#### MEMORANDUM

To: Melanie Fontes Rainer, Director, Office for Civil Rights

**Through:** Dylan de Kervor, Senior Advisor, Office for Civil Rights

From: Vatsala Kumar, Intern, Office for Civil Rights

**Date:** August 19, 2022

Re: Florida Agency for Health Care Administration

I. Action Requested

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II. Procedural History

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### III. Background

## A. History and Other Related Actions

While this memorandum focuses on actions taken by FAHCA—revisions to Florida Administrative Code 59G-1.050, as described *infra*—some history and related actions in Florida may prove helpful in providing context.

In April 2022, the Florida Department of Health (FDOH) issued guidance stating that minors should not be provided with gender-affirming care, in opposition to an HHS fact sheet. Off. of State Surgeon Gen., Fla. Dep't of Health, <u>Treatment of Gender Dysphoria for Children and Adolescents</u> (Apr. 20, 2022); *see also* Off. of Pop. Affs., U.S. Dep't of Health & Human Servs., <u>Gender-Affirming Care and Young People</u> (Mar. 2022). The same day, the Secretary of FAHCA requested that the Florida Medicaid program conduct a complete review to

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<sup>&</sup>lt;sup>1</sup> See, e.g., Kiara Alfonseca, <u>Florida Battles Federal LGBTQ Protections</u>, ABC News (July 30, 2022); Jacob Ogles, <u>Florida Pushes Forward to Ban Gender-Affirming Care for Medicaid Users</u>, Advocate (July 12, 2022); Sarah Mueller, <u>A Hearing on Banning Florida Medicaid Payments for Gender-Affirming Care Pits Religion Against Science</u>, WFSU (July 9, 2022).

<sup>&</sup>lt;sup>2</sup> 48 Fla. Admin. Reg. 2461-62 (June 17, 2022).

<sup>&</sup>lt;sup>3</sup> A public hearing held on the proposed rule is viewable online. See <u>7/8/22 Agency for Health Care Administration</u> Hearing on General Medicaid Policy Rule, Fla. Channel (July 8, 2022).

<sup>&</sup>lt;sup>4</sup> Fla. Admin. Code R. 59G-1.050 (2022).

determine whether Florida Medicaid should provide coverage for gender-affirming care. Letter from Simone Marstiller to Tom Wallace (Apr. 20, 2022).

In June 2022, Florida Medicaid issued a report finding that gender-affirming care has not been proven to be safe or effective and is "experimental and investigational." Fla. Medicaid, Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria (2022). Since services must be "medically necessary" to be covered by Florida Medicaid, including being in line with professional medical standards and not experimental or investigational, this report opened the door for the FAHCA modifications to their Medicaid policies. Fla. Agency for Health Care Admin., *Florida Medicaid: Definitions Policy* 7 (2017).

Other agencies in Florida are also using this report as justification for limitations and prohibitions on gender-affirming care. In late July 2022, FDOH submitted a petition to the Florida Board of Medicine urging them to bar physicians from providing gender-affirming care to minors. See Florida Medical Board to Weigh Blocking Treatments for Transgender Youth, CBS Miami (Aug. 1, 2022). The petition relied on both FDOH's April 2022 guidance as well as the Florida Medicaid June report. Id. On August 5, 2022, the Florida Board of Medicine held a meeting to consider the petition. Arek Sarkissian, Florida Medical Board Moves to Block Gender Affirming Treatments for Minors, Politico (Aug. 5, 2022). The meeting included a public comment period, with testimony from physicians and community organizers. Id. The Board voted to begin the process of updating their rules during the meeting. Id. The change would create a standard of care prohibiting individuals under the age of eighteen from receiving gender-affirming surgeries and hormones; it would also mandate a consent form and waiting period for older individuals. Id.; CBS Miami, supra.

#### B. FAHCA Proposed Rule and Finalization

In June 2022, FAHCA proposed an amendment to Florida Administrative Code Rule 59G-1.050, the General Medicaid Policy. 48 Fla. Admin. Reg. 2461–62 (June 17, 2022). The amendment adds the following text:

- (7) Gender Dysphoria
- (a) Florida Medicaid does not cover the following services for the treatment of gender dysphoria:
- 1. Puberty blockers;
- 2. Hormones and hormone antagonists;
- 3. Sex reassignment surgeries; and
- 4. Any other procedures that alter primary or secondary sexual characteristics.
- (b) For the purpose of determining medical necessity, including Early and Periodic Screening, Diagnosis, and Treatment (EPSDT), the services listed in subparagraph (7)(a) do not meet the definition of medical necessity in accordance with Rule 59G-1.010, F.A.C.

Id. As rulemaking authority for promulgating this amendment, the agency cites Florida Statute § 409.919 and § 409.961. Sections 409.919 and 409.961 both include the same language surrounding agency rulemaking; both state that the agency "shall adopt any rules necessary to

comply with or administer" Medicaid "and all rules necessary to comply with federal requirements." Fla. Stat. § 409.919 (2021); Fla. Stat. § 409.961 (2021).

