group of organizations

Excerpt Text:
In its proposed rule, HHS proposes to 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, and requests input on the appropriate scope and specificity of such a requirement. While we share HHS' goal of advancing the use of beneficial algorithms by covered entities, share concerns with potential discriminatory outcomes resulting from the use of health AI tools and services, and further support the intent of the 1557 rule as a whole, HHS' proposal target AI in its rules raises numerous concerns:

- HHS' evaluation of various use cases demonstrating its concerns with health AI-related discriminatory outcomes does not adequately differentiate root causes for the outcomes it then seeks to avoid.

- HHS' proposal to explicitly address an emerging technology area (AI) raises the risk of technology terms and capabilities evolving more quickly than regulations can be updated.

- Our community is working to develop a consensus standard on how to validate that biases are being identified and appropriately mitigated, and to establish an adequate infrastructure of test beds for making such standards operational. For example, providers, technology developers, governments, and others continue to address how to make AI data sets appropriately representative of the populations/communities AI tools are intended to serve and benefit.

- HHS' proposal appears to omit that providers rely on a health AI manufacturer's intended uses, whether the AI meets the definition of a medical device or not, and that its proposal would force covered entities to police their own supply chains for AI tools and services, despite realities that would make such efforts impracticable (for example, it is often infeasible to require a covered entity to audit AI and/or the datasets used to train AI they purchase). Further, the additional steps that covered entities would need to take to comply with HHS' proposed requirement are very likely to contribute to providers' already strained workload and further contribute to burnout.

- HHS' proposed rule does not account for the fact that some algorithms are specifically designed to identify and/or consider specific patient characteristics when assisting decision-making (e.g., an algorithm intended to identify certain groups of patients susceptible to a condition or that may benefit from a particular therapy).

- HHS' proposals impacting the use of AI do not adequately consider the role of transparent communication of intended uses and related risks, and of patient consent, with respect to the appropriate use of AI tools and services by covered entities.

- Under HHS' proposal, covered entities could face liability for discriminatory outcomes realized after using an AI tool for some time, presenting a significant incentive to avoid using AI tools altogether, which may not align with health AI-related liability distributions for other risks (e.g., patient safety).

- Machine translation tools are widely relied upon by providers, and serve as a critical tool in providing timely and efficacious care (particularly in the real-time communication context), and continue to be improved upon. HHS proposes to require a covered entity that uses machine translation to have translated materials reviewed by a qualified human translator when the underlying text is 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, non-literal, or technical language. HHS' rationale for such a proposal lacks a sufficient evidence base of machine translation tools being blanket categorized as not fit for purpose and could effectively force any covered entity using machine translation tools to have to further provide for a human translator's review in all circumstances.

- Implementing the proposed 1557 regulations for AI will require significant efforts to build capacity within HHS to appropriately conduct fact-specific analyses of allegations of discrimination, and to work with the covered entity to achieve compliance.

Comment Number: HHS-OS-2022-0012-DRAFT-66846-0014
All Sections: 7.10.4, 7.10.5
(b)(5)
Organization: Alliance of Multicultural Physicians

Excerpt Text:
The Proposed Rule would prohibit the discriminatory use of clinical algorithms 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 reflected a 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 de-prioritizing 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 indiscriminately 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). Alternatively, race IS a scientific category relative to being a meaningful factor in terms of predictive outcomes that includes the milieu of environmental economical sociological influencers on outcomes that individuals have. Where a so called race-based algorithm derives from an origin of understanding the population in 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68913-0003
All Sections: 7.10.6, 7.10.7, 7.10.5
(b)(5)
Organization: Multistakeholder consensus group of organizations

Excerpt Text:
As a result, we strongly urge HHS to withdraw its proposal that 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 at this time. Instead, we urge HHS to:

- Initially, clearly scope and identify its concerns, and categorize root causes and appropriate tests.

- Explore how general 1557 regulatory language already in existence may be relied upon to address its concerns with health AI and discriminatory outcomes in a technology neutral manner.

- Partner with our community to advance standardization and testing efforts that will mitigate AI bias harms, and in contributing to the appropriate distribution and mitigation of risk and liability (i.e., that those in the value chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so).

- Account for communication of use/risk and the role of patients to consent to the use of AI based on those communications.

- Consider the impact of its AI-related proposals on covered entities' practical ability to use AI tools and services, particularly for frontline safety net covered entities with limited resources, as well as the need to reduce provider burnout.

- Conduct further consultation with and outreach to the FDA, NIH, and our community to (1) gain understanding of the state of health AI technologies and deployments, including technical and legal realities of health technology supply chains, (2) ensure that its proposals impacting health AI and liability for discriminatory outcomes do not disincentivize the development and use of beneficial AI tools in healthcare, and (3) avoid misaligning liabilities for health AI-related discriminatory outcomes with the distribution of risks and liabilities related to other risks.

- With respect to machine translation, HHS should recognize that its proposed requirements could result in the widespread abandonment of machine translation tools across covered entities, ultimately harming patient care, increasing healthcare costs, and adding to provider burdens. We strongly urge HHS to consider the wide benefits that machine translation tools provide today across healthcare contexts, particularly in real-time communications, and to clarify that a mandate for review by a human interpreter does not apply to real-time communications (whether in-person or via video); and that compliance analyses will weigh the net impacts of removing machine translation tools from the care continuum entirely in assessing the reasonableness of a covered

entity's activities in using such machine translation tools under its proposed factors.

- Examine ways to build HHS' capacity to address AI-related concerns (e.g., training and staffing, enhanced public-private partnership activities, etc.).

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0043
All Sections: 7.10.3, 7.10.5
(b)(5)
Organization: Center for American Progress

Excerpt Text:
That said, we point to the numerous examples of bias, discrimination, and harm by covered entities by the ADS that may fall outside the term "clinical algorithm" [Footnote 91: Elizabeth Edwards and others, "NHeLP AHRQ Comments," (Washington: National Health Law Program, 2021), available at https://healthlaw.org/resource/nhelp-ahrq-comments/]. Such examples of harm 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, eligibility systems for Medicaid, CHIP, or Marketplace

coverage that wrongfully deny or terminate coverage, "gender conflicts" in health decisions that lead to misdiagnoses and discrimination in health care settings, utilization review practices that are based on financial motives rather than generally accepted standards of care and deny necessary behavioral health services, and service utilization control methods and payment rates that violate mental health parity [Footnote 92: Elizabeth Edwards, "Preventing Harm from Automated Decision-Making Systems in Medicaid," (Washington: National Health Law Program, 2021), available at https://healthlaw.org/preventing-harm-from-automated-decision-making-systems-in-medicaid/] [Footnote 93: Skyler Rosellini, "Limited Data Collection for LGBTQI+ Health Promotes Bias," (Washington: National Health Law Program, 2021), available at https://healthlaw.org/limited-data-collection-for-lgbtqi-health-promotes-bias/] [Footnote 94: The Kennedy Forum, "A Breakdown of UnitedHealthcare's Recent Parity Settlements," August 24, 2021, available at https://www.thekennedyforum.org/blog/a-breakdown-of-unitedhealthcares-recent-parity-settlements/].

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. For example, some may consider the Crisis Standard of Care Plans cited in the preamble as not "clinical algorithms" under a narrow definition because many were policies or ranking systems rather than automated decisions.

Comment Number: HHS-OS-2022-0012-11650-0005
All Sections: 7.10.5
(b)(5)

Organization: ND Protection & Advocacy Project

Excerpt Text:
Disparities in Crisis Standards of Care cannot be easily remedied by antidiscrimination rulemaking, but it is a good start. One way to disrupt the bias is to make it very clear that people with disabilities who do not have legal decision-makers direct their own health care in the same way everyone else does. There is often extra scrutiny applied to people with disabilities and their ability to make decisions. There are biases related to quality of life directly tied to a person's disabilities. Anyone who uses an algorithm to determine care should be responsible for effects caused by use of the algorithm, regardless of who established the algorithm.

Section 7.10.6 - Best practices to avoid/mitigate discrimination

Comment Number: HHS-OS-2022-0012-DRAFT-40175-0010
All Sections: 7.10.6
(b)(5)

Organization: California Department of Health Care Services

Excerpt Text:
[Underlined: Nondiscrimination in use of clinical algorithms]: CalHHS supports the application of nondiscrimination protections to use of clinical algorithms in covered entities' decision-making. Similar to the above discussion, California law already prohibits the State and recipients of public funding from using criteria or methods of administration that have the purpose or effect of discriminating on the basis of ethnic group identification, religion, age, sex, color, or a physical or mental disability. [Footnote 11: See California Code of Regulations title 2, section 11154(i).] Within the Medi-Cal program, DHCS has placed the highest priority on improving and promoting health equity, with a renewed focus on addressing social drivers of health in both benefit design and administration across all of our delivery systems. Most notably, this can be seen throughout our recently approved Section 1115/1915 waiver program entitled California Advancing and Innovating Medi-Cal (or CalAIM). [Footnote: https://www.dhcs.ca.gov/CalAIM/Pages/calaim.aspx] One cornerstone of the CalAIM Initiative is a comprehensive Population Health Management program that seeks, in part, to identify, measure and develop solutions that address outcome differences by race, ethnicity, language, and other factors contributing to health equity. Within this effort, DHCS seeks to move away from downstream variance in use of processes and algorithms to a standardized and preemptive use of data that reduces bias and promotes equity in risk stratification and segmentation processes.

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0010
All Sections: 7.10.4, 7.10.6
(b)(5)

Organization: Covered California

Excerpt Text:
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 issuers, many of whom may not have the resources or technical knowledge to assess whether their tools are driving 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 could take – as well as providing technical assistance and guidance – would accelerate progress and reduce harm in this area.

Comment Number: HHS-OS-2022-0012-DRAFT-64284-0010
All Sections: 7.10.6
(b)(5)

(b)(5)

Organization: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Excerpt Text:

3. A specific issue that warrants immediate correction is discrimination relating to the algorithm bias embedded in the crisis 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 this 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0013
All Sections: 7.10.2, 7.10.6

(b)(5)

Organization: National Health Council

Excerpt Text:

[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.

Comment Number: HHS-OS-2022-0012-DRAFT-69128-0016
All Sections: 7.10.6

(b)(5)

(b)(5)

Organization: American Academy of Pediatrics

Excerpt Text:
AAP supports proactively reframing clinical decision-making tools using valid, 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 xxxvii: Joseph L. Wright, Wendy S. Davis, Madeline M. Joseph, Angela M. Ellison, Nia J. Heard-Garris, Tiffani 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/e2022057998/186963/Eliminating-Race-Based-Medicine?autologincheck=redirected%3FnfToken%3D00000000-0000-0000-0000-000000000000; 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.

Comment Number: HHS-OS-2022-0012-DRAFT-70479-0018
All Sections: 7.10.6

(b)(5)

Organization: National Disability Rights Network

Excerpt Text:
[Bold/Underline: Algorithm-Supported Decision-Making]

The preamble explaining 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 precluding 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 is 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 reliance 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 any potential impacts; and train staff on the proper use of such systems in decision-making;
- Require providers, before implementing clinical algorithms, validate that the tool was tested in different populations to identify hidden biases;
- Establish a baseline understanding that providers must demonstrate, before implementing clinical algorithms, including: how the tool will address a clinical goal, how to identify and correct for potential bias, how to override the tool, and put in place ongoing oversight. We recommend providers do not use algorithmic tools that do not allow them to independently review the basis for a recommendation; and
- Require providers to collect and report comprehensive, disaggregated demographic data such as, claim denials, enrollment, complaints, and outcomes. [Footnote 16: See Allsbrook, supra note 19.]

Comment Number: HHS-OS-2022-0012-DRAFT-72260-0002
All Sections: 7.10.6, 7.10.7
(b)(5)
Organization: Mayo Clinic

Excerpt Text:
Rather than a "liability-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 their defined expectations. Standards may include required 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.

Comment Number: HHS-OS-2022-0012-DRAFT-65981-0002
All Sections: 7.10.6

(b)(5)

Organization: Medical Imaging & Technology Alliance (MITA)

Excerpt Text:
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 labelling 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.

Comment Number: HHS-OS-2022-0012-DRAFT-67206-0002
All Sections: 7.10.6

(b)(5)

(b)(5)

Organization: American College of Cardiology

Excerpt Text:

The Use of Clinical Guidelines to Improve Heart Health

The ACC is dedicated to using 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 Anstey D, Li S, Thomas L, Wang TY, Wiviott SD. Race and Sex Differences in Management and Outcomes of Patients After ST-Elevation and Non-ST-Elevation Myocardial Infarct: 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):325-331. 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. 2013;127(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: Pandey A, Keshvani 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 8]. 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 around 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 ACC, in collaboration with the American Heart Association (AHA) and multiple other healthcare stakeholder organizations, spearheaded the national 'Door to Balloon' quality initiative, to address persistent delays in life-saving cardiac procedures in the setting of heart attacks. This national quality initiative was highly successful, leading to more rapid heart attack care across the U.S. Of note, with successful implementation of the quality-of-care strategies, [bold: Black Americans had among the greatest improvements in timely heart attack care, with significant reduction in disparity] [Footnote 6: Curtis JP, Herrin J, Bratzler DW, Bradley EH, Krumholz HM. Trends in Race-Based Differences in Door-to-Balloon Times. Arch Intern Med. 2010;170(11):992–993. doi:10.1001/archinternmed.2010.165] [Footnote 7: Bradley EH, Nallamothu BK, Herrin J, et al. National efforts to improve door-to-balloon time results from the Door-to-Balloon Alliance. J Am Coll Cardiol. 2009;54(25):2423-2429. doi: 10.1016/j.jacc.2009.11.003] [Footnote 8: Krumholz HM, Herrin J, Miller LE, et al. Improvements in door-to-balloon time in the United States, 2005 to 2010. Circulation. 2011;124(9):1038-1045. doi:10.1161/CIRCULATIONAHA.111.044107] [Footnote 9: https://www.nytimes.com/2015/06/21/health/saving-heart-attack-victims-stat.html].

Nonetheless, the College is fully aware that treatment gaps can be lessened or exacerbated when "real- world," or observational, data are used to inform risk stratification and treatment decisions. Biases can also be reflected in historical datasets, including those influenced by social, cultural, economic, and other variables. Thus, great vigilance is needed by all health care stakeholders, especially medical professional societies. Learning how this data can be turned into information within the context of medical decision making is crucial. [Bold: The ACC is committed to finding ways in which risk stratification tools and algorithms can serve as the starting point for conversations and shared treatment decisions with each unique patient. The goal for each of these tools is to encourage appropriate clinical treatment while avoiding the harm of unnecessary treatment. The starting point for such decisions must always be the individual patient].

Comment Number: HHS-OS-2022-0012-DRAFT-68913-0002
All Sections: 7.10.6, 7.10.7

(b)(5)

Organization: Multistakeholder consensus group of organizations

Excerpt Text:
To be clear, we share HHS' concerns about health AI and the impact of harmful biases and are committed to advancing solutions to ensure that such harms are identified and mitigated. Providers, technology developers and vendors, health systems, insurers, and other stakeholders all benefit from understanding the distribution of risk and liability in building, testing, and using healthcare AI tools. We urge HHS to collaborate with all stakeholders to develop and operationalize frameworks that utilize risk-based approaches to align healthcare AI uses with consensus benchmarks for safety, efficacy, and equity, and to ensure the appropriate distribution and mitigation of risk and liability by supporting that those in the value chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so. HHS' proposed 1557 regulatory updates for AI bias, as drafted, would derail the progress made through public-private partnerships and standardization activities, and significantly disincentivize covered entities use of AI, ultimately robbing patients of the benefits of AI.

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0020
All Sections: 7.10.6

(b)(5)

Organization: American Academy of Family Physicians

Excerpt Text:
[Bold: The AAFP supports the approach of OCR working with covered entities on suggested actions to mitigate potential discriminatory outcomes]. These actions may include testing of algorithms before and during use and corrective action plans with efficient and achievable steps to take when error is discovered. An approach of initial warning and corrective action would be

far more effective than penalization. Such a learning environment allows physicians to work in good faith to improve the use of algorithms and may contribute to their full understanding of the creation and use of algorithms and their effects on patient care. Additionally, it is critical that algorithm developers and evaluators are transparent with physicians on the creation, evaluation, adjustment, and data collection on clinical algorithms. This gives physicians and other clinicians more opportunity to address implicit biases and determine if use of the algorithm is appropriate for a particular patient case. We appreciate ONC's consideration of clinicians' need for more transparency of AI/ML tools and the evaluation of such tools in various care settings [Hyperlink: https://www.healthit.gov/buzz-blog/health-data/minimizing-risks-and-maximizing-rewards-from-machine-learning]. We urge ONC to make this information readily available and adaptable for clinicians' use without introducing additional burden on physicians to use it in practice.

With this in mind, [bold: OCR should also consider the varying levels of liability that correspond with different medical scenarios]. Physicians should not be expected to evaluate the efficacy and safety of individual clinical algorithms while providing patient care, and therefore should not be held solely liable for the consequences of these algorithms. This is especially true if physician practices do not have the appropriate technology available to evaluate the algorithms in real-time. [Bold: The AAFP recommends liability for the consequences of the use of clinical algorithms be shared between the clinician and the algorithm creator]. This may be modeled on the risk framework proposed in the Food and Drug Administration Safety and Innovation Act (FDASIA), in which the FDA collaborated with FCC and ONC, along with solicited stakeholder input, to form best practices on an appropriate, risk-based regulatory framework that promotes innovation, protects patient safety, and avoids unnecessary and duplicative regulation [Hyperlink: https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-safety-and-innovation-act-fdasia].

In any case, individual review of each clinical decision is necessary. Decisions should be made according to clinical judgment and shared decision making, and supported by algorithms, not replaced by them. [Bold: The AAFP believes implicit bias among both physicians and health care researchers must be addressed and implicit bias training should be implemented to support culturally appropriate, patient-centered care and reduce health disparities] [Hyperlink: https://www.aafp.org/about/policies/all/implicit-bias.html]. This should include bias training related to the creation, use, and individual review of clinical algorithms to improve care delivery and the success of the algorithms.