FAHCA held a public hearing on this proposed rule on July 8, 2022. See 7/8/22 Agency for Health Care Administration Hearing on General Medicaid Policy Rule, Fla. Channel (July 8, 2022). Fifty commenters spoke, eight of whom opposed the rule. Many supporters of the rule focused on concerns surrounding gender-affirming care for youth, despite the rule's applicability to recipients of all ages. The agency also accepted written comments, due on July 11, 2022, and reportedly received approximately 1,200 total public comments. Forrest Saunders, Agency for Health Care Administration Set to Decide on Medicaid Coverage of Gender Dysphoria Therapies, WPTV (July 11, 2022). While the majority of in-person comments supported the rule, most publicly available written comments oppose it. Among those opposing the rule are a group of professors from Yale School of Medicine, Disability Rights Florida, Endocrine Society, and the Florida Policy Institute. See Letter from Anne L. Alstott et al. to Simone Marstiller & Tom Wallace re Rule No. 59G-1.050: General Medicaid Policy (July 8, 2022); Letter from Peter P. Sleasman to Simone Marstiller re Proposed Amendments to Rule 59G-1.050; Letter from Ursula Kaiser to Agency for Health Care Administration re 59G-1.050: General Medicaid Policy (July 8, 2022); Letter from Anne Swerlick to Thomas Wallace re Proposed Rule 59G-1.050, Florida Administrative Code (July 7, 2022).

On August 11, 2022, FAHCA finalized the proposed rule. *See* Fla. Admin. Code R. 59G-1.050 (2022). The new language becomes effective on August 21, 2022. The Florida Health Justice Project and the National Health Law Program joined other organizations in issuing a statement condemning the rule. Lambda Legal, Press Release, <u>LGBTQ and Health Groups</u> <u>Denounce Florida's Adoption of Anti-Transgender Health Care Rule</u> (Aug. 11, 2022).

#### IV. Jurisdictional Information

#### A. Legal Authority

Section 1557, 42 U.S.C. § 18116, and its implementing regulation, 45 C.F.R. Part 92, prohibit discrimination on the bases of race, color, national origin, sex, age, or disability in certain health programs and activities. Section 1557 provides that, except as provided in Title I of the ACA, an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or Section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the ACA.

OCR is responsible for investigating complaints and conducting compliance reviews to determine if recipients of HHS funding operate their programs and activities in compliance with Title IX and Section 1557. HHS has the authority, where appropriate, to negotiate and secure voluntary compliance agreements.

FAHCA is a recipient of Federal financial assistance through its participation in Medicaid, Title XIX of the Social Security Act of 1965, 42 U.S.C. § 1396 et seq. FAHCA and the Florida Medicaid program are subject to Section 1557 and all related antidiscrimination laws.

# B. Legal Theory

Courts have struck down similar Medicaid exclusions in other states, holding that such exclusions constitute discrimination on the basis of sex. The district court in *Flack v. Wisconsin Department of Health Services* further noted that "any attempt . . . to contend that gender-confirming care—including surgery—is inappropriate, unsafe, and ineffective is unreasonable." *Flack v. Wis. Dep't of Health Servs.*, 395 F. Supp. 3d 1001, 1014–15, 1018 (W.D. Wis. 2019); see also Fain v. Crouch, No. 20-0740, 2022 WL 3051015 (S.D. W.Va. Aug. 2, 2022) (holding that a West Virginia Medicaid exclusion of coverage for gender-affirming surgical care is a preclusion based on gender identity, which "invidiously discriminates on the basis of sex and transgender status").

Discrimination on the basis of sex can consist of either disparate treatment or disparate impact. See U.S. Dep't of Just., Title IX Manual (2021). OCR will consider pursuing this case under a disparate treatment claim. Such a claim must include proof of discriminatory intent-proof that the decision-maker decided to treat recipients differently on the basis of sex. Id. While malicious intent is not required for a disparate treatment claim, id., there is preliminary evidence that FAHCA and other Florida officials showed animus in promulgating the Medicaid exclusion, including statements by Florida officials. For example, Florida's surgeon general Joseph Ladapo has said that gender-affirming treatments are "about injecting political ideology into the health of our children." Kiara Alfonseca, Florida to Ban Gender-Affirming Care Under Medicaid for Transgender Recipients, ABC News (Aug. 12, 2022). Florida Governor Ron DeSantis has publicly ridiculed transgender individuals, referring to them as inanimate objects and mocking the idea that transgender individuals can get pregnant. Michael Moline, DeSantis Spreads Misinformation About Transgender People in Public Appearance, Fla. Phoenix (May 18, 2022). DeSantis has also likened gender-affirming care to castration and said that doctors "need to get sued" for providing gender-affirming treatments. Alfonesca, supra. Quentin Van Meter, a physician who has participated in Florida's actions and has been cited throughout Florida's justifications, has said that gender-affirming care is an "experiment" on children and a "monumental epidemic." Sarkissian, Florida Medical Board Moves, supra; Dara Kam, A Florida Medical Board Advances a Plan That Would Ban Treatments for Transgender Youths, WUSF (Aug. 6, 2022). Dr. Van Meter is the president of a conservative advocacy group which has been categorized by the Southern Poverty Law Center as a hate group, see American College of Pediatricians, Southern Poverty L. Ctr., (last visited July 22, 2022), and has been previously disqualified as an expert in court. Stephen Caruso, A Texas Judge Ruled This Doctor Was Not an Expert. A Pennsylvania Republican Invited Him to Testify on Trans Health Care, Penn. Capital-Star (Sept. 15, 2020).

These statements, alongside the FAHCA's actions and justifications, show that the intent behind this decision was highly political and medically unfounded. The exclusion goes against public opinion and medical recommendations, as many individuals and organizations have pointed out. See, e.g., Meredithe McNamara et al., <u>A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria</u> (July 8, 2022); Sarkissian, Florida

Medical Board Moves, supra (quoting University of Florida professor and Chief of Pediatric Endocrinology Michael J. Haller who called the Florida Medical Board proposal a "political maneuver"); 7/8/22 Agency for Health Care Administration Hearing, supra (recording of July 8 hearing wherein some commenters spoke against FAHCA rule); Letter from Anne L. Alstott, supra; Letter from Peter P. Sleasman, supra; Letter from Ursula Kaiser, supra; Equality Fla., Press Release, Equality Florida Decries Proposed Rule to Eliminate Medicaid Coverage for Gender Affirming Care (June 17, 2022); Fla. Coal. for Trans Liberation, Stop Rule 59G-1.050 (2022); Letter from Anne Swerlick, supra.

If direct proof of discriminatory intent is unavailable, OCR can instead utilize the *McDonnell-Douglas* burden-shifting framework to evaluate disparate treatment. This includes showing (1) that the affected individuals are members of a protected class; (2) that the affected individuals applied and were eligible for a federally-funded health program or activity; (3) that the affected individuals were denied participation because of their sex despite their eligibility; and (4) that the covered entity allowed participation to members of another sex. U.S. Dep't of Just., *supra*.

### V. Proposed Action

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#### VI. Reasons to Take Action in this Matter

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Transgender and nonbinary individuals already face heightened barriers in accessing medical care and prohibiting coverage for gender-affirming procedures under Medicaid in Florida will significantly impact transgender Floridians who cannot afford private insurance. Medicaid recipients in Florida may not be aware of OCR and their rights, and the stigma surrounding gender-affirming care may keep individuals from filing complaints with OCR. While Florida organizations are preparing to file suit against FAHCA, see Sarkissian, Groups to Sue, supra, litigation is slow, and many Floridians will be harmed by these policies in the meantime. OCR can proactively evaluate these claims and consider whether the actions contravene federal civil rights laws, remedying the situation as necessary.

\*

From: de Kervor, Dylan (HHS/OCR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BDEC12AD0974EACABABE032F2B37C91-DEKERVOR, D>

Lorden, Susie (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group

To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=e90ef156ed05483f959d8c4039d9b906-Lorden, Sus

<susie.lorden@hhs.gov>

Subject: RE: Alabama Interrogatories

Date: 2023/04/18 09:43:00

Priority: Normal Type: Note

#### Thank you!

Dylan Nicole de Kervor, Esq., MSW (she/her)

Senior Advisor to the Director

Office for Civil Rights | U.S. Department of Health & Human Services

Phone: (202) (b)(6)

From: Lorden, Susie (HHS/OCR) <susie.lorden@hhs.gov>

Sent: Tuesday, April 18, 2023 9:43 AM

To: Mars, Chayhann (HHS/OGC) < Chayhann.Mars@hhs.gov>; de Kervor, Dylan (HHS/OCR)

<Dylan.deKervor@hhs.gov>; Richards, Jacob (OS/OGC) <Jacob.Richards@hhs.gov>

Cc: Soueid, Marie (HHS/OGC) <Marie.Soueid@hhs.gov>; Jee, Lauren (HHS/OCR)

<Lauren.Jee1@hhs.gov>; Barron, Pamela (HHS/OCR) <Pamela.Barron@hhs.gov>; Roman, David

(OS/OCR) <David.Roman@hhs.gov>
Subject: RE: Alabama Interrogatories

Good morning all,

I'm just confirming that the work I've done on Section 1557 and OCR enforcement matters related to gender affirming care has not been related to minors and I have nothing to add to the information below.

Thanks, Susie

Susie Lorden, J.D. (she/her)
Civil Rights Analyst
Policy Division | Office for Civil Rights
U.S. Department of Health and Human Services

Office: (202) (b)(6)
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Susie.Lorden@hhs.gov

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From: Mars, Chayhann (HHS/OGC) < Chayhann.Mars@hhs.gov>

Sent: Tuesday, April 18, 2023 9:17 AM

To: de Kervor, Dylan (HHS/OCR) < Dylan.deKervor@hhs.gov>; Richards, Jacob (OS/OGC)

<Jacob.Richards@hhs.gov>

Cc: Soueid, Marie (HHS/OGC) < Marie.Soueid@hhs.gov>; Jee, Lauren (HHS/OCR)

<<u>Lauren.Jee1@hhs.gov</u>>; Barron, Pamela (HHS/OCR) <<u>Pamela.Barron@hhs.gov</u>>; Lorden, Susie

(HHS/OCR) <susie.lorden@hhs.gov>; Roman, David (OS/OCR) <David.Roman@hhs.gov>

Subject: RE: Alabama Interrogatories

Thank you for this Jacob and for your additions Dylan! If anyone has anything to add over the next day, please let me know. Marie and I will be preparing the response by Thursday morning.

Chayhann Mars (she/her/hers)
Civil Rights Division
Office of the General Counsel
U.S. Department of Health &Human Services
(202) (b)(6)
Chayhann.Mars@hhs.gov

From: de Kervor, Dylan (HHS/OCR) <Dylan.deKervor@hhs.gov>

Sent: Monday, April 17, 2023 6:23 PM

To: Richards, Jacob (OS/OGC) < Jacob.Richards@hhs.gov>; Mars, Chayhann (HHS/OGC)

<Chayhann.Mars@hhs.gov>

Cc: Soueid, Marie (HHS/OGC) < Marie.Soueid@hhs.gov >; Jee, Lauren (HHS/OCR)

<Lauren.Jee1@hhs.gov>; Barron, Pamela (HHS/OCR) <Pamela.Barron@hhs.gov>; Lorden, Susie

(HHS/OCR) <susie.lorden@hhs.gov>; Roman, David (OS/OCR) <David.Roman@hhs.gov>

Subject: RE: Alabama Interrogatories

This is VERY helpful.