Comment Number: HHS-OS-2022-0012-DRAFT-67206-0003
All Sections: 7.10.6

(b)(5)

Organization: American College of Cardiology

Excerpt Text:
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,

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 debates in good faith 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 it 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 [bold: widely utilized risk models are scientific, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68913-0003
All Sections: 7.10.6, 7.10.7, 7.10.5

(b)(5)

Organization: Multistakeholder consensus group of organizations

Excerpt Text:
As a result, we strongly urge HHS to withdraw its proposal that 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 at this time. Instead, we urge HHS to:

- Initially, clearly scope and identify its concerns, and categorize root causes and appropriate tests.

- Explore how general 1557 regulatory language already in existence may be relied upon to address its concerns with health AI and discriminatory outcomes in a technology neutral manner.

- Partner with our community to advance standardization and testing efforts that will mitigate AI bias harms, and in contributing to the appropriate distribution and mitigation of risk and liability (i.e., that those in the value chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so).

- Account for communication of use/risk and the role of patients to consent to the use of AI based on those communications.

- Consider the impact of its AI-related proposals on covered entities' practical ability to use AI tools and services, particularly for frontline safety net covered entities with limited resources, as well as the need to reduce provider burnout.

- Conduct further consultation with and outreach to the FDA, NIH, and our community to (1) gain understanding of the state of health AI technologies and deployments, including technical and legal realities of health technology supply chains, (2) ensure that its proposals impacting health AI and liability for discriminatory outcomes do not disincentivize the development and use of beneficial AI tools in healthcare, and (3) avoid misaligning liabilities for health AI-related discriminatory outcomes with the distribution of risks and liabilities related to other risks.

- With respect to machine translation, HHS should recognize that its proposed requirements could result in the widespread abandonment of machine translation tools across covered entities, ultimately harming patient care, increasing healthcare costs, and adding to provider burdens. We strongly urge HHS to consider the wide benefits that machine translation tools provide today across healthcare contexts, particularly in real-time communications, and to clarify that a mandate for review by a human interpreter does not apply to real-time communications (whether in-person or via video); and that compliance analyses will weigh the net impacts of removing machine translation tools from the care continuum entirely in assessing the reasonableness of a covered

entity's activities in using such machine translation tools under its proposed factors.

- Examine ways to build HHS' capacity to address AI-related concerns (e.g., training and staffing, enhanced public-private partnership activities, etc.).

Comment Number: HHS-OS-2022-0012-DRAFT-67206-0004
All Sections: 7.10.6

(b)(5)

Organization: American College of Cardiology

Excerpt Text:
[Bold: A relentless drive for self-improvement and the quest for the strongest, most timely science are ingrained in the mission and activities of the College. To that end, we constantly challenge ourselves to ensure that we are providing the most 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 to acknowledge 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 those 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 validated models, wherein each of the independent or 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. The result is that most frontline clinical models rely on inputs that "carry" additional information through mathematical correlation, not physiological causation. This is particularly the case when models attempt to account for social determinants of health, well- documented to account for as much or more variation in outcomes as medical treatment itself.

Comment Number: HHS-OS-2022-0012-DRAFT-68873-0004
All Sections: 7.10.4, 7.10.6

(b)(5)

Organization: Fenway Community Health Center

Excerpt Text:
Clinical Algorithms

The proposed rule states that a covered entity must not discriminate against any individual on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision-making. This provision is not intended to hinder the use of clinical algorithms; but to prevent discrimination given the recent increasing reliance on clinical algorithms in health care decision-making. This is an important provision, especially as more and more health care organizations collect and use sexual orientation and gender identity (SOGI) data to improve quality of care. The collection and use of SOGI data, along with anatomical inventory information, can inform clinical decision support, preventive screenings, and population health management [Footnote 32: Grasso C, Goldhammer H, Thompson J, Keuroghlian AS. Optimizing gender-affirming medical care through anatomical inventories, clinical decision support, and population health management in electronic health record systems. J Am Med Inform Assoc. 2021 Oct 12;28(11):2531-2535. doi: 10.1093/jamia/ocab080. PMID: 34151934; PMCID: PMC8510278]. It can also reduce the likelihood that a transgender, nonbinary, or intersex patient will experience culturally nonresponsive or even discriminatory treatment in health care. For example, an entry in the electronic medical record of simply "male" would likely lead a provider

away from screening for cervical cancer or a breast exam, when it may be relevant to a patient whose sex assigned at birth was female. The collection and use of SOGI data in a culturally responsive, affirming way can prevent discrimination from influencing decision-making related to a TGD patient [Footnote 33: Grasso C, Goldhammer H, Brown RJ, Furness BW (2020). Using sexual orientation and gender identity data in electronic health records to assess for disparities in preventive health screening services. International Journal of Medical Informatics Volume 142, October 2020, 104245. https://doi.org/10.1016/j.ijmedinf.2020.104245].

Given the plethora of anti-transgender and anti-LGBT laws and policies being adopted by states across the U.S., it is especially important that SOGI data not be used to discriminate in health care or insurance coverage against LGBTQIA+ individuals [Footnote 34: Richgels C, Cahill S, Thompson J, Dunn M (2021). State bills restricting access of transgender youth to health care, school facilities, and school athletics threaten health and well-being. Boston: The Fenway Institute. https://fenwayhealth.org/wp- content/uploads/Anti-trans-legislation-policy-brief-FINAL.pdf]. Fear that SOGI data will be used in discriminatory ways may cause individual patients to not answer this question, or to not disclose their sexual or gender minority status. We support this provision.

Comment Number: HHS-OS-2022-0012-DRAFT-72260-0005
All Sections: 7.10.6

(b)(5)

Organization: Mayo Clinic

Excerpt Text:
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, FDA regulations (e.g., 21 CFR 820) and international standards (e.g., ISO 14971) have already 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66235-0005
All Sections: 7.10.6, 7.10.1

(b)(5)

Organization: National Association of Health Underwriters

Excerpt Text:
[Bold: Algorithms and Nondiscrimination Requirements]
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, 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 individual 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.

Comment Number: HHS-OS-2022-0012-DRAFT-39385-0005
All Sections: 7.10.6
(b)(5)

Organization: American Hospital Association

Excerpt Text:
USE OF CLINICAL ALGORITHMS TO SUPPORT DECISION-MAKING IN COVERED HEALTH PROGRAMS AND ACTIVITIES

As 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- conscious variables may be appropriate and justified under certain circumstances. The Department also notes that the use of clinical algorithms 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." 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 earlier morbidity and mortality from prostate cancer [Footnote 1: American Cancer Society. Cancer Facts & Figures for African American/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-cff-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 or 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 the risks of over-deterrence when [italic: enforcing] Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-67206-0005
All Sections: 7.10.6

(b)(5)

Organization: American College of Cardiology

Excerpt Text:
Some clinical models do include a race variable as OCR notes in the proposed 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 thresholds for risk, as established in the guidelines, a clinician may choose to treat the patient with a series of preventive medications, including statins and anti-hypertension medications, as well as counseling the patient on healthy lifestyle choices. [Bold:The ACC had done 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 the 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 included. For example, selecting 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. We know that biology does not sufficiently vary across race to explain the difference in observed cardiovascular outcomes in the United States. On the other

hand, it reflects the unfortunate truth that Black Americans, controlling for a host of other clinical variables such as cholesterol and blood pressure, still endure a higher risk of having a heart attack or stroke. Capturing that risk in the ASCVD Risk Estimator is intended to alert both clinicians and patients to that population risk, potentially resulting in a more aggressive treatment strategy to manage that risk as it manifests in the individual patient. From that perspective, one could argue the inclusion of the race variable draws attention to disparities in outcomes and proactively focuses attention on patients that are indeed at the highest risk. In the ASCVD risk model, the race variable is efficient in the sense it is easy for a patient or clinician to assess and accurately predict risk. [Bold: Still, we are committed to ongoing monitoring of the model, consideration of iterative revisions, and feedback on its use in clinical practice].

[Bold: The dilemma of race variables in predictive models is illustrative of the dual responsibility of the cardiovascular clinician to address the consequences of racial and structural injustice and its manifestation in health disparities. The clinician's first obligation is to provide the best possible care to each patient. Patients present bearing the burdens of society as it is, not as we wish it to be]. By understanding how these social burdens manifest as clinical risk, clinicians can endeavor to attenuate that risk at the individual patient level. However, the ACC also believes it has a responsibility to address the structural drivers of this disparity, with the ambition of reducing the variation in risk across race by reducing the social and structural disparities which drive it.

[Bold: The ultimate goal of the ACC is to equip clinicians and patients with as much information as possible to guide the development of a shared, effective care plan. The ACC/AHA guidelines repeatedly emphasize the importance of shared decision making, wherein the clinician and patient discuss the goals and risks of treatment and customize a care plan that accounts for the values of the patient].

Under such a model of care, the ASCVD Risk Estimator and other models like it are but one input in a comprehensive process of assessing and managing cardiovascular risk.

As shown above, medical specialty societies like the ACC have specialized and detailed expertise in the development and utilization of clinical algorithms, including those that utilize patient characteristics such as race to help assist in the clinical decision-making process. The ACC welcomes the opportunity to provide additional information to OCR and other regulatory agencies to help understand the real-world implications of clinical algorithm development and working together to ensure the clinical and scientific expertise of the College's members can help inform policy development processes.

Comment Number: HHS-OS-2022-0012-DRAFT-67206-0006
All Sections: 7.10.6

(b)(5)

Organization: American College of Cardiology

Excerpt Text:
Use of clinical algorithms in decision-making (§ 92.210)

More Specific Guidance Is Needed

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 health care in a nondiscriminatory manner and the misappropriation 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 decide, 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 in 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 a number of factors. While discrimination often is only thought of in terms of denying access to something that would otherwise be accessible based on a protected factor, in healthcare these decisions are more complex.

The utilization of patient characteristics to help in the medical decision-making process that are also protected classes (age, sex, disability, or race) does not inherently mean a clinician is discriminating against a patient but instead may be working to determine the most appropriate course of action based on the unique characteristics of a patient. For example, when determining the appropriate treatment for a patient presenting with aortic stenosis (AS), a clinician will factor in the age, gender, underlying health, and other factors to determine if they are a candidate for surgical replacement of the valve or should undergo another form of treatment such as transcatheter aortic valve replacement (TAVR).

Existing data also show that not only do women undergo surgical aortic valve replacement (SAVR) for aortic stenosis less frequently than men, but when they do, they have worse outcomes with SAVR than do men, with worse in-hospital mortality and higher cost compared with men [Footnote 10: Itchhaporia D. Transcatheter aortic valve replacement in women. Clin Cardiol. 2018 Feb;41(2):228-231. doi: 10.1002/clc.22912. Epub 2018 Feb 27. PMID: 29485678; PMCID: PMC6489724]. This gender specific data, combined with improved survival in women

as compared with men with AS who undergo TAVR, despite their older age and higher rates of vascular complications, bleeding events, and strokes, shows when protected class demographic information for a patient can directly influence medical decision making, including determining what treatment a patient should or should not receive. While the clinician should discuss the underlying factors and risks with the patient and ensure they understand the decision-making process, the age of the patient is a factor that impacts the most appropriate form of care for the patient.

Another example where protected categories, such as gender, is used as a deterministic variable to help with clinical decision making is the Tisdale Risk Score for QT Prolongation, a measure of delayed ventricular repolarization. The Tisdale Risk Score algorithm increases the risk for QT prolongation for women, based on literature that states "it is well described that women are at higher risk for the development of pro-arrhythmias caused by drugs with an effect on cardiac repolarization, i.e. drugs that further prolong the QTc interval [Footnote 11: Darpo B, Karnad DR, Badilini F, Florian J, Garnett CE, Kothari S, Panicker GK, Sarapa N. Are women more susceptible than men to drug-induced QT prolongation? Concentration-QTc modelling in a phase 1 study with oral rac-sotalol. Br J Clin Pharmacol. 2014 Mar;77(3):522-31. doi: 10.1111/bcp.12201. PMID: 23819796; PMCID: PMC4371537]. There are also instances where race should be considered for the appropriate course of action. One such example is the suggested use of isosorbide dinitrate plus hydralazine in black individuals with heart failure.

Comment Number: HHS-OS-2022-0012-DRAFT-9033-0007
All Sections: 7.10.6

(b)(5)

Organization:

Excerpt Text:
• Explicitly prohibits discrimination in the use of clinical algorithms to support decisionmaking in covered health programs and activities.
1. Require plan/description of clinical algorithms for language service provision, prepanned 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)

Comment Number: HHS-OS-2022-0012-DRAFT-64284-0009
All Sections: 7.10.6

(b)(5)

Organization: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Excerpt Text:
2. 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 nor 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., clinician bias 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 in 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.

Section 7.10.7 - OCR framework for regulating in this area; relevant factors; defenses

Comment Number: HHS-OS-2022-0012-DRAFT-72260-0001
All Sections: 7.10.7
(b)(5)
Organization: Mayo Clinic

Excerpt Text:
[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 intertwined 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 their access to the underlying data and control over the 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 directions.

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.

Comment Number: HHS-OS-2022-0012-DRAFT-68913-0001
All Sections: 7.10.1, 7.10.7, 7.10.5
(b)(5)
Organization: Multistakeholder consensus group of organizations

Excerpt Text:
In its proposed rule, HHS proposes to 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, and requests input on the appropriate scope and specificity of such a requirement. While we share HHS' goal of advancing the use of beneficial algorithms by covered entities, share concerns with potential discriminatory outcomes resulting from the use of health AI tools and services, and further support the intent of the 1557 rule as a whole, HHS' proposal target AI in its rules raises numerous concerns:

- HHS' evaluation of various use cases demonstrating its concerns with health AI-related discriminatory outcomes does not adequately differentiate root causes for the outcomes it then seeks to avoid.

- HHS' proposal to explicitly address an emerging technology area (AI) raises the risk of technology terms and capabilities evolving more quickly than regulations can be updated.

- Our community is working to develop a consensus standard on how to validate that biases are being identified and appropriately mitigated, and to establish an adequate infrastructure of test beds for making such standards operational. For example, providers, technology developers, governments, and others continue to address how to make AI data sets appropriately representative of the populations/communities AI tools are intended to serve and benefit.

- HHS' proposal appears to omit that providers rely on a health AI manufacturer's intended uses, whether the AI meets the definition of a medical device or not, and that its proposal would force covered entities to police their own supply chains for AI tools and services, despite realities that would make such efforts impracticable (for example, it is often infeasible to require a

covered entity to audit AI and/or the datasets used to train AI they purchase). Further, the additional steps that covered entities would need to take to comply with HHS' proposed requirement are very likely to contribute to providers' already strained workload and further contribute to burnout.

- HHS' proposed rule does not account for the fact that some algorithms are specifically designed to identify and/or consider specific patient characteristics when assisting decision-making (e.g., an algorithm intended to identify certain groups of patients susceptible to a condition or that may benefit from a particular therapy).

- HHS' proposals impacting the use of AI do not adequately consider the role of transparent communication of intended uses and related risks, and of patient consent, with respect to the appropriate use of AI tools and services by covered entities.

- Under HHS' proposal, covered entities could face liability for discriminatory outcomes realized after using an AI tool for some time, presenting a significant incentive to avoid using AI tools altogether, which may not align with health AI-related liability distributions for other risks (e.g., patient safety).

- Machine translation tools are widely relied upon by providers, and serve as a critical tool in providing timely and efficacious care (particularly in the real-time communication context), and continue to be improved upon. HHS proposes to require a covered entity that uses machine translation to have translated materials reviewed by a qualified human translator when the underlying text is 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, non-literal, or technical language. HHS' rationale for such a proposal lacks a sufficient evidence base of machine translation tools being blanket categorized as not fit for purpose and could effectively force any covered entity using machine translation tools to have to further provide for a human translator's review in all circumstances.

- Implementing the proposed 1557 regulations for AI will require significant efforts to build capacity within HHS to appropriately conduct fact-specific analyses of allegations of discrimination, and to work with the covered entity to achieve compliance.

Comment Number: HHS-OS-2022-0012-DRAFT-67830-0011
All Sections: 7.10.4, 7.10.7

(b)(5)

Organization: U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Excerpt Text:
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 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 Cong. (Oct. 14, 2021).] While race, ethnicity, and socioeconomic indicators can 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- 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72260-0002
All Sections: 7.10.6, 7.10.7
(b)(5)
Organization: Mayo Clinic

Excerpt Text:
Rather than a "liability-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 their defined expectations. Standards may include required 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68913-0002
All Sections: 7.10.6, 7.10.7

(b)(5)

Organization: Multistakeholder consensus group of organizations

Excerpt Text:
To be clear, we share HHS' concerns about health AI and the impact of harmful biases and are committed to advancing solutions to ensure that such harms are identified and mitigated. Providers, technology developers and vendors, health systems, insurers, and other stakeholders all benefit from understanding the distribution of risk and liability in building, testing, and using healthcare AI tools. We urge HHS to collaborate with all stakeholders to develop and operationalize frameworks that utilize risk-based approaches to align healthcare AI uses with consensus benchmarks for safety, efficacy, and equity, and to ensure the appropriate distribution and mitigation of risk and liability by supporting that those in the value chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so. HHS' proposed 1557 regulatory updates for AI bias, as drafted, would derail the progress made through public-private partnerships and standardization activities, and significantly disincentivize covered entities use of AI, ultimately robbing patients of the benefits of AI.

Comment Number: HHS-OS-2022-0012-DRAFT-72260-0003
All Sections: 7.10.7

(b)(5)

Organization: Mayo Clinic

Excerpt Text:
[Bold: 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 reaching 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 publication. 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.

Comment Number: HHS-OS-2022-0012-DRAFT-68913-0003
All Sections: 7.10.6, 7.10.7, 7.10.5

(b)(5)

Organization: Multistakeholder consensus group of organizations

Excerpt Text:
As a result, we strongly urge HHS to withdraw its proposal that 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 at this time. Instead, we urge HHS to:

- Initially, clearly scope and identify its concerns, and categorize root causes and appropriate tests.

- Explore how general 1557 regulatory language already in existence may be relied upon to address its concerns with health AI and discriminatory outcomes in a technology neutral manner.

- Partner with our community to advance standardization and testing efforts that will mitigate AI bias harms, and in contributing to the appropriate distribution and mitigation of risk and liability (i.e., that those in the value chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so).

- Account for communication of use/risk and the role of patients to consent to the use of AI based on those communications.

- Consider the impact of its AI-related proposals on covered entities' practical ability to use AI tools and services, particularly for frontline safety net covered entities with limited resources, as well as the need to reduce provider burnout.

- Conduct further consultation with and outreach to the FDA, NIH, and our community to (1) gain understanding of the state of health AI technologies and deployments, including technical and legal realities of health technology supply chains, (2) ensure that its proposals impacting health AI and liability for discriminatory outcomes do not disincentivize the development and use of beneficial AI tools in healthcare, and (3) avoid misaligning liabilities for health AI-related discriminatory outcomes with the distribution of risks and liabilities related to other risks.

- With respect to machine translation, HHS should recognize that its proposed requirements could result in the widespread abandonment of machine translation tools across covered entities, ultimately harming patient care, increasing healthcare costs, and adding to provider burdens. We strongly urge HHS to consider the wide benefits that machine translation tools provide today across healthcare contexts, particularly in real-time communications, and to clarify that a mandate for review by a human interpreter does not apply to real-time communications (whether in-person or via video); and that compliance analyses will weigh the

net impacts of removing machine translation tools from the care continuum entirely in assessing the reasonableness of a covered

entity's activities in using such machine translation tools under its proposed factors.

- Examine ways to build HHS' capacity to address AI-related concerns (e.g., training and staffing, enhanced public-private partnership activities, etc.).

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0006
All Sections: 7.10.2, 7.10.7

(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:
- 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 user s of AI to safeguard against adverse bias and outcomes.

Comment Number: HHS-OS-2022-0012-DRAFT-67206-0007
All Sections: 7.10.7

(b)(5)

Organization: American College of Cardiology

Excerpt Text:
[Bold: The College believes it is important that OCR clearly provide guidance to 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 clinician actions and decisions based in part on patient characteristics that are also protected classes, OCR will help ensure all 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 this additional specificity in rulemaking, OCR can ensure covered entities continue to trust clinical algorithms as a tool to help treat patients and encourage the continued research and development of these tools to advance patient care. It is essential that the rulemaking process does not lead to unintended consequences that not only expose clinicians to liability, but also stifles innovation and research into important scientific discussions around race, age, disability status, the health of individuals, and the most appropriate course of action to care for a patient.

Comment Number: HHS-OS-2022-0012-DRAFT-67206-0008
All Sections: 7.10.7

(b)(5)

Organization: American College of Cardiology

Excerpt Text:
Clinical algorithms are not new to medicine and have been utilized for decades in the most widely accepted devices and practices, ranging from simple calculations to notate a patient's vital signs and health such as in pulse oximeters 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 FDA 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.

Section 7.11 - Telehealth Services (§92.211)

No comments are associated with this issue

Section 7.11.1 - Generally

Comment Number: HHS-OS-2022-0012-DRAFT-75452-0001

All Sections: 7.10.1, 7.11.1, 5.1.1

(b)(5)

Organization: NAACP Legal Defense and Education Fund, Inc.

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-46192-0001
All Sections: 5.2.2, 7.10.1, 5.2.1, 7.11.1, 6.1

(b)(5)

Organization: American Nurses Association

Excerpt Text:
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 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 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. [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].

Comment Number: HHS-OS-2022-0012-DRAFT-64284-0001
All Sections: 6.2.1, 5.2.2, 5.2.3, 5.10.2, 5.7.1, 7.10.1, 5.8.1, 10.1, 7.11.1, 8.1

(b)(5)

Organization: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0017
All Sections: 7.11.1

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
[Bold/Underline: III. Ensuring that All Individuals are Able to Access Healthcare is and Should Remain a Priority]

[Italics: A. The Inclusion of Telehealth in the New Rule Ensures that Health Programs Can Be Accessible to All People]

The COVID pandemic illuminated to many the importance of telehealth for providing accessible healthcare. The advantages of telehealth services include being cost-effective and convenient. It also can provide care to people with mobility limitations, or those in rural areas who don't have access to a local doctor or clinic. [Footnote 16: Stephanie Watson, Telehealth: The advantages and disadvantages, Harvard Health Publishing (Oct. 12, 2020), https://www.health.harvard.edu/staying-healthy/telehealth-the-advantages-and-disadvantages.] Telehealth is particularly necessary for LGBTQ+ communities who might lack LGBTQ+ affirming healthcare services in their area. [Footnote 17: Telemedicine and COVID-19: Tips for the LGBTQ Community, HRC (May 15, 2020), https://www.hrc.org/news/telemedicine-and-covid-19-tips-for-the-lgbtq-community.] This use of technology was crucial throughout the pandemic and continues to break access barriers for those seeking healthcare. The new rule ensures that health programs can be accessible to all people and are accountable to nondiscrimination standards. [Footnote 18: Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47,824 (Aug. 4, 2022).] We welcome this positive clarification.

Comment Number: HHS-OS-2022-0012-DRAFT-37768-0002
All Sections: 7.10.1, 7.11.1

(b)(5)

Organization: Massachusetts Health Connector

Excerpt Text:
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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0026
All Sections: 5.7.1, 5.8.1, 7.11.1

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
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 skills or familiarity with telehealth prior to the appointment. Also, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0029
All Sections: 7.8.3, 7.11.1

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
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, 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 Decision Impact on Telemedicine & Privacy (July 2022), https://mailchi.mp/cchpca/telehealth-policy-heats-up-with-abortion-decision-plus- telehealth-sud-recommendations-from-white-house-more (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 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.

Comment Number: HHS-OS-2022-0012-DRAFT-72212-0004
All Sections: 7.11.1

(b)(5)

Organization: Senate Democrats

Excerpt Text:
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, 47918 (proposed § 92.211)]. The use of telemedicine has risen, particularly following 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_1357633X20963893.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/].

Comment Number: HHS-OS-2022-0012-DRAFT-68054-0004
All Sections: 7.10.1, 7.11.1

(b)(5)

Organization: Washington Health Benefit Exchange

Excerpt Text:
The proposed rule also extends to clinical algorithms and telehealth, practices that can both improve health care and assist in addressing disparities, but can also perpetuate biases and health disparities if not well designed and implemented.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0045
All Sections: 7.11.1
(b)(5)

Organization: Center for American Progress

Excerpt Text:
XVI. Nondiscrimination in the Delivery of Health Programs and Activities Through Telehealth Services (§ 92.211)

We support the inclusion of the provision on telehealth and the recognition of it as a tool to improve access for patients who, for various reasons, are unable or prefer to receive services in person. Such need has been highlighted during the COVID-19 pandemic, when telehealth proved to be a life-saver for people across the country [Footnote 95: Sanuja Bose and others, "Medicare Beneficiaries In Disadvantaged Neighborhoods Increased Telemedicine Use During The COVID-19 Pandemic," Health Affairs, May 2022, available at https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01706]. While telehealth has been useful for all populations, telehealth has not been equitable for LEP patients and people with disabilities, and service platforms are not yet made available at all to people with disabilities or people with limited English proficiency [Footnote 96: Uscher-Pines, Lori, Natasha Arora, Maggie Jones, Abbie Lee, Jessica L. Sousa, Colleen M. McCullough, Sarita D. Lee, Monique Martineau, Zachary Predmore, Christopher M. Whaley, and Allison J. Ober, Experiences of Health Centers in Implementing Telehealth Visits for Underserved Patients During the COVID-19 Pandemic: Results from the Connected Care Accelerator Initiative. Santa Monica, CA: RAND Corporation, 2022 https://www.rand.org/pubs/research_reports/RRA1840-1.html] [Footnote 97: Madjid Karimi and others, "National Survey Trends in Telehealth Use in 2021: Disparities in Utilization and Audio vs. Video Services," (Washington: Assistant Secretary for Planning and Evaluation, 2022), available at http://www.aspe.hhs.gov/sites/default/files/documents/4e1853c0b4885112b2994680a58af9ed/telehealth-hps-ib.pdf]. To address growing accessibility concerns, OCR and DOJ's Civil Rights Division provided guidance in July on nondiscrimination in telehealth for both of these populations [Footnote 98: U.S. Department of Health and Human Services, "Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons," July 29, 2022, available at https://www.hhs.gov/sites/default/files/guidance-on-nondiscrimination-in-telehealth.pdf].

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0059
All Sections: 7.11.1
(b)(5)

Organization: Justice in Aging

Excerpt Text:

Nondiscrimination in the delivery of health programs and activities through telehealth services (§ 92.211)

Justice in Aging supports the comments on nondiscrimination in telehealth submitted by CCD, the Disability and Aging Collaborative, and the Leadership Council of Aging Organizations (LCAO). While recent Medicare data has shown widespread use of telehealth, [Footnote 54: CMS, Certain Medicare Beneficiaries, Such as Urban and Hispanic Beneficiaries, Were More Likely Than Others to Use Telehealth During the First Year of the COVID-19 Pandemic (Sept. 2, 2022), https://default.salsalabs.org/T2b57d7b3-d86b-43e6-b759-2877feb85e3c/c1296d64-f6cc-4611-b6f7-8bf196aac2d2.] including among individuals dually eligible for Medicaid and Medicare, we want to emphasize the importance of ensuring telehealth is always used to supplement, not supplant, in-person services. This is especially important for older adults with chronic conditions for whom care disruptions can be particularly harmful. According to one study comparing ambulatory care use during the pandemic to pre-pandemic levels, disparities existed in delayed and forgone care by race and ethnicity, rural and urban residency, and Medicare-Medicaid dual eligibility status. [Footnote 55: Aditi Pathak et al., Telehealth for Medicare Beneficiaries with Chronic Conditions: No Panacea for COVID-19 Pandemic Access Challenges, American Institutes for Research (July 29, 2022), https://www.air.org/resource/brief/telehealth-medicare-beneficiaries-chronic-conditions-no-panacea-covid-19- pandemic.]

Comment Number: HHS-OS-2022-0012-DRAFT-69031-0008
All Sections: 7.10.1, 7.11.1

(b)(5)

Organization: Howard Brown Health

Excerpt Text:
[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 expansion 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: Apple DE, Lett E, Wood S, Freeman Baber K, Chuo J, Schwartz LA, Petsis D, Faust H, Dowshen 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.2020.0166]. 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0088
All Sections: 7.11.1

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[Bold: H. HHS should clarify telehealth nondiscrimination provisions do not apply to abortion.]

HHS should clarify that proposed § 92.211 on nondiscrimination through telehealth services does not apply to prescribing abortion pills or referring for abortion.

Comment Number: HHS-OS-2022-0012-DRAFT-40175-0009
All Sections: 7.11.1

(b)(5)

Organization: California Department of Health Care Services

Excerpt Text:
[Underlined: Telehealth:] CalHHS welcomes the NPRM reaffirming the application of nondiscrimination policies to health programs and activities provided through telehealth services. Consistent with the rationale in the preamble, CalHHS agrees this is particularly important given our experience during the ongoing COVID-19 public health emergency (PHE), and the increasing prevalence of and reliance on telehealth modalities throughout the entire health care system. In light of the referenced accessibility challenges and technological gaps apparent in certain locales or with respect to certain populations, California continues to place the highest priority on beneficiary choice and enabling use of the modality that is best for the individual's health needs and circumstances. To that effect, in recent legislation codifying post-PHE

telehealth policies in the Medi-Cal 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.] beneficiaries are afforded the right to access any covered services through traditional in-person encounters or through an array of approved telehealth modalities, on a voluntary basis. If a beneficiary prefers to access covered care via face-to-face interaction, both the Medi-Cal provider and managed care plan are required to offer or arrange such care according to the beneficiary's choice.

Section 7.11.2 - Comments related to accessibility in telehealth services

Comment Number: HHS-OS-2022-0012-DRAFT-38066-0011
All Sections: 7.11.2
(b)(5)

Organization: Covered California

Excerpt Text:
Prohibiting discrimination in telehealth services

As 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 disability status. A unified federal approach for covered entities would benefit individuals, providers, and carriers, as many variables determine whether a patient has access to high-quality non-discriminatory telehealth services, and a piecemeal approach may leave some patients out. When choosing how to provide telehealth services, an issuer or provider could choose to contract with a vendor or provide the services in-house, and in both cases, there are a variety of technical solutions 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 encounters in order to provide adequate, culturally appropriate care to all individuals no matter their preferred spoken language.

Covered California also encourages HHS to require parity in access and reimbursement between real-time audio-visual telehealth services and those that are accessible to those without high-speed internet such as real-time text-only or audio-only visits while 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 materials to increase digital literacy among enrollees who do not have experience or comfort with telehealth services.

Comment Number: HHS-OS-2022-0012-DRAFT-67996-0013
All Sections: 7.11.2
(b)(5)

Organization: The Alabama Disabilities Advocacy Program

Excerpt Text:
Nondiscrimination in the delivery of health programs and activities through telehealth services (§ 92.211)

The increased use of telehealth during and since the COVID-19 pandemic is another technology-driven change in health care delivery that has benefitted some people with disabilities while

simultaneously creating new barriers for others. This is unsurprising given how heterogenous disabled people are. Disabilities and health conditions, even the same diagnosis, can have wide variance in their particular functional impact on disabled individuals, who themselves vary widely in their physical, educational, cultural, and socio- economic backgrounds. Someone who has aged into hearing loss and someone who is culturally Deaf and fluent in American Sign Language have different communication needs. Both might encounter barriers to using telehealth but for different reasons: an older person might need assistance with video call technology in her home and prefer to call in using her own amplified phone during the video call so she can speak with a provider while the Deaf person needs the provider's proprietary video call technology to seamlessly integrate a pinned ASL interpreter with the video screen so they can simultaneously follow a provider's facial expressions and demonstrations while seeing what the provider is saying.

ADAP supports this new provision that is specific to telehealth given the ubiquity of telehealth as a unique mode of health care delivery that has expanded greatly during the pandemic and which is likely to continue being widely used even without a public health emergency in place. It is a mode of delivery that offers patients with and without disabilities several advantages: an appointment usually can be obtained sooner, health care can be obtained in the privacy of one's home without exposure to viruses or having to interact with strangers, transportation costs can be avoided, and it may be possible to forego losing wages for lost hours or having to make childcare arrangements.

ADAP has had a dearth of clients with telehealth-specific issues. However, as an organization committed to advocating for Alabamians with disabilities, ADAP would like to reiterate the general lack of broadband access for lower income and/or rural Alabamians with disabilities. This continued lack of access will inevitably lead to issues down the road as telehealth becomes more ubiquitous. The nondiscrimination provisions and HHS' implementation of them should take this fact into account, and ADAP requests the agency to keep this reality in mind.

Comment Number: HHS-OS-2022-0012-DRAFT-65767-0014
All Sections: 7.11.2
(b)(5)
Organization: National Health Council

Excerpt Text:
[Bold: Telehealth]

We support the proposed rule's provision on telehealth. Telehealth is a tool to improve access to health care for many patients. As the use of telehealth expanded during the COVID-19 pandemic, access has not been equitable for individuals with limited English proficiency 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66191-0002
All Sections: 7.11.2

(b)(5)

Organization: Dignity, Inc dba DignityUSA

Excerpt Text:
Ensuring that telehealth visits are included in this Rule and that patients using private insurance are not discriminated against will make care more accessible to many who have faced challenges in obtaining needed care.

Comment Number: HHS-OS-2022-0012-DRAFT-70479-0020
All Sections: 7.11.2

(b)(5)

Organization: National Disability Rights Network

Excerpt Text:
[Bold: § 92.211 - Nondiscrimination in the delivery of health programs and activities through telehealth services]

We support the specific addition of telehealth in this proposed rulemaking and believe that all entities would benefit from a provision addressing accessibility in telehealth given that a significant number of people with disabilities rely on these services. Telehealth is important for many people with disabilities for whom it may be difficult to leave the house, regardless of a pandemic, but it becomes useless to them if it is inaccessible. Including accessibility of telehealth in the 1557 nondiscrimination rule is necessary so that health care providers and all related entities do not overlook and, directly or indirectly, discriminate against beneficiaries with disabilities because of inaccessible telehealth services.

Requiring covered entities to comply with standards like the Web Content Accessibility Guidelines (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.

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0022
All Sections: 7.11.2

(b)(5)

(b)(5)

Organization: American Academy of Family Physicians

Excerpt Text:

Nondiscrimination in the Delivery of Health Programs and Activities Through Telehealth Services (§ 92.211)

HHS is proposing to require that covered entities provide telehealth services in a manner that does not discriminate on a protected basis and provides effective communication for individuals with disabilities and limited English proficiency (LEP). OCR is seeking comment on this approach and whether covered entities and others would benefit from a specific provision addressing accessibility in telehealth services. OCR is also seeking comment on challenges with accessibility specific to telehealth and recommendations for telehealth accessibility standards that would supplement the ICT standards (proposed § 92.204) and effective communication requirements (proposed § 92.202).

[Bold: The AAFP supports the proposal to require covered entities to provide telehealth services in a manner that does not discriminate on a protected basis and provides effective communication for individuals with disabilities and LEP]. The Academy appreciates and supports the recent HHS Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons [Hyperlink: https://www.aafp.org/news/practice-professional-issues/hhs-doj-telehealth-guidance.html] [Hyperlink: https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html?utm_campaign=OATannouncements20220823&utm_medium=email&utm_source=govdelivery]. The growth of telehealth as a modality of care delivery during the COVID-19 pandemic reinforces the need to ensure this technology is accessible to all patients, including people with disabilities and those with limited English proficiency. The AAFP has long advocated that the use of telehealth be expanded as an appropriate and efficient means to enhance patient- physician collaborations, increase access to care, improve health outcomes by enabling timely care interventions and decrease costs. Telehealth policies should be designed to support existing patient-physician relationships and refrain from enabling virtual only/DTC telehealth companies to expand and inhibit in-person care.