I have added a couple sentences regarding the March 2022 Guidance.

Dylan Nicole de Kervor, Esq., MSW (she/her)

Senior Advisor to the Director

Office for Civil Rights | U.S. Department of Health & Human Services

Phone: (202) (b)(6)

From: Richards, Jacob (OS/OGC) < Jacob.Richards@hhs.gov>

Sent: Monday, April 17, 2023 5:27 PM

To: Mars, Chayhann (HHS/OGC) < Chayhann.Mars@hhs.gov>; de Kervor, Dylan (HHS/OCR)

Hey all,	
(5)	

Jaco	ob de
	ob Richards (he/him)
	istant Regional Counsel, Region IX
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	partment of Health and Human Services
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	t: Monday, April 17, 2023 12:56 PM
	Richards, Jacob (OS/OGC) < <u>Jacob Richards@hhs.gov</u> >; de Kervor, Dylan (HHS/OCR)
	/lan.deKervor@hhs.gov>
	Soueid, Marie (HHS/OGC) < <u>Marie.Soueid@hhs.gov</u> >; Jee, Lauren (HHS/OCR) uren.Jee1@hhs.gov>; Barron, Pamela (HHS/OCR) < <u>Pamela.Barron@hhs.gov</u> >; Lorden, Susie
	IS/OCR) <susie.lorden@hhs.gov>; Roman, David (OS/OCR) <david.roman@hhs.gov></david.roman@hhs.gov></susie.lorden@hhs.gov>
	iject: RE: Alabama Interrogatories
Hi J	acob,
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Chayhann Mars (she/her/hers)	
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Office of the General Counsel	
J.S. Department of Health &Human	Services
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hayhann.Mars@hhs.gov	
rom: Richards, Jacob (OS/OGC) < Jac	cob.Richards@hhs.gov>
ent: Monday, April 17, 2023 3:06 P	
	ayhann.Mars@hhs.gov>; de Kervor, Dylan (HHS/OCR)
:Dylan.deKervor@hhs.gov>	
	e.Soueid@hhs.gov>; Jee, Lauren (HHS/OCR)
	mela (HHS/OCR) < <u>Pamela.Barron@hhs.gov</u> >; Lorden, Susie
	; Roman, David (OS/OCR) < <u>David.Roman@hhs.gov</u> >
ubject: RE: Alabama Interrogatorie	S
Ii Chayhann,	
)(5)	

Jacob Richards (he/him)

Assistant Regional Counsel, Region IX Office of the General Counsel Department of Health and Human Services 90 Seventh Street, Suite 4-500 San Francisco, CA 94103-6705 Phone: (202) (b)(6)

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From: Mars, Chayhann (HHS/OGC) < Chayhann.Mars@hhs.gov>

Sent: Monday, April 17, 2023 8:22 AM

To: de Kervor, Dylan (HHS/OCR) < Dylan.deKervor@hhs.gov>

**Cc:** Soueid, Marie (HHS/OGC) < <u>Marie.Soueid@hhs.gov</u>>; Jee, Lauren (HHS/OCR)

<<u>Lauren.Jee1@hhs.gov</u>>; Barron, Pamela (HHS/OCR) <<u>Pamela.Barron@hhs.gov</u>>; Lorden, Susie

(HHS/OCR) <<u>susie.lorden@hhs.gov</u>>; Roman, David (OS/OCR) <<u>David.Roman@hhs.gov</u>>; Richards, Jacob

(OS/OGC) < <u>Jacob.Richards@hhs.gov</u>> **Subject:** RE: Alabama Interrogatories

Thanks for your quick response, Dylan.

(b)(5)			
(b)(5)			

### Chayhann

From: de Kervor, Dylan (HHS/OCR) < Dylan.deKervor@hhs.gov>

Sent: Monday, April 17, 2023 10:33 AM

To: Mars, Chayhann (HHS/OGC) < Chayhann.Mars@hhs.gov>

Cc: Soueid, Marie (HHS/OGC) < Marie.Soueid@hhs.gov >; Jee, Lauren (HHS/OCR)

<Lauren.Jee1@hhs.gov>; Barron, Pamela (HHS/OCR) <Pamela.Barron@hhs.gov>; Lorden, Susie

(HHS/OCR) <<u>susie.lorden@hhs.gov</u>>; Roman, David (OS/OCR) <<u>David.Roman@hhs.gov</u>>; Richards, Jacob

(OS/OGC) < <u>Jacob.Richards@hhs.gov</u>> **Subject:** RE: Alabama Interrogatories

Hi Chayanne,

Sorry for the delay.

OCR technically does not work on issues related to "transitioning treatments for transgender minors." We have only addressed this issue in as much as it relates to our work addressing the provision of care in a non-discriminatory manner. This is <u>not</u> specific to minors.

Do you have an example of what might constitute a responsive document?

Individuals who have worked non-discriminatory provision of gender-affirming care:

- Dylan Nicole de Kervor, Senior Advisor Section 1557 policy and enforcement, including 2022
   NPRM and gender affirming care guidance
- • Susie Lorden, Policy Advisor Section 1557 policy and enforcement, including 2022 NPRM
- David Roman, Policy Advisor Section 1557 policy and enforcement, including 2022 NPRM
- Jacob Richards (OGC but assisting Section 1557 team) 2022 NPRM

We also have regional staff who work on enforcement. Please let me know if you would need their information as well.