We encourage HHS and OCR to consider ways to support small, independent practices with the resources, tools, and technology to effectively ensure telehealth services are accessible for these populations without undue financial or administrative burden. We also encourage OCR to collaborate with Congress to create a pilot program to fund digital health literacy programs for patients, digital health navigators, point-of-care interpretive services, digital tools with non-English language options, and tools with assistive technology [Hyperlink: https://www.aafp.org/dam/AAFP/documents/advocacy/health_it/ehr/LT-WhiteHouse-CommunityHealthTechnology-032822.pdf]. The AAFP has advocated for further studies of telehealth policies to determine whether they are improving access to care for underserved communities, protecting patient safety, and advancing health equity, including for those with disabilities and LEP.

Similarly, the AAFP recognizes the disparities between individuals with access to broadband internet compared to those without it. Many patients experience technology and infrastructure barriers to using video telehealth visits, making audio-only a valuable method to accessing care. The lack of modern broadband infrastructure has proven to be a primary barrier to equitable telehealth and digital health access for rural Americans, who are 10 times more likely to lack broadband access than their urban counterparts, leading to fewer audio/video visits [Footnote 16: Kelly A Hirko, Jean M Kerver, Sabrina Ford, Chelsea Szafranski, John Beckett, Chris Kitchen, Andrea L Wendling, Telehealth in response to the COVID-19 pandemic: Implications for rural health disparities, Journal of the American Medical Informatics Association, Volume 27, Issue 11, November 2020, Pages 1816–1818, https://doi.org/10.1093/jamia/ocaa156] [Footnote 17: Congressional Research Service. (2019). Broadband Loan and Grant Programs in the USDA's Rural Utilities Service. https://sgp.fas.org/crs/misc/RL33816.pdf] [Footnote 18: Velasquez D, Mehrotra A. (2020). Ensuring The Growth Of Telehealth During COVID-19 Does Not Exacerbate Disparities in Care. Health Affairs. 10.1377/forefront.20200505.591306]. There also exist disparities in access to technology that is essential for successful video telehealth visits. One in three households headed by someone over the age of 65 do not have a computer and more than half of people over age 65 do not have a smartphone [Footnote 19: Ryan C, Lewis JM. (2017). Computer and Internet Use in the United States: 2015. American Community Survey Reports. https://www.census.gov/content/dam/Census/library/publications/2017/acs/acs-37.pdf]. A report from the Assistant Secretary for Planning and Evaluation (ASPE) also found that Black, Latino, Asian, and elderly patients, as well as those without a high-school diploma, were more likely to rely on audio-only telehealth visits [Footnote 20: Karimi M, Lee EC, Couture SJ, et al. National Survey Trends in Telehealth Use in 2021: Disparities in Utilization and Audio vs. Video Services. https://aspe.hhs.gov/sites/default/files/documents/4e1853c0b4885112b2994680a58af9ed/telehealth-hps- ib.pdf]. [Bold: The AAFP urges HHS to work with Congress to ensure the implementation of permanent telehealth policies ensures coverage of and fair payment for audio-only telehealth services]. This is essential to facilitate equitable access to care after the PHE-related telehealth flexibilities expire.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0023
All Sections: 7.11.2

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
Finally, the Proposed Rule, for the first time, addresses nondiscrimination in the delivery 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, including across state lines, 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. Ass'n 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/789666.] 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 telehealth services for people with disabilities and LEP individuals to ensure that covered entities maximize access to telehealth services while preserving confidentiality, data privacy, and security.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0025
All Sections: 7.11.2

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[Bold: F. Discrimination in the Delivery of Healthcare through Telehealth 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://pubmed.ncbi.nlm.nih.gov/35786564/.] 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 Rainie, Pew Research Center, Digital Divides — Feeding America, (February 9, 2017), http://www.pewinternet.org/2017/02/09/digital-divides-feeding-america; Thiru M. Annaswamy et al., Telemedicine Barriers and Challenges for Persons with Disabilities: COVID-19 and

Beyond, 13 Disability Health J. 4 (July 9, 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 either 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. 1138 (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 way that worsens existing inequities. Many states, including California, are in the process of enacting or proposing state legislation to address some of these issues, concurrent with proposed federal legislation and rulemaking. [Footnote 72: Center for Connected Health Policy and California Telehealth Policy Coalition, https://www.cchpca.org/california/pending-legislation/; https://www.cchpca.org/federal/pending-legislation/.]

The States support the Proposed Rule's clarification that providers and covered entities must equitably provide telehealth services to patients, while prohibiting discriminatory practices in the delivery of telehealth services. 87 Fed. Reg. at 47,918. Equitable access to telehealth services requires that patients have proper technological equipment, knowledge and skills, and reliable internet or telecommunication services. Infrastructure and technological barriers in telehealth services differ by race, income, and geographic location, among other factors. [Footnote 73: Allison F. Perry et al., Institute for Healthcare Improvement, Telemedicine: Ensuring Safe, Equitable, Person-Centered Virtual Care (2021), https://www.ihi.org/resources/Pages/IHIWhitePapers/telemedicine-safe-equitable-person-centered- virtual-care.aspx.] Recent guidance published by HHS provides examples of discriminatory acts in the delivery of telehealth services for covered entities and providers to consider in development of policies and processes. [Footnote 74: U.S. Dept. of Health and Human Servs., Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons (July 29, 2022), https://www.hhs.gov/sites/default/files/guidance-on-nondiscrimination-in- telehealth.pdf.] Under the Proposed Rule, covered entities must ensure accessibility of telehealth platforms (87 Fed. Reg. at 47,864-65), communication for individuals with disabilities through auxiliary aids and services (id. at 47,863-64), and language assistance services for LEP individuals (id.). Consequently, the Proposed Rule helps protect consumers and providers from discrimination while encouraging improved access to telehealth. HHS should remind covered entities of all of their responsibilities regarding communication with individuals with disabilities, and auxiliary aids and services, including responsibilities set forth in prior HHS guidance. [Footnote 75: See e.g., U.S. Dept. of Health and Human Servs., Example of a Policy and Procedure for Providing Auxiliary Aids for Persons with Disabilities (2013), https://www.hhs.gov/civil-rights/for-providers/clearance-medicare-providers/auxiliary-aids-persons-disabilities/index.html.]

Comment Number: HHS-OS-2022-0012-DRAFT-65941-0026
All Sections: 7.11.2

(b)(5)

(b)(5)

Organization: Blue Cross Blue Shield Association

Excerpt Text:

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 their delivery of services through telehealth. This 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 on 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 agree with the proposed approach to include specific provisions related 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 they 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 in this Proposed Rule.

Comment Number: HHS-OS-2022-0012-DRAFT-65871-0003
All Sections: 7.11.2, 10.1, 6.2.5

(b)(5)

Organization: AARP

Excerpt Text:

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 the federal civil rights statutes the HHS Department enforces.

Comment Number: HHS-OS-2022-0012-DRAFT-66630-0003
All Sections: 7.11.2

(b)(5)

Organization: The Century Foundation

Excerpt Text:
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, March 23, 2021, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2777779]. 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: Carli Friedman and Laura VanPuymbrouck, "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.

Comment Number: HHS-OS-2022-0012-DRAFT-73220-0039
All Sections: 7.11.2

(b)(5)

Organization: National Immigration Law Center

Excerpt Text:
Nondiscrimination in the Delivery of Health Programs and Activities Through Telehealth Services (§ 92.211)

The COVID-19 pandemic has demonstrated the growing importance of telehealth services, yet it appears that few, if any, telehealth platforms are adequately prepared to serve individuals with LEP. We support OCR's proposal to prohibit discrimination in the delivery of telehealth, however, we encourage the addition of more specific standards. For example, in the absence of the ability to integrate video interpreters into telehealth platforms, we have heard through community partners that some providers are simultaneously using telephonic interpretation services with their patients with LEP. This presents a confusing and complex situation for

individuals who may already face barriers due to low technology literacy. OCR should require that covered entities must contract with telehealth providers that can integrate interpretation services into their platform to provide meaningful access to individuals with LEP. In addition, all 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 who have LEP. We caution against use of automatic translation and captioning technology on telehealth platforms as a substitute for live-interpretation and believe such technology would not be aligned with the proposed rule's language around machine translation.

Comment Number: HHS-OS-2022-0012-1003-0004
All Sections: 7.11.2
(b)(5)

Organization: URAC

Excerpt Text:
The rule also requires covered entities to take appropriate steps to ensure that communication with individuals with disabilities is as effective as communication with others in all health programs and activities. We hope to see this proposal in the final rule. Additionally, we appreciate HHS building upon nondiscrimination requirements in health care settings by requiring covered entities to ensure that health programs provided through electronic and information technology, including via telehealth, are accessible for individuals with disabilities to the extent that it does not result in financial or administration burdens.

Comment Number: HHS-OS-2022-0012-DRAFT-66245-0004
All Sections: 7.11.2
(b)(5)

Organization: Institute for Exceptional Care

Excerpt Text:
[Bold: Telehealth]

IEC supports [Hyperlink: telehealth; https://telerehab.pitt.edu/ojs/Telerehab/article/view/6402], which can increase access to equitable health care for people with disabilities. Telehealth reduces travel. [Hyperlink: Travel; https://healthlaw.org/telehealth-and-disability-challenges-and-opportunities-for-care/] can be particularly difficult for people with IDD. Public transportation is on a set schedule and does not go everywhere. Paratransit services need to be scheduled in advance, are not available in all places, and can be expensive. Frequently, rideshare options are not accessibility to mobility-impaired individuals and are expensive. Hospitals' and clinics' accessible parking is usually in high demand and might be in short supply. Travel can require a caregiver to accompany the person with IDD. Telehealth also allows people with anxiety and

other diagnosis to avoid environments they might find overwhelming. Telehealth also increases the number of specialists that patients with IDD can access, as location would less of a factor in specialist.

However, health-care providers need to be aware of disparities in access to technology and the Internet. [Hyperlink: Telehealth; https://healthlaw.org/telehealth-and-disability-challenges-and-opportunities-for-care/] does not work for many physical exams. It is challenging for people with mobility and sensory disabilities to move in a way that is needed for certain telehealth visits. Some people with IDD might not be capable of explaining their medical issues in a telehealth session. Not all telehealth is covered by insurance. In addition, some people with IDD might find telehealth to be challenging because of the system being complicated and/or not having digital literacy. Many people with IDD might not have access to the Internet and other technology that telehealth requires.

Comment Number: HHS-OS-2022-0012-DRAFT-66790-0004
All Sections: 7.11.2

(b)(5)

Organization: The Arc of Pennsylvania

Excerpt Text:
4. Recognize the critical need for broadband connectivity and assistive technology access for people with disabilities. Since the start of the pandemic, it's been evident the important role broadband connectivity and the ability to access assistive technology is for people with disabilities, especially those with medical complexities. It enabled individuals to get information, utilize telehealth services, and address mental health issues due to social isolation. Prioritization for expanding broadband connectivity and access to assistive technology will give people with disabilities the option to utilize online services or formats for their healthcare.

5. Enable flexibility of telehealth services to include accessibility for people with disabilities. The COVID-19 pandemic brought about change to the delivery of healthcare. Telehealth is now an option for many services and needs to be made more accessible. People with disabilities rely heavily on telehealth services due to the fact that it eliminates some barriers to health care access. Telehealth eliminates transportation barriers, alleviates some anxieties for people with sensory and behavioral disabilities, and lowers risk of transmission of viruses one would get in an in-person setting. Providers need to be trained on how to effectively communicate to patients with disabilities and how to accommodate accessibility needs on a virtual platform.

Comment Number: HHS-OS-2022-0012-DRAFT-73220-0040
All Sections: 7.11.2

(b)(5)

Organization: National Immigration Law Center

Excerpt Text:
We also encourage OCR to consider how telehealth can expand individuals with LEPs' access to health care. For example, rather than use interpretation services, particularly for sensitive services like mental 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 in 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 Medicare and Medicaid services to reduce barriers to individuals with LEP's access to multilingual providers who are out of their state.

OCR should also specify that other growing digital platforms should be accessible for individuals with LEP. We are aware of the growing use and reliance on patient web portals and apps for provider-patient interactions that include features such as non-simultaneous communications. Few of these products appear to be available in-language. We encourage OCR to specify that such platforms are telehealth services subject to nondiscrimination and access standards.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0044
All Sections: 7.11.2
(b)(5)
Organization: Center for American Progress

Excerpt Text:
As a basic step, OCR should require telehealth platforms to allow additional attendees such as a third party interpreter, a personal care assistant, or a family member [Footnote 99: American Association of People with Disabilities, "Making Telehealth Accessible for People with Disabilities," February 26, 2021, available at https://medium.com/disability-in-the-time-of-covid-19/making-telehealth-accessible-for-people-with-disabilities-30d7f341d51c#:~:text=While%20telehealth%20has%20created%20increased%20access%20to%20care,delivery%2C%20and%20the%20policy%20context%20that%20surrounds%20it. and Omolola E. Adepoju and others, "Telemedicine During the Pandemic: Leaving The Visually Impaired And Others With Disabilities Behind?," Health Affairs, September 6, 2022, available at https://www.healthaffairs.org/content/forefront/telemedicine-during-pandemic-leaving-visually-impaired-and-others-disabilities-behind]. These designated individuals could offer communication assistance to individuals like people with disabilities, in addition to the provision 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, telehealth appointment reminders, and log-on details – must be accessible to people with LEP and people with disabilities. Similarly, platforms should be adopted to meet the needs of people who are autistic, deaf or hard of hearing, blind, deafblind, have physical disabilities that affect mobility, or otherwise have difficulty in communicating via traditional telehealth models. Examples of accommodations in telehealth platforms can include, but are not limited to, text

readable by screen-readers, high-contrast software, captions on videos, and options other than computer mouse navigation [Footnote 100: Omolola E. Adepoju and others, "Telemedicine During the Pandemic: Leaving The Visually Impaired And Others With Disabilities Behind?," Health Affairs, September 6, 2022, available at https://www.healthaffairs.org/content/forefront/telemedicine-during-pandemic-leaving-visually-impaired-and-others-disabilities-behind]. However, even individuals with the same disability might require different telehealth accommodations – thus, covered entities must proactively ensure that telehealth visits are equally accessible and effective for disabled individuals.

Comment Number: HHS-OS-2022-0012-DRAFT-20039-0005
All Sections: 7.11.2

(b)(5)

Organization: The Colorado Health Foundation

Excerpt Text:
Throughout the pandemic, Coloradans have benefited from accessing care via telehealth and it has become clear that continued access to services in this format is essential to access to care. The Foundation commends HHS for clarifying that nondiscrimination requirements apply to health programs and activities provided through telehealth services.

Comment Number: HHS-OS-2022-0012-DRAFT-68873-0005
All Sections: 7.11.2

(b)(5)

Organization: Fenway Community Health Center

Excerpt Text:
Telehealth

The proposed rule specifically addresses nondiscrimination in the provision of health programs and activities through telehealth services. This provision clarifies that covered entities have an affirmative duty to not discriminate in their delivery of such services through telehealth. We support this provision, as telehealth provides critical access to the services that Fenway Health and few other community health centers in the country are able to provide. Telehealth is especially important to TGD patients who may live a far distance from a provider who offers affirming care. Telehealth also expands access to mental and behavioral health services, which is critical to LGBTQIA+ people who may face discrimination in healthcare located closer to their home.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0006
All Sections: 7.11.2

(b)(5)

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
We also want to applaud the essential decision to include coverage of telehealth under ACA's Section 1557. Telehealth has had a pivotal impact on expanding healthcare access to communities that have otherwise struggled to receive traditional healthcare in the past. This change in 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 traditionally struggled to find local, culturally competent healthcare providers. Allowing for LGBTQI+ people living in these communities 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 is included in the final rule.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0060
All Sections: 7.11.2

(b)(5)

Organization: Justice in Aging

Excerpt Text:
We also recommend ensuring nondiscrimination in telehealth includes accessibility for people with LEP and people with disabilities in all aspects of telehealth care—from scheduling, to setting up and using a platform, to the actual appointment and follow-up.

Comment Number: HHS-OS-2022-0012-DRAFT-66244-0007
All Sections: 7.11.2

(b)(5)

Organization: Association of American Medical Colleges (AAMC)

Excerpt Text:
[Bold and Italics: Nondiscrimination in the Delivery of Health Programs and Activities Through Telehealth Services (§ 92.211)]
[Bold: The AAMC supports the proposal creating an affirmative duty for covered entities to not discriminate in the delivery of telehealth services and to ensure such services are accessible to people with limited English proficiency and individuals with disabilities.] 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 nondiscrimination protections to health care services and programs provided via telehealth.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0007
All Sections: 7.11.2

(b)(5)

Organization: Health Care For All

Excerpt Text:
Telehealth Access

We support the inclusion of the provision explicitly prohibiting 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 6: Sanuja Bose 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 Corportation (2022) https://www.rand.org/pubs/research_reports/RRA1840-1.html] [Footnote 8: Madjid Marimi 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/4e1853c0b4885112b2994680a58af9ed/telehealth-hps-ib.pdf]. Most service platforms are not yet made available at all to people with disabilities or people with LEP.

As referenced previously, the HCFA HelpLine 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 access to computers/devices and sufficient internet connectivity and those who do not due to socioeconomic, sociocultural and other barriers. This regulation makes clear that health program beneficiaries and consumers are protected from discrimination under law, and policymakers should work with providers and consumer groups to make sure the legal protections are reflected in the on-the-ground consumer experience, especially for people with disabilities and LEP.