Thanks, Dylan

Dylan Nicole de Kervor, Esq., MSW (she/her)

Senior Advisor to the Director

Office for Civil Rights | U.S. Department of Health & Human Services

Phone: (202) (b)(6)

From: Mars, Chayhann (HHS/OGC) < Chayhann.Mars@hhs.gov>

Sent: Monday, April 17, 2023 10:21 AM

To: de Kervor, Dylan (HHS/OCR) < <u>Dylan.deKervor@hhs.gov</u>>
Co: Soueid, Marie (HHS/OGC) < <u>Marie.Soueid@hhs.gov</u>>

Subject: Re: Alabama Interrogatories

Resending to include a subject line. Happy Monday!

From: Mars, Chayhann (HHS/OGC)

Sent: Monday, April 17, 2023 10:19:59 AM

**To:** de Kervor, Dylan (HHS/OCR) < <u>Dylan.deKervor@hhs.gov</u>> **Cc:** Soueid, Marie (HHS/OGC) < <u>Marie.Soueid@hhs.gov</u>>

Subject:

Good morning Dylan,

In addition to our previous question about documents, can you please provide a list of potential custodians (who may have their files searched for responsive documents) who work on issues that relate to transitioning treatments for transgender minors? We need their names, titles, and descriptors of how they're related to the transitioning treatment for transgender minors.

We may not end up identifying all of the names that you provide, but we would appreciate having the list in the meantime.

I know you are focus on the 1557 Rule this week, so if you would like us to coordinate with someone else at OCR on this matter, please let us know.

Kindly, Chayhann Mars (she/her/hers) Civil Rights Division Office of the General Counsel U.S. <u>Department</u> of Health &Human Services (202) (b)(6) Chayhann.Mars@hhs.gov

**Sender:** de Kervor, Dylan (HHS/OCR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BDEC12AD0974EACABABE032F2B37C91-DEKERVOR, D>

Lorden, Susie (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group

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Sent Date: 2023/04/18 09:43:47 Delivered Date: 2023/04/18 09:43:00 From: de Kervor, Dylan (HHS/OCR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BDEC12AD0974EACABABE032F2B37C91-DEKERVOR, D>

Mars, Chayhann (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group

To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=752ca150aa9949cc842f533553763eec-Mars, Chayh

<Chayhann.Mars@hhs.gov>

Soueid, Marie (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group

CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=5beffe93ff1d4e4a901b62b5d9f8a123-Soueid, Mar

<Marie.Soueid@hhs.gov>

Subject: RE: Alabama Interrogatories

Date: 2023/04/20 13:19:00

**Priority:** Normal **Type:** Note

This looks great, thank you both!

### Dylan Nicole de Kervor, Esq., MSW (she/her)

Senior Advisor to the Director Office for Civil Rights | U.S. Department of Health & Human Services

Phone: (202) (b)(6)

From: Mars, Chayhann (HHS/OGC) < Chayhann.Mars@hhs.gov>

Sent: Thursday, April 20, 2023 1:07 PM

**To:** de Kervor, Dylan (HHS/OCR) <Dylan.deKervor@hhs.gov> **Cc:** Soueid, Marie (HHS/OGC) <Marie.Soueid@hhs.gov>

Subject: RE: Alabama Interrogatories

Hi Dylan,

We've prepared the following response to the interrogatory:

(b)(5)			

This language may be narrowed further by the litigators working on the case. Please let me know if you'd like to discuss or have any concerns/feedback before we share this.

Chayhann Mars (she/her)

Attorney
Civil Rights Division
Office of the General Counsel
U.S. Department of Health & Human Services

	: de Kervor, Dylan (HHS/OCR) < <u>Dylan.deKervor@hhs.gov</u> >
	: Monday, April 17, 2023 6:23 PM
	tichards, Jacob (OS/OGC) < <u>Jacob.Richards@hhs.gov</u> >; Mars, Chayhann (HHS/OGC) yhann.Mars@hhs.gov>
	oueid, Marie (HHS/OGC) < Marie. Soueid@hhs.gov>; Jee, Lauren (HHS/OCR)
	ren.Jee1@hhs.gov>; Barron, Pamela (HHS/OCR) < Pamela.Barron@hhs.gov>; Lorden, Susie
	/OCR) <susie.lorden@hhs.gov>; Roman, David (OS/OCR) <david.roman@hhs.gov></david.roman@hhs.gov></susie.lorden@hhs.gov>
	ect: RE: Alabama Interrogatories
This	is VERY helpful.
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Dyla	n Nicole de Kervor, Esq., MSW (she/her)
Seni	or Advisor to the Director
	e for Civil <u>Rights   U.</u> S. Department of Health &Human Services ee: (202 <sup>(b)(6)</sup>
Fron	n: Richards, Jacob (OS/OGC) < Jacob.Richards@hhs.gov>
Sent	: Monday, April 17, 2023 5:27 PM
To: N	Mars, Chayhann (HHS/OGC) < Chayhann.Mars@hhs.gov>; de Kervor, Dylan (HHS/OCR)
	an.deKervor@hhs.gov>
	oueid, Marie (HHS/OGC) < Marie. Soueid@hhs.gov>; Jee, Lauren (HHS/OCR)
	ren.Jee1@hhs.gov>; Barron, Pamela (HHS/OCR) < Pamela.Barron@hhs.gov>; Lorden, Susie
	/OCR) < susie.lorden@hhs.gov >; Roman, David (OS/OCR) < David.Roman@hhs.gov >
Subj	ect: RE: Alabama Interrogatories
Hey	all,