Comment Number: HHS-OS-2022-0012-DRAFT-9033-0008
All Sections: 7.11.2

(b)(5)

Organization:

Excerpt Text:
• 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 sub-standard measures of competency or qualification (if requirements differ from those of employee interpreters) constitutes substandard provision of care to constitutionally 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 patient or patients with other communication needs for whom use of technology, portals, websites, instructions all have inherent challenges that may have discriminatory impacts.

Comment Number: HHS-OS-2022-0012-DRAFT-65776-0008
All Sections: 7.11.2

(b)(5)

Organization: Tennessee Primary Care Association

Excerpt Text:
[Bold: Nondiscrimination in the Delivery of Health Programs and Activities 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 nondiscrimination languages align for this 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/4e1853c0b4885112b2994680a58af9ed/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 include a third party such as an interpreter or use of auxiliary aids and services. Second, all 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 models. Before the telehealth interaction [embedded hyperlink text (https://www.ncqa.org/wp-content/uploads/2022/05/NCQA-TelehealthAndEquity-Whitepaper-Draft5.pdf)], providers should assess for visual, cognitive, intellectual, mobility as well as functional needs to maximize the patient's health care experience. TPCA recommends that OCR consider including notification of telehealth services in the list of electronic communications that must include the notice of availability of language assistance services and auxiliary aids and services. By adopting these recommendations, health care facilities, including health centers, will be equipped with the necessary tools and technology to continue to offer high quality, accessible care through telehealth.

Comment Number: HHS-OS-2022-0012-DRAFT-66854-0008
All Sections: 7.11.2

(b)(5)

Organization: Wisconsin Primary Health Care Association

Excerpt Text:
Nondiscrimination in the Delivery of Health Programs and Activities Through 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 nondiscrimination languages align for this 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/4e1853c0b4885112b2994680a58af9ed/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 include 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 models. Before the telehealth interaction, [embedded hyperlink text (https://www.ncqa.org/wp-content/uploads/2022/05/NCQA-TelehealthAndEquity-Whitepaper-Draft5.pdf)] providers should assess for visual, cognitive, intellectual, mobility as well as functional needs to maximize the patient's health care experience. WPHCA recommends that OCR consider including notification of telehealth services in the list of electronic communications that must include the notice of availability of language assistance services and auxiliary aids and services. By adopting these recommendations, health care facilities, including Community Health Centers, will be equipped with the necessary tools and technology to continue to offer high quality, accessible care through telehealth.

Telehealth has been a critical tool in Wisconsin, improving access to care, efficiently deploying providers, and addressing systemic inequities in access to health care resulting from lack of transportation options, inflexible work hours, lack of child care, and other barriers.

Comment Number: HHS-OS-2022-0012-DRAFT-39933-0009
All Sections: 7.11.2

(b)(5)

Organization: Minnesota Association of Community Health Centers

Excerpt Text:
[Bold: Nondiscrimination in the Delivery of Health Programs and Activities 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 nondiscrimination languages align for this

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 [underlined/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 include 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 models. [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 of telehealth services in the list of electronic communications that must include the notice of availability of language assistance services and auxiliary aids and services. By adopting these recommendations, health care facilities, including health centers, will be equipped with the necessary tools and technology to continue to offer high quality, accessible care through telehealth.

Section 8 - Religious Freedom and Conscience

Comments associated with this issue are included in the subsections below

Section 8.1 - Generally

Comment Number: HHS-OS-2022-0012-DRAFT-9915-0001
All Sections: 8.1

(b)(5)

(b)(5)

Organization:

Excerpt Text:
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!

Comment Number: HHS-OS-2022-0012-DRAFT-64284-0001
All Sections: 6.2.1, 5.2.2, 5.2.3, 5.10.2, 5.7.1, 7.10.1, 5.8.1, 10.1, 7.11.1, 8.1
(b)(5)

Organization: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-44558-0013
All Sections: 8.1
(b)(5)

Organization: Equitas Health

Excerpt Text:
[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 those harms and that elevated 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.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0013
All Sections: 8.1
(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
To ensure alignment with international human rights norms, we also urge the Department to clarify that existing religious refusal laws do not relieve health care providers of their 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 60 (Mar. 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. 14, 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) (2008); 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 Section IV. below for a more detailed discussion of human rights in the context of sexual and reproductive health.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0014
All Sections: 8.1

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Bold: 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,' pause any agency investigation or enforcement activity during consideration and made 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 an exemption could have on third parties.'" [Footnote 34: Morrison, "HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate in Health Care." https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-in-health-care-1]

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0019
All Sections: 8.6, 8.1
(b)(5)

Organization: Concerned Women for America

Excerpt Text:
Finally, this Rule is an affront to rights of conscience and religious freedom. The Constitution 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 intrusion or threat. 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, 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 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 determination does not otherwise limit the application 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 killing unborn babies or maiming vulnerable children.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0022
All Sections: 2, 8.1
(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: B. International human rights law requires the government to ensure that 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. 93, 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 103: 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, protects 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 of an impermissible infringement on women's rights, [Footnote 105: Special Rapporteur on Freedom of Religion or Belief, Interim Rep. of The Special Rapporteur on Freedom of Religion or Belief, para. 24, U.N. Doc. A/72/365 (Aug. 28, 2017).] and has expressed concern over the use of "religious liberty" to justify the refusal of providing goods and services to women and LGBTQI individuals. [Footnote 106: Id. para. 37, U.N. Doc. A/72/365 (Aug. 28, 2017).]

Accordingly, human rights standards require that where a refusal of care based on religious or conscience belief is permitted, it does not infringe on others' access to health care. [Footnote 107: 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), paras. 14, U.N. Doc. E/C.12/GC/22 (2016).] They require the government to ensure that health care providers' refusal to provide reproductive health care, including abortion care, on grounds of conscience does not jeopardize access to reproductive health care. [Footnote 108: Id. 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) (2008); 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).]

UN human rights experts have noted the United States' particular obligations in this regard. At the conclusion of its 2015 fact-finding visit to the United States, the UN Working Group on Discrimination Against Women reiterated that:

[Italics: Refusal to provide sexual and reproductive health services on the grounds of religious freedom should not be permitted where such refusal would effectively deny women immediate access to the highest attainable standard of reproductive health care and affect the implementation of rights to which they are entitled under both international human rights standards and domestic law.] [Footnote 109: 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. 71, 95(i), U.N. Doc. A/HRC/19/41 (Nov. 17, 2011)]

We therefore urge the Department to explicitly delineate the limitations of religious refusal laws. Specifically, the Department should clarify that health care entities are responsible for ensuring that patients do not experience discrimination even if individual providers object to providing that care. The final rule should address the harm caused by discrimination that occurs under the guise of a religiously motivated denial of care, which does not relieve a health care provider of their obligation to provide nondiscriminatory care.

To more closely align with international human rights standards, the final rule should ensure that health care providers' religious refusals to provide sexual and reproductive health care services do not result in discrimination against their patients and do not prevent a patient's access to care.

Comment Number: HHS-OS-2022-0012-DRAFT-0636-0003
All Sections: 8.1

(b)(5)

Organization:

Excerpt Text:
It is hard to overstate the radicalness of the change that the Biden administration wants to impose on our nation. If this rule went 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 profoundly evil to attempt to force people to say things they believe are lies. Alexander Solzhenitsyn pointed out how the communist regime 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.

Comment Number: HHS-OS-2022-0012-DRAFT-54859-0003
All Sections: 8.1
(b)(5)

Organization: Texas Catholic Conference of Bishops

Excerpt Text:
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 3 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.

Comment Number: HHS-OS-2022-0012-DRAFT-64680-0004
All Sections: 8.1
(b)(5)

Organization: Kansas Catholic Conference

Excerpt Text:
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- Secularizes] faith-based charities.

Comment Number: HHS-OS-2022-0012-DRAFT-66316-0005
All Sections: 8.1

(b)(5)

Organization: American Association of Christian Schools

Excerpt Text:
Additionally, our institutions are concerned that the proposed rule could reach 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" (47912). These programs would likely fall 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 fairly 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 [Italics: 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 conscience and religious liberty will be protected in light of these legal challenges.

Comment Number: HHS-OS-2022-0012-DRAFT-0636-0006
All Sections: 8.1

(b)(5)

Organization:

Excerpt Text:
I am also struck 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 it goes forward, there will be no diversity of views on transgenderism or abortion in health care and tremendous discrimination against huge numbers of people who do not accept a radical modern ideology with totalitarian tendencies. How is that in conformity with the so-called ideal of "diversity and inclusion"?

Comment Number: HHS-OS-2022-0012-DRAFT-66316-0006
All Sections: 8.1

(b)(5)

Organization: American Association of Christian Schools

Excerpt Text:
The process described by HHS in Subpart D—Procedures, section 92.302 to 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 it 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)" (47886). 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 (2018) 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), RFRA 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 purpose causes our institutions to fear that their fundamental freedoms will be recklessly violated. Our Christian educational institutions need a meaningful explanation of how these cases will protect their conscience rights and religious liberty in light of this far-reaching proposed rule.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0069
All Sections: 8.1

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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, gender identity, or abortion) they must, in most cases, submit an objection or complaint to OCR—the very entity tasked with evaluating sexual orientation, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66316-0007
All Sections: 8.1

(b)(5)

(b)(5)

Organization: American Association of Christian Schools

Excerpt Text:
Under this 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 attempts 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0072
All Sections: 8.1

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[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 much 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/.]

Comment Number: HHS-OS-2022-0012-DRAFT-75461-0008
All Sections: 8.1

(b)(5)

Organization: Charlotte Lozier Institute

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-66244-0008
All Sections: 8.1

(b)(5)

Organization: Association of American Medical Colleges (AAMC)

Excerpt Text:
[Bold and Italics: Notification of Views Regarding Application of Federal Conscience and Religious Freedom Laws (§ 92.302)]

[Bold: 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66316-0008
All Sections: 8.1

(b)(5)

Organization: American Association of Christian Schools

Excerpt Text:
[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 program 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.

Comment Number: HHS-OS-2022-0012-DRAFT-67830-0008
All Sections: 8.1

(b)(5)

Organization: U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Excerpt Text:
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 statutory text, congressional intent, and a commitment to health equity. [Footnote 6: 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 follow 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 7: 42 U.S.C. §§ 2000bb to 2000bb-4.]

Section 8.2 - Title IX Exception

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0012
All Sections: 8.2

(b)(5)

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Bold: H. It is critical that the final rule prioritizes patient access to care and 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 may place 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 the 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 Healthcare, AP NEWS (Jul. 24, 2022), https://apnews.com/article/abortion-health-religion-new-york-oregon-8994d9b5fd0040d40d19fd1e44c31 3d8; Amy Littlefield, Women of Color More Likely to Give Birth in Hospitals Where Catholic Beliefs Hinder Care, REWIRE NEWS GROUP (Jan. 19, 2018), https://rewirenewsgroup.com/2018/01/19/women-color-likely-give-birth- hospitals-catholic-beliefs-hinder-care/; Kira Shepherd, et al., Bearing Faith: The Limits of Catholic Health Care for Women of Color, COLUMBIA LAW SCHOOL LAW, RIGHTS, AND RELIGION PROJECT (2018), https://lawrightsreligion.law.columbia.edu/bearingfaith; See also, U.S. CATHOLIC HEALTHCARE ASSOCIATION, CATHOLIC HEALTHCARE IN THE UNITED STATES (2022), https://www.chausa.org/docs/default-source/default-document-library/the-strategic- profile.pdf.] In fact, women of color disproportionately give birth in Catholic hospitals, and therefore also experience denials of care related to reproductive health care at much higher

rates, including when attempting to access hormonal birth control, IUD placement, abortion, sterilization and IVF care. [Footnote 63: Amy Littlefield, Women of Color More Likely to Give Birth in Hospitals Where Catholic Beliefs Hinder Care, REWIRE NEWS GROUP (Jan. 19, 2018), https://rewirenewsgroup.com/2018/01/19/women-color-likely-give-birth- hospitals-catholic-beliefs-hinder-care/; Kira Shepherd, et al., Bearing Faith: The Limits of the Catholic Health Care for Women of Color, COLUMBIA LAW (2018), https://lawrightsreligion.law.columbia.edu/sites/default/files/content/BearingFaith.pdf.] Religious exemptions can facilitate sex discrimination against patients, and a blanket exemption would exacerbate patients' lack of access to care, especially in those areas.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0012
All Sections: 9.1.1, 8.2

(b)(5)

Organization: Health Care For All

Excerpt Text:
Enforcement

We support strong enforcement of § 1557 and welcome OCR's 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 eclipse 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." Undoubtedly, the government has a deep and compelling interest in ensuring that taxpayer dollars are not used to advance discriminatory policies, such as those that may curtail access to life-preserving care like gender-affirming services. Therefore, the review process for religious exemptions must include analyses addressing whether there is a compelling justification in each case and provide clear notice about why a request was approved or denied.

Comment Number: HHS-OS-2022-0012-DRAFT-75461-0002
All Sections: 7.8.3, 8.2
(b)(5)

Organization: Charlotte Lozier Institute

Excerpt Text:
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 protect 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://lozierinstitute.org/the- equality-act-threatening-life-and-equality/ detailing the history and purpose of Title IX's religious exception and abortion-neutrality provision.)

Comment Number: HHS-OS-2022-0012-DRAFT-67830-0020
All Sections: 8.2
(b)(5)

Organization: U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Excerpt Text:
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 include 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 this should not be incorporated into Section 1557.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0020
All Sections: 8.2
(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
[Bold: IV. Religious Exemptions and Non-Discrimination Protections]

[Italics: A. The Proposed Rule Appropriately Addresses Religious Exemptions]

Omitting the Title IX's religious exemption, which is harmful and has no place in a health care nondiscrimination rule, correctly interprets the statute. Inclusion of the Title IX religious exemption would exceed HHS's authority because the text of the ACA referenced Title IX only for purposes of identifying the ground of discrimination it addresses– on the basis of sex– and its enforcement mechanisms. Indeed, 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, that would wreak havoc if applied to the ACA by allowing health care providers to deny essential health care services for any reason related to sex including 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). We appreciate that the proposed rule clarifies that "the application of the Title IX exception for entities controlled by religious organizations" is irrelevant because Title IX concerns education whereas the present rule concerns healthcare. To support this distinction, the new rule correctly notes that "[w]hereas students and families typically make a choice to attend religious educational institutions, patients seeking healthcare are much more likely to be driven by…other factors unrelated to the question of whether the healthcare provider is controlled by or affiliated with a religious organization." [Footnote 24: Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47,824 (Aug. 4, 2022).] 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 new rule states that "while not incorporating the Title IX religious exception, the Department is fully committed to respecting conscience and religious freedom laws when applying this rule." [Footnote 25: Id.]

Comment Number: HHS-OS-2022-0012-DRAFT-74249-0003
All Sections: 8.2

(b)(5)

Organization: interACT: Advocates for Intersex Youth

Excerpt Text:
We likewise strongly support HHS's proposal not to graft onto the ACA any categorical exception or 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 import such exceptions into a statute where Congress declined to extend them. This

is especially true with respect to Title IX's uniquely broad religious exception, which stands in stark contrast to narrower religious or conscience exceptions Congress has chosen to adopt with respect to health care.

Comment Number: HHS-OS-2022-0012-DRAFT-44558-0003
All Sections: 8.2

(b)(5)

Organization: Equitas Health

Excerpt Text:
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 referenced Title IX only to identify the ground 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 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 exemption, which does not allow the Department to consider the potential harm of granting an exemption.

Comment Number: HHS-OS-2022-0012-DRAFT-66316-0003
All Sections: 8.2

(b)(5)

Organization: American Association of Christian Schools

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-64680-0003
All Sections: 8.2

(b)(5)

Organization: Kansas Catholic Conference

Excerpt Text:
3. [Bold: Title IX]- Enshrines gender identity and sexual orientation ideology in education. This is harmful to minors and is a violation of Catholic religious liberties.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0003
All Sections: 8.2

(b)(5)

Organization: Center for American Progress

Excerpt Text:
b. Religious Exemptions

We also firmly support the Department's decision to omit 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 LGBTQ Patients and Families, NAT'L HEALTH L. PROG. (June 13, 2022), https://healthlaw.org/health-care-refusals-how-they-undermine-standards-of-care-part-ii-the-impact-of-health-care-refusals-discrimination-and-mistreament-on-lgbtq-patients-and-families/]. Women and LGBTQI+ individuals are most impacted by denials of care and those who typically have fewer options face an even greater risk of harm, such as those with lower incomes; those who live in rural areas; and those who face systematic discrimination, such as people with disabilities and women of color. Due to the increase in religiously affiliated hospital systems, particularly in certain areas of the country, it can also be impossible for some of the more marginalized populations to seek care elsewhere if they face a denial [Footnote 3: See Tess Solomon et al., Bigger and Bigger: the Growth of Catholic Health Systems, CMTY. CATALYST (2020), https://www.communitycatalyst.org/resources/publications/document/2020-Cath-Hosp-Report-2020-31.pdf; Lois Uttley & Christine Khaikin, Growth of Catholic Hospitals and Health Systems, MERGER WATCH (2016)].

A lack of information and transparency when individuals are denied health care also contributes to the increase in risk. Patients have been sent home from a health care facility without being informed of their own health status and treatment options despite the clear violation of informed consent, creating a barrier for that patient to obtain appropriate care. When a lack of information is combined with the need for urgent care, such as with some pregnancy complications, a patient's health, and even their life, is put at risk [Footnote 4: See, e.g., Julia Kaye et al., Health Care Denied, ACLU (May 2016), https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied (includes the story of Tamesha Means, who was turned away from a Catholic hospital - the only hospital in her community - in the midst of a painful, nonviable miscarriage); Nat'l Women's L. Ctr., Below the Radar: Health Care Providers' Religious Refusals Can Endanger Pregnant Women's Lives and health, NAT'L WOMEN'S L. CTR. (Jan. 2011), https://nwlc.org/wp-content/uploads/2015/08/nwlcbelowtheradar2011.pdf (includes the stories of two women who were refused the full spectrum of appropriate care for an ectopic pregnancy at their local emergency rooms)].

The denial of information and services, whether due to religious objections or for other reasons, can violate the standards of care, as established by the medical community. Allowing such denials is in direct conflict with the purpose of Section 1557, to ensure all people can receive

medically appropriate health care without discrimination, and the ACA itself, to expand access to health care.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0004
All Sections: 8.2

(b)(5)

Organization: Colors+

Excerpt Text:
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 ground 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75461-0004
All Sections: 7.8.3, 8.2

(b)(5)

Organization: Charlotte Lozier Institute

Excerpt Text:
II.) The NPRM Incorrectly Interprets Section 1557 To Exclude Title IX's 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) [italic: 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 inconsistent 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 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 jurisprudence. CLI queries how the Department's proposed interpretation can be reconciled with Franciscan Alliance's clear rejection of the similar 2016 regulation.

Comment Number: HHS-OS-2022-0012-DRAFT-69031-0004
All Sections: 8.2

(b)(5)

Organization: Howard Brown Health

Excerpt Text:
We also support the omission of Title IX's overly broad religious exemption. There are already many federal laws around conscious 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0004
All Sections: 6.2.4, 8.2

(b)(5)

Organization: Health Care For All

Excerpt Text:
Pregnancy Status and Reproductive Rights

Abortion is a critical part of the 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 with "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 incorporate 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 and cause life-threatening situations for individuals based upon their pregnancy related condition.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0006
All Sections: 8.2

(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
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 ground 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).

Comment Number: HHS-OS-2022-0012-DRAFT-75461-0006
All Sections: 8.2

(b)(5)

Organization: Charlotte Lozier Institute

Excerpt Text:
Moreover, the Department has signaled that it believes it has a compelling state 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, then, 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 health care entities from which they seek care may be limited in the care they provide. Incorporation of Title IX's religious exception would therefore seriously compromise Congress's principal objective in the ACA of increasing access to health care.

NPRM at p. 47840-1.

This alleged disjunction 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 providers to provide abortion services in order to prevent "discrimination." It also suggests that the Department's position is that the religious and conscience rights of providers ought not be respected if patients happen to be unaware of the provider's religious or ethical commitments. In short, it seems that any claim under RFRA will be opposed in court by the Department. CLI requests clarification of the Department's view of the extent of protection existing federal religious and conscience protections would provide and an explanation of why Title IX's explicit religious exemption is not also required to provide robust protection to healthcare providers.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0006
All Sections: 8.2

(b)(5)

Organization: Center for American Progress

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-68873-0006
All Sections: 8.2

(b)(5)

Organization: Fenway Community Health Center

Excerpt Text:
Religious Exemption

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 also support the omission of Title IX's religious exemption, which is harmful and has no place in a health care nondiscrimination rule. 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).

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. The strength of the protections that this final rule offers are all undermined by the ability to deny care base on a religious exemption. While the revised approach contemplates a case-by-case process, in doing so, it still grants validity to the application of religious exemption in a healthcare setting, which, by its very nature is still discrimination. Religious protections cover free exercise of worship. For example, saying a prayer before eating lunch in the workplace, wearing a hijab in an educational setting, or practicing religious traditions without persecution. It does not include denial of healthcare. "True religious freedom protects an individual's right to worship—or not—and harms no one" [Footnote 35: Simonoff C, Wang T, Cahill S. In its third year in office, the Trump Administration dramatically expanded discriminatory anti-LGBT policies. The Fenway Institute. 2020. https://fenwayhealth.org/wp-content/uploads/Trump-Administration-Year-3-Brief.pdf]. The application of religious exemption in a healthcare setting is harmful and damaging to the health of already vulnerable populations. We ask for the omission of Title IX's religious exemption without any additional process for application in the healthcare setting.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0064
All Sections: 8.2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[Bold: 6. The Proposed Rule would harm religious liberty.]

[Bold: A. Section 1557 incorporates Title IX's religious exemption.]

Title IX contains a 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 [Italics: et seq]." [Footnote 202: 42 U.S.C. § 18116 (emphasis added).] Section 1557 citation of Title IX's entire 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 it 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 so 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0065
All Sections: 15.2, 8.2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
As a textual manner, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0066
All Sections: 15.2, 8.4.3, 8.2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
The Proposed Rule state 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 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, 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 their 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 objection of "increasing access to health care." [Footnote 205: 87 Fed. Reg. 47840.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0067
All Sections: 8.4.3, 8.2
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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).

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0007
All Sections: 8.3, 8.2
(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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 ground 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. 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.

Comment Number: HHS-OS-2022-0012-DRAFT-66750-0007
All Sections: 8.2

(b)(5)

Organization: Jacobs Institute of Women's Health

Excerpt Text:
- Require that any entity receiving a religious exemption include the existence and scope of such exemption in its required notices.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0070
All Sections: 8.4.2, 8.2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 adopted 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 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 214: Franciscan All. v. Becerra, No. 21-11174, at *10 (5th Cir. Aug. 26, 2022).]

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0008
All Sections: 8.2, 2

(b)(5)

Organization: Center for American Progress

Excerpt Text:
c. The Danforth Amendment

We strongly support the Proposed Rule's repeal 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 to Section 1557 via 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, 463 n.9 (1988) (Stevens, J., dissenting) (Court presumes that "Congress is aware of this longstanding presumption [disfavoring 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 Health Programs and Activities, 81 Fed. Reg. 31376, 31377 (May 18, 2016)] [Footnote 16: Id. at 31380]. Abortion is a critical form of health care, and patients seek or need abortion care for a wide variety of reasons, including personal reproductive health decisions, miscarriage management, or emergency procedures related to adverse pregnancy outcomes. Patients not only deserve but require nondiscriminatory access to abortion care, in accordance with the congressional intent of Section 1557. The Danforth Amendment should not be included because it is the Department's responsibility to ensure regulations accurately implement the protections provided in Section 1557, not limit the protections, contrary to Congress's intent.

Abortion patients already face additional barriers to care that often lead to an inability to access abortion care altogether, especially following the Dobbs v. Jackson Women's Health Org. decision declaring that there is no federal constitutional right to abortion [Footnote 17: Dobbs v. Jackson Women's Health Org., 142 S.Ct. 2228 (2022)]. Within 30 days of the Dobbs decision, eleven states had banned abortion, with some imposing criminal penalties [Footnote 18: Marielle Kirstein, Rachel K. Jones & Jesse Philbin, One Month Post-Roe: At Least 43 Abortion Clinics Across 11 States Have Stopped Offering Abortion Care, Guttmacher (July 28, 2022), https://www.guttmacher.org/article/2022/07/one-month-post-roe-least-43-abortion-clinics-across-11-states-have-stopped-offering]. This number continues to grow: 26 states are likely to ban or have already banned abortion, leaving people without access to care in their state. Many people are not able to travel to another state to access abortion, or are significantly delayed by

the cost and logistical arrangements required to do so. Delays in accessing abortion, or being unable to access abortion at all, pose risks to people's health.

While abortion is very safe at any point in pregnancy, risks increase with gestational age. And because pregnancy and childbirth are far more medically risky than abortion, forcing people to carry a pregnancy to term exposes them to an increased risk of physical harm [Footnote 19: Elizabeth Raymond & David Grimes, The Comparative Safety of Legal Induced Abortion and Childbirth in the United States, 119 J. Obstet. Gynecol. 215 (Feb. 2012)]. U.S. maternal health outcomes are worsening at an alarming rate, with Black women and birthing people bearing the brunt of this crisis–a persisting legacy of discrimination, unequal distribution of resources, and inequitable access to care. Indeed, as of 2020, the national maternal mortality rate for Black women was approximately three times the rate for white women [Footnote 20: Donna L. Hoyert, Maternal Mortality Rates in the United States, 2020, CDC (Feb. 2022), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/E-stat-Maternal-Mortality-Rates-2022.pdf]. Because of the heightened mortality and morbidity risks faced by Black women and birthing people, it is particularly unconscionable to force the continuation of an unwanted pregnancy. Restrictions on abortion care have far reaching consequences, both deepening existing inequities and worsening health outcomes for pregnant people and people giving birth. Adding the Danforth Amendment to Section 1557 would compound the harms of barriers that patients already face when seeking care. Evidence shows that when a person is denied a wanted abortion their household falls deeper into poverty, and that impact lasts for years [Footnote 21: Advancing New Standards in Reproductive Health, The Harms of Denying a Woman a Wanted Abortion Findings from the Turnaway Study, https://www.ansirh.org/sites/default/files/publications/files/the_harms_of_denying_a_woman_a_wanted_abortion_4-16-2020.pdf]. Every person should be able to choose whether or not to continue a pregnancy.

Abortion care is a normal and important part of the spectrum of reproductive health care and those seeking this care must be able to get evidence-based information, referrals, and services to the greatest extent possible. Applying the Danforth Amendment in the health care context would cause life-threatening situations and hinder a person's equal access to a health program or provider based upon their pregnancy related condition.

We strongly support the Department's position that "as a textual matter, the more natural understanding of 'grounds prohibited' is that it refers simply to the basis on which discrimination is prohibited."

Comment Number: HHS-OS-2022-0012-DRAFT-66147-0009
All Sections: 8.2

(b)(5)

Organization: Physicians for Reproductive Health

Excerpt Text:
IV. [Bold: Discrimination based on Personal or Religious Beliefs]

As health care 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, fertility care, and gender affirming care. A provider's personal or religious beliefs should never dictate the care a patient receives. The very purpose of Section 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 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/BearingFaith.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.

a. [Bold: The Danforth Amendment]

The application of the Danforth Amendment, also known as Title IX religious refusals 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 has been enjoined in court, largely because applying these provisions to the health care context could have life-threatening implications. Delays in abortion care due to questions of compliance with this provision would put providers in impossible situations and put patients receiving this life-saving care at risk.

As discussed above abortion care is a normal and important part of the spectrum of reproductive health care and those seeking this care must be able to get evidence-based information, referrals, and services to the greatest extent possible. Applying the Danforth Amendment in the health care context would cause life-threatening situations and hinder a person's equal access to a health program or provider based upon their pregnancy related condition.

Comment Number: HHS-OS-2022-0012-DRAFT-43609-0009
All Sections: 8.2
(b)(5)

(b)(5)

Organization: Endocrine Society

Excerpt Text:
Omission 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 ground 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 pernicious 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75461-0009
All Sections: 7.8.3, 8.2

(b)(5)

Organization: Charlotte Lozier Institute

Excerpt Text:
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 unfettered access to abortion - at the expense of those healthcare providers that have genuine religious or moral objections.

Comment Number: HHS-OS-2022-0012-DRAFT-67830-0009
All Sections: 8.2

(b)(5)

Organization: U.S. House Committees on Energy and Commerce, Ways and Means, and

Education and Labor

Excerpt Text:
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. This proposal clarifies the Trump Administration's 2020 rule that indicated the application of such exemptions in its preamble but not explicitly in the rule itself. Nothing in Section 1557's antidiscrimination 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, misapplied outside of the education context, and deeply harmful to individuals accessing health care services.

Section 8.3 - Relationship to other laws (92.3(c))

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0007
All Sections: 8.3, 8.2
(b)(5)

Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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 ground 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. 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.

Section 8.4 - Process for raising conflict (Notification of Views Regarding Application of Laws) (§ 92.302)

Comment Number: HHS-OS-2022-0012-DRAFT-72212-0015
All Sections: 8.4

(b)(5)

Organization: Senate Democrats

Excerpt Text:
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 32: Id. at 47841, 47918-19 (Proposed § 92.302)]. This 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 them further at risk [Footnote 33: See e.g. ACOG Committee on Health Care for Underserved Women, Opinion, Increasing Access to Abortion, No. 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.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0018
All Sections: 8.4

(b)(5)

Organization: Colors+

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-39586-0024
All Sections: 8.4
(b)(5)
Organization: Eating Disorders Coalition for Research, Policy & Action

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-66818-0003
All Sections: 8.4
(b)(5)
Organization: NCPA

Excerpt Text:
[Bold: 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 exception, 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.

[Bold: 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 this 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0004
All Sections: 8.4
(b)(5)

Organization: American Academy of Family Physicians

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0047
All Sections: 4.3.1.2.5, 4.3.1.2.4, 8.4, 4.3.1.2.3
(b)(5)

Organization: Center for American Progress

Excerpt Text:
XVIII. Notification of Views Regarding Application of Federal Conscience and Religious Freedom Laws (§ 92.302)

The federal government has a compelling interest in preventing discrimination in health care. The very purpose of Section 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.

It is crucial that the Department's Final Rule includes the Proposed Rule's revised approach to religious exemptions. Expansion of religious exemptions in health care settings disproportionately harms vulnerable populations including women - especially women of color - and LGBTQI+ individuals who are seeking a wide range of care, including gender-affirming and reproductive care [Footnote 101: Emily London and Maggie Siddiqi, "Religious Liberty Should Do No Harm," (Washington: Center for American Progress, 2019) available at https://www.americanprogress.org/article/religious-liberty-no-harm/].

Data from CAP's 2022 nationally representative survey shed light on occurrences when doctors and other health care providers refuse to provide care for religious reasons. For example [Footnote 102: Caroline Medina and Lindsay Mahowald, "Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities," (Washington: Center for American Progress, 2022), available at https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/]:

? 8 percent of LGBQ respondents (including 14 percent of LGBQ respondents of color), 12 percent of transgender or nonbinary respondents (including 20 percent of transgender or nonbinary respondents of color), and 53 percent of intersex respondents reported that, in the past year, a health care provider refused to see them due to the provider's religious beliefs or the stated religious tenets of the hospital or health care facility.

Denial of medical care for religious purposes negatively affects patients who require the denied care, not only by creating delays that may result in harm but also because the stress of being denied care and fear of encountering similar denials is detrimental and can engender avoidance behavior [Footnote 103: National Academies of Sciences, Engineering, and Medicine, "Understanding the Well-Being of LGBTQI+ Populations" (Washington: 2020), available at https://www.nap.edu/read/25877/chapter/1]. The 2020 version of Section 1557 disregarded those harms by implementing regulations that improperly incorporated a religious exemption that violated the plain language of the statute and is contrary to the express purpose of Section 1557. We strongly support the Proposed Rule's case-by-case process, which 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.

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0005
All Sections: 8.4

(b)(5)

Organization: Colors+

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-43889-0006
All Sections: 8.4

(b)(5)

Organization: American Academy of Family Physicians

Excerpt Text:
Laws (§ 92.302)

As mentioned above, HHS is proposing to establish a process in which an individual or organization may indicate 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 non-emergency care that violates their personal code of ethics, so 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-relationships.html]. [Bold: We appreciate HHS reaffirming conscience protections. The AAFP is also committed to ensuring all patients have access to health care, regardless of actual or perceived race, color, religion, gender, sexual orientation, gender identity, ethnic affiliation, health, age, 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/health/ST-ConscienceObjection-012118.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 Medical Treatment and Labor Act (EMTALA) requires that physicians provide treatment to any patient who presents with an emergency condition "until the emergency medical condition is resolved or stabilized" [Footnote 5: ACEP, EMTALA Fact Sheet, available at: https://www.acep.org/life-as-aphysician/ethics-- legal/emtala/emtala-fact-sheet/]. EMTALA properly defers to the medical judgment of the physician(s) responsible for treating the patient to determine how best to achieve the designated objective of stabilization under established clinical guidelines and the latest advancements in medical science. Just as EMTALA does not specify particular treatments, it also does not allow for physicians to withhold specific treatments from particular patients for non-medical reasons. Rather, if a treatment is "required to stabilize the medical condition," it must be provided [Footnote 6: 42 U.S.C. § 1395dd(b)(1)(A) (1986)]. When faced with a pregnant patient suffering from an emergency medical condition, in order to comply with EMTALA, clinicians must promptly provide stabilizing treatment to that pregnant patient. It is essential for physicians providing emergency care to have access to the full suite of interventions and treatments, consistent with evidence-based clinical guidelines—and they must be able to act without hesitation. Because pregnancy termination is part of the medically indicated treatment to stabilize patients in certain emergency scenarios, physicians—to comply with EMTALA and the principles of medical ethics—must, and do, consider abortion a necessary treatment option. [Bold: The AAFP encourages HHS to align exemptions under this provision with EMTALA's requirements under emergency medical conditions].

Aside from aligning this section with EMTALA, the AAFP believes HHS' outlined process for conscience or religious objections allows physicians and organizations to make appropriate claims to protect their right to not provide specific procedures, while ensuring historically underserved individuals are still able to access the necessary, high-quality, respectful, and comprehensive care they need and deserve. However, the AAFP is concerned that delays in the review process or a higher volume of claims may result in disruptions in care or inappropriate denials of care while an entity is awaiting a case decision. [Bold: To address this, the AAFP recommends HHS publish the anticipated timeframe for review of exemption claims, notify individuals and/or organizations when they anticipate their review to be complete, and instruct the individual/organization to notify patients if they will not be offering the service or treatment under review during that period]. The AAFP also recommends HHS publicize de-identified data on conscience claims and review timelines to ensure public and private entities can monitor any access issues, should they occur.

Comment Number: HHS-OS-2022-0012-DRAFT-72280-0067
All Sections: 8.4

(b)(5)

Organization: Justice in Aging

Excerpt Text:

Notification 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0068
All Sections: 8.4
(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[Bold: B. The proposed conscience and religious objection process is an empty gesture.]

The Proposed Rules 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.]

Comment Number: HHS-OS-2022-0012-DRAFT-20041-0009
All Sections: 5.9.2, 8.4
(b)(5)

Organization: Colors+

Excerpt Text:

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.