(b)(5)	
(6)(3)	

Jacob

## Jacob Richards (he/him)

Assistant Regional Counsel, Region IX
Office of the General Counsel
Department of Health and Human Services
90 Seventh Street, Suite 4-500
San Francisco, CA 94103-6705

Phone: (202) (b)(6) Fax: (415) 437-8188 jacob.richards@hhs.gov CONFIDENTIALITY NOTICE: This e-mail and any attachments contain information from the Department of Health and Human Services and are intended solely for the use of the named recipient or recipients. This e-mail may contain privileged communications or work product. Any dissemination of this e-mail by anyone other than an intended recipient is strictly prohibited. If you believe you have received this e-mail in error, notify the sender immediately and permanently delete the e-mail, any attachments, and all copies thereof. Thank you for your prompt attention to this matter.

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From: Mars, Chayhann (HHS/OGC) < Chayhann.Mars@hhs.gov>

Sent: Monday, April 17, 2023 12:56 PM

To: Richards, Jacob (OS/OGC) < <u>Jacob.Richards@hhs.gov</u>>; de Kervor, Dylan (HHS/OCR)

<Dvlan.deKervor@hhs.gov>

Cc: Soueid, Marie (HHS/OGC) < Marie.Soueid@hhs.gov>; Jee, Lauren (HHS/OCR)

<Lauren.Jee1@hhs.gov>; Barron, Pamela (HHS/OCR) <Pamela.Barron@hhs.gov>; Lorden, Susie

(HHS/OCR) <susie.lorden@hhs.gov>; Roman, David (OS/OCR) <David.Roman@hhs.gov>

Subject: RE: Alabama Interrogatories

Hi Jacob,

(b)(5)			

Chayhann Mars (she/her/hers)
Civil Rights Division
Office of the General Counsel
U.S. Department of Health & Human Services
(202)(5)(6)

Chayhann.Mars@hhs.gov

From: Richards, Jacob (OS/OGC) < Jacob.Richards@hhs.gov>

Sent: Monday, April 17, 2023 3:06 PM

To: Mars, Chayhann (HHS/OGC) < Chayhann.Mars@hhs.gov>; de Kervor, Dylan (HHS/OCR)

<Dylan.deKervor@hhs.gov>

Cc: Soueid, Marie (HHS/OGC) < Marie.Soueid@hhs.gov >; Jee, Lauren (HHS/OCR)

<<u>Lauren.Jee1@hhs.gov</u>>; Barron, Pamela (HHS/OCR) <<u>Pamela.Barron@hhs.gov</u>>; Lorden, Susie

(HHS/OCR) <<u>susie.lorden@hhs.gov</u>>; Roman, David (OS/OCR) <<u>David.Roman@hhs.gov</u>>

Subject: RE: Alabama Interrogatories

Hi Chayhann,

b)(5)		

Jacob

Jacob Richards (he/him)

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Office of the General Counsel
Department of Health and Human Services
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San Francisco, CA 94103-6705

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From: Mars, Chayhann (HHS/OGC) < Chayhann.Mars@hhs.gov>

Sent: Monday, April 17, 2023 8:22 AM

To: de Kervor, Dylan (HHS/OCR) < Dylan.deKervor@hhs.gov>

Cc: Soueid, Marie (HHS/OGC) < Marie.Soueid@hhs.gov>; Jee, Lauren (HHS/OCR)

<<u>Lauren.Jee1@hhs.gov</u>>; Barron, Pamela (HHS/OCR) <<u>Pamela.Barron@hhs.gov</u>>; Lorden, Susie

(HHS/OCR) <<u>susie.lorden@hhs.gov</u>>; Roman, David (OS/OCR) <<u>David.Roman@hhs.gov</u>>; Richards, Jacob

(OS/OGC) < <u>Jacob.Richards@hhs.gov</u>> **Subject:** RE: Alabama Interrogatories

Thanks for your quick response, Dylan.

(b)(5)		

#### Chayhann

From: de Kervor, Dylan (HHS/OCR) < Dylan.deKervor@hhs.gov>

Sent: Monday, April 17, 2023 10:33 AM

To: Mars, Chayhann (HHS/OGC) < <a href="mailto:Chayhann.Mars@hhs.gov">Chayhann.Mars@hhs.gov</a>>

Cc: Soueid, Marie (HHS/OGC) <Marie.Soueid@hhs.gov>; Jee, Lauren (HHS/OCR)

<<u>Lauren.Jee1@hhs.gov</u>>; Barron, Pamela (HHS/OCR) <<u>Pamela.Barron@hhs.gov</u>>; Lorden, Susie

(HHS/OCR) <<u>susie.lorden@hhs.gov</u>>; Roman, David (OS/OCR) <<u>David.Roman@hhs.gov</u>>; Richards, Jacob

(OS/OGC) < <u>Jacob.Richards@hhs.gov</u>> **Subject:** RE: Alabama Interrogatories

Hi Chayanne,

Sorry for the delay.

OCR technically does not work on issues related to "transitioning treatments for transgender minors." We have only addressed this issue in as much as it relates to our work addressing the provision of care in a non-discriminatory manner. This is <u>not</u> specific to minors.

Do you have an example of what might constitute a responsive document?