Section 8.4.1 - Pre-enforcement exemption

Comment Number: HHS-OS-2022-0012-DRAFT-69942-0011
All Sections: 5.9.1, 8.4.1

(b)(5)

Organization: Health Care For All

Excerpt Text:
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 in 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.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0012
All Sections: 8.4.1

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
5. [Bold: Requiring entities that receive a religious exemption to provide notice of that

exemption.] While entities will be required to issue a notice of nondiscrimination, 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.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0021
All Sections: 8.4.2, 8.4.3, 8.4.1

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
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. This does not means that a religious organization is free to discriminate against LGBTQ+ individuals under the pretext of religious freedom. For example, the new rule points out that "even if the rule substantially burdened religious practices, a religious exemption would not be required if that burden was the result of the government's advancement of a compelling interest by means that were least restrictive of religious exercise in particular contexts." The new rule further states that the "U.S. Supreme Court has made it clear that a fact-sensitive, case-by-case analysis of such burdens and interests is needed under [Religious Freedom Restoration Act] RFRA, something the Title IX exception does not allow." [Footnote 26: Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47,824 (Aug. 4, 2022) (Citing examples, Gonzales v. O Centro Espírita Beneficente União do Vegetal, 546 U.S. 418, 430-31 (2006) (when applying RFRA, courts look "beyond broadly formulated interests justifying the general applicability of government mandates and scrutinized the asserted harm of granting specific exemptions to particular religious claimants"); cf. Ramirez v. Collier, 142 S. Ct. 1264, 1281 (2022) (holding that the Religious Land Use and Institutionalized Persons Act, which applies RFRA's test for religious exemptions in the prison context, "requires that courts take cases one at a time, considering only `the particular claimant whose sincere exercise of religion is being substantially burdened'")).] Ensuring access to health care free from discrimination is a compelling government interest.

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0027
All Sections: 8.4.1

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
[Bold: III. NEW PROCESS FOR SUBMISSION OF A CONSCIENCE OR RELIGIOUS 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 unattainable. 87 Fed. Reg at 47,886. 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 47,886. 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 47,885-6. HHS's determination would be with respect to a particular recipient, certain provisions or modified application of certain provisions of the regulation, and certain contexts, procedures, or healthcare services. Id. at 47,886. 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 when 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. Tex. 2021), supports this approach. The court's ruling applies only to the specific plaintiff and only with respect to a requirement that it perform or provide insurance coverage for services related to gender transition or abortion. 553 F. Supp. 3d at 375-78. The court never considered a wholesale exemption, such that the plaintiff and recipient of federal funds could discriminate against those seeking healthcare as it saw fit. (HHS has expressly confirmed it intends to abide by the injunctions upheld by the Franciscan Alliance court, in the event they remain in place.)]

Moreover—and of critical importance to the States and their residents—the newly proposed provision allows HHS to assess the danger to individuals in need of healthcare, which is an essential consideration before exempting covered entities under federal conscience and religious freedom laws. 87 Fed. Reg. at 47,842, 46. Granting exemptions that affect underserved populations who already face a lack of healthcare access will only compound negative health outcomes. Careful consideration of these populations is thus essential.

This potential peril to individuals' health and wellbeing highlights why the healthcare context is fundamentally distinct from the education context, and why exemptions applicable in education should not be incorporated to apply to healthcare. A patient cannot always select an alternate healthcare facility or health plan with the forethought inherent in choosing an educational institution. 87 Fed. Reg. at 47,840-41. Scarcity of healthcare options is even more dangerous in emergencies. There is no life-or-death parallel in education. HHS addressed this singular aspect of healthcare when it incorporated only the bases of discrimination under Title IX, and not the Title IX exceptions. Id. HHS takes the same approach with Title VI, the Age Act, and Section

504, cleanly addressing any inconsistencies in past rules. Id. at 47,839. The States commend this approach of incorporating into Section 1557 only the grounds of discrimination, which tracks the plain language of Section 1557.

There are, however, some potential gaps in the notice provisions. Section 92.302 does not explicitly state that covered entities that notify HHS of their view that they are exempt from certain provisions due to the application of a federal conscience or religious freedom laws may not act as if exempted until receipt of a favorable determination from HHS. The Proposed Rule also does not expressly state that covered entities cannot refuse healthcare or coverage simply by deeming themselves exempt from Section 1557, but choosing not to notify HHS pursuant to § 92.302. In short, the notice requirements as currently drafted are permissive, not mandatory. The Proposed Rule could therefore benefit from clarification, and making explicit that the provisions are not optional for recipients who seek to refuse care. [Footnote 79: Relatedly, there may also be some ambiguity by what is meant by an "open case." 87 Fed. Reg. at 47,886. The States assume that that HHS considers a notification pursuant to § 92.302 an open case, similar to if HHS had received a complaint of discrimination, or had an open investigation, but the States are concerned with any implication that covered entities that are not the subject of any open investigation or "case" may simply choose to refuse care.]

Section 8.4.2 - Case law discussion - Religious Sisters, Franciscan Alliance

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0021
All Sections: 8.4.2, 8.4.3, 8.4.1

(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
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. This does not means that a religious organization is free to discriminate against LGBTQ+ individuals under the pretext of religious freedom. For example, the new rule points out that "even if the rule substantially burdened religious practices, a religious exemption would not be required if that burden was the result of the government's advancement of a compelling interest by means that were least restrictive of religious exercise in particular contexts." The new rule further states that the "U.S. Supreme Court has made it clear that a fact-sensitive, case-by-case analysis of such burdens and interests is needed under [Religious Freedom Restoration Act] RFRA, something the Title IX exception does not allow." [Footnote 26: Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47,824 (Aug. 4, 2022) (Citing examples, Gonzales v. O Centro Espírita Beneficente União do Vegetal, 546 U.S. 418, 430-31 (2006) (when applying RFRA, courts look "beyond broadly formulated interests justifying the general applicability of government mandates and scrutinized the asserted harm of granting specific exemptions to particular religious claimants"); cf. Ramirez v. Collier, 142 S. Ct. 1264, 1281 (2022) (holding that the Religious Land Use and Institutionalized Persons Act, which applies RFRA's test for

religious exemptions in the prison context, "requires that courts take cases one at a time, considering only `the particular claimant whose sincere exercise of religion is being substantially burdened'")).] Ensuring access to health care free from discrimination is a compelling government interest.

Comment Number: HHS-OS-2022-0012-DRAFT-66316-0004
All Sections: 8.4.2
(b)(5)

Organization: American Association of Christian Schools

Excerpt Text:
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 morally repugnant 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 upholding 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 workers, without offering any affirmative conscience or religious liberty protections is no shield for our institutions and will likely result in further needless litigation.

Comment Number: HHS-OS-2022-0012-DRAFT-54859-0004
All Sections: 8.4.2
(b)(5)

Organization: Texas Catholic Conference of Bishops

Excerpt Text:
However, religious liberty is a not a concession from the beneficence 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 required 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 views 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 exercises, whether communicative 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: "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)].

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0070
All Sections: 8.4.2, 8.2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 adopted 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 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 214: Franciscan All. v. Becerra, No. 21-11174, at *10 (5th Cir. Aug. 26, 2022).]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0071
All Sections: 8.4.2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
Further, HHS is now appealing a decision in [Italics: Christian Employers Alliance v. EEOC] (8th 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 there should be conscience and religious exemptions to Section 1557 regulations, and it is doubtful that OCR would seriously give effect to those legal protections through the proposed notification process when its litigation positions say otherwise.

To the extent that health care entities and professionals notify 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 an entity 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 seeking guidance or technical assistance in good faith.

Section 8.4.3 - Coats-Snowe Amendment, Church Amendments, Religious Freedom Restoration Act (RFRA), Section 1553 of the ACA, Section 1303 of the ACA, Weldon Amendment

Comment Number: HHS-OS-2022-0012-DRAFT-67830-0010
All Sections: 8.4.3

(b)(5)

Organization: U.S. House Committees on Energy and Commerce, Ways and Means, and Education and Labor

Excerpt Text:
We urge HHS to implement all sections of this rule—particularly the provision allowing covered

entities to proactively notify HHS of their 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.

Comment Number: HHS-OS-2022-0012-DRAFT-71656-0014
All Sections: 8.4.3

(b)(5)

Organization: Center for Reproductive Rights

Excerpt Text:
[Italics: 3. Religious exemptions based on other federal statutes must be weighed against their harm to patients.]

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, at times insurmountable 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 66: 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 how any exemption granted does not further discrimination, and how any denied exemption would have undermined the goals of Section 1557 if granted. Additionally, the Department should ensure that determinations of discrimination are not unduly delayed due to

the time-sensitive nature of health care. Delays in care can result in increased negative health outcomes or prevent patients from accessing care entirely.

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0019
All Sections: 8.4.3
(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
[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.

Comment Number: HHS-OS-2022-0012-DRAFT-70854-0021
All Sections: 8.4.2, 8.4.3, 8.4.1
(b)(5)

Organization: Human Rights Campaign

Excerpt Text:
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. This does not means that a religious organization is free to discriminate against LGBTQ+ individuals under the pretext of religious freedom. For example, the new rule points out that "even if the rule substantially burdened religious practices, a religious exemption would not be required if that burden was the result of the government's advancement of a compelling interest by means that were least restrictive of religious exercise in particular contexts." The new rule further states that the "U.S. Supreme Court has made it clear that a fact-sensitive, case-by-case analysis of such burdens and interests is needed under [Religious Freedom Restoration Act] RFRA, something the Title IX exception does not allow." [Footnote 26: Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47,824 (Aug. 4, 2022) (Citing examples, Gonzales v. O Centro Espírita Beneficente União do Vegetal, 546 U.S. 418, 430-31 (2006) (when applying RFRA, courts look "beyond broadly formulated interests justifying the general applicability of government mandates and scrutinized the asserted harm of granting specific exemptions to particular religious claimants"); cf. Ramirez v. Collier, 142 S. Ct. 1264, 1281 (2022) (holding that the Religious Land Use and Institutionalized Persons Act, which applies RFRA's test for religious exemptions in the prison context, "requires that courts take cases one at a time, considering only `the particular claimant whose sincere exercise of religion is being substantially burdened'")).] Ensuring access to health care free from discrimination is a compelling government interest.

Comment Number: HHS-OS-2022-0012-DRAFT-75461-0005
All Sections: 8.4.3

(b)(5)

Organization: Charlotte Lozier Institute

Excerpt Text:
Despite refusing to recognize Title IX's religious exemption, the Department seeks 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 their 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 exception 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 ab initio. 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 puts the burden on the Department not to burden those rights in the first place. CLI requests further explanation as to whether the Department's promised 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0066
All Sections: 15.2, 8.4.3, 8.2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
The Proposed Rule state 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 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, 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 their 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 objection of "increasing access to health care." [Footnote 205: 87 Fed. Reg. 47840.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0067
All Sections: 8.4.3, 8.2

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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).

Comment Number: HHS-OS-2022-0012-DRAFT-65731-0007
All Sections: 8.4.3

(b)(5)

Organization: SIECUS: Sex Ed for Social Change

Excerpt Text:
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.

Comment Number: HHS-OS-2022-0012-DRAFT-69075-0007
All Sections: 8.4.3

(b)(5)

Organization: 38 Members of Congress

Excerpt Text:
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 53 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 if doing so shifts the burden to third parties without considering this harm to third parties.

Comment Number: HHS-OS-2022-0012-DRAFT-68884-0007
All Sections: 8.4.3

(b)(5)

Organization: Center for American Progress

Excerpt Text:
Additionally, there are already numerous federal laws that allow health care 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 their 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 exemptions in the health care 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 London & 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 triumphed 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 simply protecting the rights of religious people, RFRA was expanded and misused to discriminate")].

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0073
All Sections: 8.4.3

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
At a minimum, federal regulations should uphold existing medical conscience and 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 Section 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/ocr- bostock-notification.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 rules, it has blatantly disregarded and ignored those right, 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-bidens-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 Regulation entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," RIN 0945-AA18.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0074
All Sections: 8.4.3

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 their programs must be run to comply with the Free Exercise Clause and the Establishment Clause of the First Amendment." [Footnote 221: 86 Fed. Reg. 67,067 (Nov. 24, 2021) (Delegation of Authority); see also Letter from Lisa J. Pino, Director, Office for Civil Rights, to Xavier Becerra, Secretary, on Decision—Sign Delegation of Authority on the Religious Freedom Restoration Act and the Religion 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 this OCR rule. In the proposed rule, the Agency must explain how it will fulfill its statutory duty to protect and enforce conscience protection laws within its 1557 regulations, while at the same time proposing to rescind the Conscience Rule giving effect to those protections.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0075
All Sections: 8.4.3, 8.6, 8.5

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[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 those 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. 20-35507 (9th Cir. Jul. 22, 2021).] Apart from violating the First Amendment, such a regulation of health insurance providers to coopt 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0076
All Sections: 8.4.3

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
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 attack 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 223: 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 (or 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 is 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 protection laws exist, HHS fails to explain how those 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0077
All Sections: 8.4.3
(b)(5)
Organization: Ethics & Public Policy Center

Excerpt Text:
The Department also states that recognition of statutory rights must take into 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 sterilization procedures, including 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 of 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. 585 (2021), the government does not have a compelling intertest 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 interests in a manner that does not burden religion, it must do so."

HHS states that "OCR would also consider the application of Federal conscience and religious freedom laws, where relevant." [Footnote 228: 87 Fed. Reg. 47867.] But since HHS recently withdrew the delegation of authority from OCR to enforce RFRA. [Footnote 229: 86 Fed. Reg. 67067.] any perfunctory statement that HHS will comply and follow RFRA and other conscience protection laws is suspect. HHS must explain specifically how it intends to uphold its duty to enforce conscience and religious freedom protection laws in relation to its proposed regulations.

Comment Number: HHS-OS-2022-0012-DRAFT-66212-0008
All Sections: 8.4.3

(b)(5)

Organization: National Association of Chain Drug Stores

Excerpt Text:
[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 defer to a court of competent jurisdiction to make such determinations instead.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0086
All Sections: 8.4.3

(b)(5)

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[Bold: F. HHS must recognize application of Section 1303 of the ACA.]

The Proposed Rule cites Section 1303 of the ACA which contains special rules related to abortion but fails to elaborate on its implications. Under Section 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 for the performance of an abortion on a minor." [Footnote 245: 42 U.S.C. § 18023(c)(1).] Thus, any suggestion that the Proposed Rule preemptions state abortion laws is contrary to law.

Further, Section 1303 states:

Nothing in this Act shall be construed to have any effect on Federal laws regarding—
- (i) conscience protection;
- (ii) willingness or refusal to provide abortion; and
- (iii) 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 op-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. § 18023(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).]

Section 8.5 - Gender identity

Comment Number: HHS-OS-2022-0012-DRAFT-69064-0001
All Sections: 8.6, 8.5

(b)(5)

Organization: FOREST DIRECT PRIMARY CARE

Excerpt Text:
The changes propose to redefine discrimination based on sex to include gender identity, sexual orientation, and "pregnancy-related conditions," including termination of pregnancy. The proposed rule leaves open the question as to whether HHS will exempt entities who object based

on conscience stating, "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." In effect, this proposed rule, if finalized, would render it discriminatory for medical professionals and health care entities to decline to perform abortions, transgender interventions, and other procedures that many doctors, including myself, find objectively and scientifically harmful and unethical.

Elective, induced abortion is neither "healthcare" nor a procedure intended to treat a "pregnancy-related conditions." It is a procedure that intentionally kills an innocent, genetically distinct, preborn, human child – and to varying degrees wounds the mother. Blocking normal puberty development and/or removing normal, healthy breasts or genitalia from men or women, especially children, is irreversibly harmful. No physician should be forced to participate in abortions or transgender "interventions"; physicians have promised, "to do no harm."

This proposed rule is a best a threat to, but appears to intentionally dismantle, conscience protections for medical professionals. In the name of "health equity," it pushes harmful, unscientifically proven (especially in the long term) ideologies that will ultimately drive good medical professionals out of the industry if they are forced to do procedures that they find unethical and harmful to their patients, such as blocking normal puberty, prescribing cross-se hormones, or taking the life of a child before her first breath. The final rules must include clear and robust conscience protections for all health care professionals.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0015
All Sections: 8.6, 8.5

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Italics: The harm to religious liberty and freedom of conscience]

In the preamble 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:

- [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 abide by the proposed nondiscrimination policy. Ibid., 54220.] The proposed regulations could require health care organizations to open their bathrooms, locker rooms, and shower facilities to everyone regardless of sex or to provide "comparable" facilities, regardless of an organization's religious beliefs on the matter. [Footnote 37: The preamble to the proposed regulations noted, "HHS does not propose to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex." Ibid., 54181. Presumably, if a covered entity failed to provide such "comparable facilities," regardless of sex, it could be found in violation of the proposed regulations. Notably, the Department made no estimate of the cost to covered entities for ensuring compliance with the proposed regulations in this respect.]
- [Bold: Employers and individuals purchasing health insurance.] As previously noted and also discussed in more detail in a subsequent section of these comments, if the proposed regulations require private insurers that receive any enrollee subsidy on an Obamacare exchange or any other type of federal financial assistance to make all of their health insurance products comport with the gender identity mandate it would make it much more difficult (and in some cases, practically impossible) for private employers and individuals to avoid paying for coverage of sex-reassignment surgeries and treatments through their insurance plans contrary to their religious belief or moral convictions.
- [Bold: Taxpayers.] We anticipate that because the proposed regulation would apply to all insurance plans receiving taxpayer-funded subsidies on Obamacare exchanges and to all state Medicaid plans, which are funded with both state and federal tax dollars, the proposed regulation would make American taxpayers complicit in funding coverage of controversial surgeries and treatments.

Instead, HHS should incorporate Title IX's religious exemption status, given that it's "applicable by extension." The existing approach default exempts religious organizations. This is the preferred approach, too. Even the Obama-era rule acknowledges the Religious Freedom Restoration Act and respects it on a case-by-case basis. The Trump administration incorporated Title IX's religious institution exemption to the Section 1557 rule. It stated that sex

discrimination does not apply if it conflicts with your sincerely held religious beliefs. This precedent is wholly removed from the current department's Section 1557 proposed rule. The department does not provide an explanation for why the existing religious exemption process is inadequate, nor does the department provide a justification for why this proposed process will better protect religious individuals and institutions.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0049
All Sections: 8.5

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
The term "cisgender" is not universally accepted; in fact, it is rejected outright by biologists and others who view it as an "ideological stance" akin to asserting a religious belief. [Footnote 122: Colin Wright, @SwipeWright, 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/SwipeWright/status/1377272252895387656.] 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. Giatti, Catholic League calls out Air Force gender ideology 'fiction' for fellowship excluding 'cisgender' men, The Christian Post (Sept. 29, 2022), https://www.christianpost.com/news/catholic-league-slams-air-force-for- gender-ideology-fiction.html.]

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0075
All Sections: 8.4.3, 8.6, 8.5

(b)(5)

Organization: Ethics & Public Policy Center

Excerpt Text:
[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 those 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. 20-35507 (9th Cir. Jul. 22, 2021).] Apart from violating the First Amendment, such a regulation of health insurance providers to coopt 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.

Section 8.6 - Abortion (not related to neutrality)

Comment Number: HHS-OS-2022-0012-DRAFT-10243-0001
All Sections: 8.6
(b)(5)

Organization:

Excerpt Text:
This regulation concerns me, because it might impact my ability to receive quality 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 decision 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, including 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 reaction to a traumatic event in which deeply held morals or values are violated. 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 in their professional opinion think abortion and gender transition are not in the best interest of their patients. There needs to be an extremely firm foundation to prove these things even need regulation like this, and given the contentious nature of this, and the fact that many physicians have made the determination these acts are not best for their patients there is not a sufficient ground for this regulation.

There was a letter signed by 30,000 American physicians in 2019 which details why "It Is Never Necessary to Intentionally Kill a Fetal Human Being to Save a Woman's Life"[3]. I present the medical facts therin as reasons why this regulation does not solve any problem or help women. [Footnote 3: https://www.thepublicdiscourse.com/2019/02/49619/]

There was also a study using data from Sweden in 2011 which followed up with results of sex reassignment surgery. It found outcomes from sex reassignment surgery were far worse with much higher mortality rates largely due to suicide.[Footnote 4: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0016885]

In light of these facts, I do not think the proposed regulation would benefit the American people, women, children, or those struggling with gender dysphoria. Additionally, there is no evidence this regulation is needed, effective, or would provide an improvement in care for the target populations.

Comment Number: HHS-OS-2022-0012-DRAFT-66187-0001
All Sections: 8.6

(b)(5)

Organization: Pennsylvania Catholic Conference

Excerpt Text:
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/generalcounsel/rulemaking/upload/2022.comments.1557.regulations.final_.pdf

Healthcare 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 exclude 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.

Comment Number: HHS-OS-2022-0012-DRAFT-40054-0001
All Sections: 8.6

(b)(5)

Organization: Virginia Catholic Conference

Excerpt Text:
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 appalling 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 their conscience.

Comment Number: HHS-OS-2022-0012-DRAFT-37946-0001
All Sections: 8.6
(b)(5)

Organization: Montana Catholic Conference

Excerpt Text:
The Montana Catholic Conference stands in opposition to all forms of unjust discrimination and finds laudable 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 also risk providing, what is, in effect, an abortion mandate. The proposed repeal of the current cross reference to the abortion-neutrality provision in 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 eliminated.

Comment Number: HHS-OS-2022-0012-DRAFT-35444-0001
All Sections: 8.6
(b)(5)

Organization: New York State Catholic Conference

Excerpt Text:
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 unjustly 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. This is particularly disturbing because HHS has repeatedly sought to suppress this right in litigation over abortion and gender transition.

Comment Number: HHS-OS-2022-0012-DRAFT-69064-0001
All Sections: 8.6, 8.5
(b)(5)

Organization: FOREST DIRECT PRIMARY CARE

Excerpt Text:
The changes propose to redefine discrimination based on sex to include gender identity, sexual orientation, and "pregnancy-related conditions," including termination of pregnancy. The proposed rule leaves open the question as to whether HHS will exempt entities who object based on conscience stating, "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." In effect, this proposed rule, if finalized, would render it discriminatory for medical professionals and health care entities to decline to perform abortions, transgender interventions,

and other procedures that many doctors, including myself, find objectively and scientifically harmful and unethical.

Elective, induced abortion is neither "healthcare" nor a procedure intended to treat a "pregnancy-related conditions." It is a procedure that intentionally kills an innocent, genetically distinct, preborn, human child – and to varying degrees wounds the mother. Blocking normal puberty development and/or removing normal, healthy breasts or genitalia from men or women, especially children, is irreversibly harmful. No physician should be forced to participate in abortions or transgender "interventions"; physicians have promised, "to do no harm."

This proposed rule is a best a threat to, but appears to intentionally dismantle, conscience protections for medical professionals. In the name of "health equity," it pushes harmful, unscientifically proven (especially in the long term) ideologies that will ultimately drive good medical professionals out of the industry if they are forced to do procedures that they find unethical and harmful to their patients, such as blocking normal puberty, prescribing cross-se hormones, or taking the life of a child before her first breath. The final rules must include clear and robust conscience protections for all health care professionals.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0015
All Sections: 8.6, 8.5
(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Italics: The harm to religious liberty and freedom of conscience]

In the preamble 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:

- [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 abide by the proposed nondiscrimination policy. Ibid., 54220.] The proposed regulations could require health care organizations to open their bathrooms, locker rooms, and shower facilities to everyone regardless of sex or to provide "comparable" facilities, regardless of an organization's religious beliefs on the matter. [Footnote 37: The preamble to the proposed regulations noted, "HHS does not propose to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex." Ibid., 54181. Presumably, if a covered entity failed to provide such "comparable facilities," regardless of sex, it could be found in violation of the proposed regulations. Notably, the Department made no estimate of the cost to covered entities for ensuring compliance with the proposed regulations in this respect.]
- [Bold: Employers and individuals purchasing health insurance.] As previously noted and also discussed in more detail in a subsequent section of these comments, if the proposed regulations require private insurers that receive any enrollee subsidy on an Obamacare exchange or any other type of federal financial assistance to make all of their health insurance products comport with the gender identity mandate it would make it much more difficult (and in some cases, practically impossible) for private employers and individuals to avoid paying for coverage of sex-reassignment surgeries and treatments through their insurance plans contrary to their religious belief or moral convictions.
- [Bold: Taxpayers.] We anticipate that because the proposed regulation would apply to all insurance plans receiving taxpayer-funded subsidies on Obamacare exchanges and to all state Medicaid plans, which are funded with both state and federal tax dollars, the proposed regulation would make American taxpayers complicit in funding coverage of controversial surgeries and treatments.

Instead, HHS should incorporate Title IX's religious exemption status, given that it's "applicable by extension." The existing approach default exempts religious organizations. This is the preferred approach, too. Even the Obama-era rule acknowledges the Religious Freedom Restoration Act and respects it on a case-by-case basis. The Trump administration incorporated Title IX's religious institution exemption to the Section 1557 rule. It stated that sex discrimination does not apply if it conflicts with your sincerely held religious beliefs. This precedent is wholly removed from the current department's Section 1557 proposed rule. The department does not provide an explanation for why the existing religious exemption process is

inadequate, nor does the department provide a justification for why this proposed process will better protect religious individuals and institutions.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0016
All Sections: 8.6

(b)(5)

Organization: The Heritage Foundation

Excerpt Text:
[Italics: Conflict with existing federal right to conscience]

Health care policy, at bottom, should concern itself with the well-being of patients and providers. And a basic moral principle is at stake for health care providers: their 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., 54216]

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 those 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 obstetricians from declining to refer patients for abortions? Or would it have required coverage and provision of abortions, as with sex-reassignment surgeries? Because of this extreme ambiguity, the proposed 2022 regulation could risk serious conflict with long-standing and widely accepted law and policies protecting conscience. [Footnote 39: Specifically, the Church Amendments prevent the government from forcing any individual or entity receiving certain federal dollars to "perform or assist in the performance of any sterilization procedure or abortion" or make its facilities available for such procedures if doing so would violate religious or moral beliefs about abortion. 42 U.S. Code § 300a-7 et seq. Likewise, the Weldon Amendment, attached to every HHS appropriations bill since fiscal year 2004, prohibits any government receiving certain federal dollars from discriminating against health care entities (including health insurance plans) because it "does not provide, pay for, provide coverage of, or refer for abortions." For example, see the Consolidated Appropriations Act, 2010, Public Law No. 111–117. Even the ACA prohibits qualified health plans offered on state and federal exchanges from "discriminat[ing] against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions." Public Law 111–148 as amended by Public Law 111–152. See also U.S. Department of Health and Human Services, "Overview of Federal Statutory Health Care Provider Conscience Protections," http://www.hhs.gov/ocr/civilrights/faq/providerconsciencefaq.html]

Comment Number: HHS-OS-2022-0012-DRAFT-66757-0019
All Sections: 8.6, 8.1

(b)(5)

Organization: Concerned Women for America

Excerpt Text:
Finally, this Rule is an affront to rights of conscience and religious freedom. The Constitution 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 intrusion or threat. 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, 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 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 determination does not otherwise limit the application 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 killing unborn babies or maiming vulnerable children.

Comment Number: HHS-OS-2022-0012-DRAFT-64680-0002
All Sections: 8.6

(b)(5)

Organization: Kansas Catholic Conference

Excerpt Text:
For a comprehensive review of our concerns, including annotations, 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 Program and Activities RIN 0945-AAl 7

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.

Comment Number: HHS-OS-2022-0012-DRAFT-54859-0002
All Sections: 8.6

(b)(5)

Organization: Texas Catholic Conference of Bishops

Excerpt Text:

The TCCB appreciates this opportunity to submit comments on HHS's proposed 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: its 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 3: 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.

At the outset, 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, 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 (Sep. 7, 2022), available at https://www.usccb.org/sites/default/files/about/general-counsel/rulemaking/upload/2022.comments.1557.regulations.final_.pdf].

We also wish to express our care and concern for those persons who experience same-sex attraction or gender dysphoria. Such persons must be accepted with respect, compassion, and sensitivity and every sign of unjust discrimination toward them should be avoided. As the bishops' chairmen stated on behalf of the USCCB in response to the proposed rulemaking:

[Italic: Catholic health care ministries serve everyone, no matter their race, sex, belief system, or any other characteristic. The same excellent care will be provided in a Catholic hospital to all patients, including patients who identify as transgender, whether it be for a broken bone or for cancer, but we cannot do what our faith forbids. We object to harmful [bold: procedures], not to [bold: patients]. [emphasis added] [Footnote 5: United States Conference of Catholic Bishops, Bishop Chairmen Condemn Harmful Regulations Forcing Gender Ideology and Potentially Abortion on Health Care Workers and Religious Hospitals, (July. 27, 2022), available at https://www.usccb.org/news/2022/bishop-chairmen-condemn-harmful-regulations-forcing-gender-ideology-and- potentially]

In that regard, the NPRM would affect our covered health programs and activities under Section 1557 of the ACA by requiring compliance with civil rights law construed by the agency to include sexual orientation and gender identity (SOGI) [Footnote 6: Specifically, Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act of 1973]. The proposed rules address nondiscrimination on the basis of "sex" by reading into that word novel conceptions of gender identity and sexual orientation. This new Section 1557 regulation would have legal binding force on Catholic healthcare providers in Texas. Among other provisions, covered Catholic healthcare providers would have to set up policies and procedures, give notice requirements, establish grievance processes, and be subject to damages for any violations related to Section 1557.

The proposed rules adopt a view of the human person that does not acknowledge the meaning and importance of sexual difference in an effort to advance gender ideology, a construct that denies biological sex and is divorced from scientific and ontological reality. Categorically refusing to perform, pay for, or provide counsel on so-called "gender transition or other gender-affirming care" (e.g., gender transition/reassignment surgeries, sterilizations, puberty suppression prescription drugs, or cross-sex hormones) would be considered discrimination [Footnote 7: NPRM proposed paragraph (b)(4)]. However, Catholic healthcare providers do not consider such procedures to be authentic healthcare in that they do not help persons to harmonize such feelings of dissonance and attractions within a broader context of integral personal development [Footnote 8: See e.g., United States Conference of Catholic Bishops, Ethical and Religious Directives for Catholic Health Care Services (ERDs), 6th Ed. (Jun. 2018), available at https://www.usccb.org/resources/ethical-religious-directives-catholic-health- service-sixth-edition-2016-06_3.pdf ("Catholic health care organizations are not permitted to engage in immediate material cooperation in actions that are intrinsically immoral, such as abortion, euthanasia, assisted suicide, and direct sterilization."); Vatican Congregation for Catholic Education, "Male and Female He Created Them" Towards a Path of Dialogue on the Question of Gender Theory, at 35 (2019), available at https://www.vatican.va/roman_curia/congregations/ccatheduc/documents/rc_con_ccatheduc_doc_20190202_maschio- e-femmina_en.pdf ([Education on sexuality and affectivity] means "learning how to accept our body, to care for it and to respect its fullest meaning")]. In reality, these procedures often are irreversible, interrupt natural bodily developmental processes, and can result in infertility and other serious health risks - especially for children [Footnote 9: See e,g., American College of Pediatricians, Gender Dysphoria in Children, (Nov. 2018), available at https://acpeds.org/position-statements/gender-dysphoria-in-children (citations omitted)].

The proposed rulemaking would conflict with Texas law in various ways. For example, all persons in Texas are protected under general provisions that guarantee religious liberty and conscience rights under our state religious freedom law that prohibits government entities from substantially burdening a person's free exercise of religion [Footnote 10: See Tex. Civ. Prac. & Rem. Code, Chapter 110]. In specific contexts, medical providers (e.g., physicians, nurses, staff members, or employees of a hospital or other health care facility) possess protections from having to, for example, perform or participate in abortions [Footnote 11: See Tex. Occ. Code, Chapter 103]. Child-welfare providers are also protected from having to provide, facilitate, or

refer a person for services that conflict with the provider's sincerely held beliefs [Footnote 12: See Tex. Hum. Res. Code, Sec. 45.004].

Comment Number: HHS-OS-2022-0012-DRAFT-74710-0031
All Sections: 8.6

(b)(5)

Organization: Attorneys General of California, New York, Massachusetts, and nineteen other States

Excerpt Text:
HHS has recognized that many patients live in communities "with limited options to access healthcare from non-religiously affiliated healthcare providers." 87 Fed. Reg. at 47,840. Further, HHS is aware that healthcare consumers do not know that their healthcare providers may limit care due to their religious affiliation. Id. at 47,840–41. 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 Tess 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 infertility services. [Footnote 51: See, e.g.,U. S. Conference of Catholic Bishops, Ethical and Religious Directives for Catholic Health Care Services 16–19 (6th Ed. 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. [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 and Medicaid. 42 C.F.R. §§ 482.1 to 482.104. These conditions ensure patient rights: "the right to participate in the development and implementation of his or her plan of care" and the "right to make informed decisions regarding his or her care . . . includ[ing] . . . being involved in care planning and treatment." Id. at § 482.13(b)(1)-(2).]

Comment Number: HHS-OS-2022-0012-DRAFT-54859-0005
All Sections: 8.6

(b)(5)

Organization: Texas Catholic Conference of Bishops

Excerpt Text:
Our second concern relates to the portion of the NPRM that would repeal 45 CFR 92.6(b), a provision in the 2020 Rule that expressly included Title IX's statutory abortion neutrality provision [Footnote 19: See 45 CFR 86.18(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, while 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) "[italic: notwithstanding any directly conflicting state laws or mandate 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. Di Camillo and Jozef D. Zalot, Medical Interventions During Pregnancy In Light of Dobbs, Nat'l. Catholic Bioethics Center on Health Care and the Life Sciences, Vol. 47 No. 8 (Aug. 2022), available at https://static1.squarespace.com/static/5e3ada1a6a2e8d6a131d1dcd/t/62ffd37462c1db0164bdbd2c/1660932980925/E%26M_August_22_update.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/5e3ada1a6a2e8d6a131d1dcd/t/6308d97eb5d7e63d95e021e1/1661524350670/D E+70+-+Amici+Brief+of+CHLA+et+al.pdf ("Defendants' have created unnecessary confusion given the fact that everyone agrees that medical treatments to save the life of the mother that unintentionally cause the death of the unborn child are permitted. The confusion arises in that, despite there being treatment options for all pregnancy complications that do not involve abortion, Defendants insist that all health care providers have a duty under EMTALA to perform an intentional abortion")]. Second, this exact issue was recently addressed in Texas and the Administration's HHS EMTALA guidance was enjoined from being enforced in Texas because the guidance went beyond EMTALA's authorizing text [Footnote 21: State of Texas v. Becerra, No. 5:22-CV-185-H (N.D. Texas 2022), available at https://www.documentcloud.org/documents/22187203-txemtalarlg082322.].

Additionally, the recent Dobbs v. Jackson Women's Health Organization decision suggests that the appropriate standard that will govern if abortion regulations undergo a constitutional challenge should be rational-basis review. State laws regulating abortion, like other health and welfare laws, are entitled to a strong presumption of validity [Footnote 22: 597 U.S. (2022) (slip op., at 77)]. Smuggling in an emergency abortion exception via federal rulemaking would be an end-run around the states. Furthermore, it would also interrupt the return of this issue to the people and their elected representatives in the democratic process [Footnote 23: 597 U.S. (2022)

(Kavanaugh, J., concurring) (slip op., at 11)]. Federal rulemaking should not step outside the bounds of that newly controlling precedent.

Comment Number: HHS-OS-2022-0012-DRAFT-74699-0006
All Sections: 8.6
(b)(5)
Organization: The Heritage Foundation

Excerpt Text:
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 respected 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.

Comment Number: HHS-OS-2022-0012-DRAFT-75521-0075
All Sections: 8.4.3, 8.6, 8.5
(b)(5)
Organization: Ethics & Public Policy Center

Excerpt Text:
[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 those 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. 20-35507 (9th Cir. Jul. 22, 2021).] Apart from violating the First Amendment, such a regulation of health insurance providers to coopt 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.

Section 8.7 - Additional procedural information; burdens on recipients; additional factors; alternatives

No comments are associated with this issue