Individuals who have worked non-discriminatory provision of gender-affirming care:

- Dylan Nicole de Kervor, Senior Advisor Section 1557 policy and enforcement, including 2022
   NPRM and gender affirming care guídance
- Susie Lorden, Policy Advisor Section 1557 policy and enforcement, including 2022 NPRM
- David Roman, Policy Advisor Section 1557 policy and enforcement, including 2022 NPRM
- Jacob Richards (OGC but assisting Section 1557 team) 2022 NPRM

We also have regional staff who work on enforcement. Please let me know if you would need their information as well.

Thanks, Dylan

Dylan Nicole de Kervor, Esq., MSW (she/her)
Senior Advisor to the Director
Office for Civil Rights | U.S. Department of Health &Human Services

Phone: (202) (b)(6)

From: Mars, Chayhann (HHS/OGC) < Chayhann. Mars@hhs.gov>

Sent: Monday, April 17, 2023 10:21 AM

To: de Kervor, Dylan (HHS/OCR) < Dylan.deKervor@hhs.gov> Cc: Soueid, Marie (HHS/OGC) <Marie.Soueid@hhs.gov>

Subject: Re: Alabama Interrogatories

Resending to include a subject line. Happy Monday!

From: Mars, Chayhann (HHS/OGC)

Sent: Monday, April 17, 2023 10:19:59 AM

To: de Kervor, Dylan (HHS/OCR) < Dylan.deKervor@hhs.gov> Cc: Soueid, Marie (HHS/OGC) < Marie. Soueid@hhs.gov>

Subject:

Good morning Dylan,

In addition to our previous question about documents, can you please provide a list of potential custodians (who may have their files searched for responsive documents) who work on issues that relate to transitioning treatments for transgender minors? We need their names, titles, and descriptors of how they're related to the transitioning treatment for transgender minors.

We may not end up identifying all of the names that you provide, but we would appreciate having the list in the meantime.

I know you are focus on the 1557 Rule this week, so if you would like us to coordinate with someone else at OCR on this matter, please let us know.

Kindly,

Chayhann Mars (she/her/hers)

Civil Rights Division

Office of the General Counsel

U.S. Department of Health & Human Services

(202 (b)(6)

Chayhann.Mars@hhs.gov

Sender: de Kervor, Dylan (HHS/OCR) </0=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BDEC12AD0974EACABABE032F2B37C91-DEKERVOR, D>

Mars, Chayhann (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=752ca150aa9949cc842f533553763eec-Mars, Chayh

**Recipient:** <Chayhann.Mars@hhs.gov>; Soueid, Marie (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5beffe93ff1d4e4a901b62b5d9f8a123-Soueid, Mar

Sent Date: 2023/04/20 13:19:51 Delivered Date: 2023/04/20 13:19:00 Mars, Chayhann (HHS/OGC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=752CA150AA9949CC842F533553763EEC-MARS, CHAYH

(Chayhann.Mars@hhs.gov>

de Kervor, Dylan (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91-Dekervor, D

(Dylan.deKervor@hhs.gov>

Soueid, Marie (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group

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(Marie.Soueid@hhs.gov>

Subject: RE: Alabama Interrogatories

Date: 2023/04/20 13:06:54

Priority: Normal

Type: Note

Hi Dylan,

We've prepared the following response to the interrogatory:

(b)(5)			

This language may be narrowed further by the litigators working on the case. Please let me know if you'd like to discuss or have any concerns/feedback before we share this.

#### Chayhann Mars (she/her)

Attorney
Civil Rights Division
Office of the General Counsel
U.S. Department of Health & Human Services
(202)(6)(6)
Chayhann.Mars@hhs.gov

From: de Kervor, Dylan (HHS/OCR) < Dylan.de Kervor@hhs.gov>

Sent: Monday, April 17, 2023 6:23 PM

To: Richards, Jacob (OS/OGC) < Jacob.Richards@hhs.gov>; Mars, Chayhann (HHS/OGC)

<Chayhann.Mars@hhs.gov>

Cc: Soueid, Marie (HHS/OGC) <Marie.Soueid@hhs.gov>; Jee, Lauren (HHS/OCR)

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(HHS/OCR) <susie.lorden@hhs.gov>; Roman, David (OS/OCR) <David.Roman@hhs.gov>

Subject: RE: Alabama Interrogatories

This is VERY helpful.

I have added a couple sentences regarding the March 2022 Guidance.

# Dylan Nicole de Kervor, Esq., MSW (she/her) Senior Advisor to the Director

Office for Civil Rights | U.S. Department of Health & Human Services

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Sent: Monday, April 17, 2023 5:27 PM

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Subject: RE: Alabama Interrogatories

Hey all,

(b)(5)

b)(5)		

Jacob

Jacob Richards (he/him)

Assistant Regional Counsel, Region IX
Office of the General Counsel
Department of Health and Human Services
90 Seventh Street, Suite 4-500
San Francisco. CA 94103-6705
Phone: (202)

Fax: (415) 437-8188 jacob.richards@hhs.gov

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HHS/OCR) <susie.lorden@hhs.gov>; Roman, David (OS/OCR) <david.roman@hhs.gov></david.roman@hhs.gov></susie.lorden@hhs.gov>				
Subject: RE: Alabama Interrogatories				
li Jacob,				
5)				
Shareharan Maray (aba (bara)				
Chayhann Mars (she/her/hers)				
Civil Rights Division				
Office of the General Counsel				
J.S. Department of Health &Human Services				
202 <sup>(b)(6)</sup>				
Chayhann.Mars@hhs.gov				
rom: Richards, Jacob (OS/OGC) < Jacob.Richards@hhs.gov	>			
Sent: Monday, April 17, 2023 3:06 PM				
o: Mars, Chayhann (HHS/OGC) < Chayhann. Mars@hhs.gov	>; de Kervor, Dylan (HHS/OCR)			
:Dylan.deKervor@hhs.gov>				
c: Soueid, Marie (HHS/OGC) < Marie. Soueid@hhs.gov>; Je	e, Lauren (HHS/OCR)			
:Lauren.Jee1@hhs.gov>; Barron, Pamela (HHS/OCR) < Pam				
HHS/OCR) <susie.lorden@hhs.gov>; Roman, David (OS/OC</susie.lorden@hhs.gov>				
Subject: RE: Alabama Interrogatories				
and the meaning interrogationes				
li Chayhann,				

Jacob

Jacob Richards (he/him)
Assistant Regional Counsel, Region IX
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Department of Health and Human Services
90 Seventh Street, Suite 4-500
San Francisco, CA 94103-6705
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(b)(5)			

Chayhann

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- David Roman, Policy Advisor Section 1557 policy and enforcement, including 2022 NPRM
- Jacob Richards (OGC but assisting Section 1557 team) 2022 NPRM

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Thanks, Dylan

Dylan Nicole de Kervor, Esq., MSW (she/her)

Senior Advisor to the Director

Office for Civil Rights | U.S. Department of Health & Human Services

Phone: (202) (b)(6)

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Kindly, Chayhann Mars (she/her/hers) Civil Rights Division Office of the General Counsel U.S. Department of Health & Human Services (202) (b)(6) Chayhann.wars@hhs.gov

> Mars, Chayhann (HHS/OGC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP Sender: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=752CA150AA9949CC842F533553763EEC-MARS, CHAYH

<Chayhann.Mars@hhs.gov>

de Kervor, Dylan (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91-Dekervor, D

(FYDIBOHF23SPDLT)/cri=Recipients/cn=5beffe93ff1d4e4a901b62b5d9f8a123-Soueid, Mar

<Marie.Soueid@hhs.gov>

Sent Date: 2023/04/20 13:06:53 Delivered Date: 2023/04/20 13:06:54 October 3, 2022

Secretary Xavier Becerra
U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW Washington, DC 20201

Re: 1557 NPRM—Docket ID HHS-OS-2022-0012; RIN 0945-AA17

Dear Secretary Becerra:

First Liberty Institute ("First Liberty") submits this comment responding to the Department of Health and Human Services' ("The Department's") Office for Civil Rights ("OCR") proposed rule, "Nondiscrimination in Health Programs and Activities" in Section 1557 of the Patient Protection and Affordable Care Act.

First Liberty is the largest legal organization in the nation dedicated exclusively to defending religious liberty for all Americans by pro bono legal representation of individuals and institutions of diverse faiths—Catholic, Protestant, Islamic, Jewish, Buddhist, Falun Gong, Native American religious practitioners, and others. For over thirty years, First Liberty attorneys have worked to defend religious freedom in the courts, including the U.S. Supreme Court, as well as testifying before Congress, and advising federal, state, and local officials about constitutional and statutory protections for religious liberty.

First Liberty opposes the Department's proposed revisions to its Section 1557 regulations because the revisions violate the Religious Freedom Restoration Act ("RFRA"), as multiple federal courts have already found. [Footnote 1: 42 U.S.C. § 2000bb, et seq.; see Franciscan All. v. Becerra, No. 21-1174, 2022 WL 3700044 (5th Cir. Aug. 26, 2022), Christian Employers All. v. EEOC, 2022 WL 1573689, at \*1 (D.N.D. May 16, 2022); Religious Sisters of Mercy v. Azar, 513 F. Supp. 3d 1113, 1147–49 (D.N.D. 2021).] Millions of Americans hold sincere religious beliefs about gender, sex, human life, and the body, and First Liberty represents clients from a wide variety of faith backgrounds whose religious exercise would be substantially burdened by the proposed Rule.

First Liberty represents multiple religious healthcare providers and entities, including Nurse Practitioners with religious objections to prescribing abortifacient and sterilizing medications, and a Physician's Assistant whose religious beliefs prevent her from prescribing gender-transition hormones or referring patients for gender-transition surgery.

Religious healthcare providers and institutions will continue to be targeted, sued, and eventually forced out of the healthcare field if Federal regulations do not permit them to follow their consciences. If enacted, the proposed Rule would also violate the Free Exercise Clause of the First Amendment because it is not neutral or generally applicable, and its mechanism for granting exemptions treats religious objections less favorably than secular objections. The Supreme Court's decision in Bostock v. Clayton County does not apply to Section 1557 or require the reinterpretation of "sex discrimination" to include sexual orientation and gender identity. On the contrary, Bostock recognizes robust protections for religious Americans, including the First Amendment and RFRA. Furthermore, the proposed Rule fails to respect existing state laws that protect religious liberty for healthcare providers. Every state has some form of religious freedom or conscience law in place. [Footnote 2: New Hampshire and Vermont do not have specific statutes protecting medical rights of conscience, but they have constitutional provisions and nondiscrimination laws that apply. Sarah M. Estelle, Religious Liberty in the States 2022, CENTER FOR RELIGION, CULTURE, AND

DEMOCRACY, https://religiouslibertyinthestates.s3.us-east-

2.amazonaws.com/Religious\_Liberty\_in\_the\_States\_Report-2022.pdf.] Indeed, 23 states have enacted versions of the Religious Freedom Restoration Act, which apply the strict scrutiny test to government attempts to regulate conscience.[Footnote 3: Id., State Religious Freedom Restoration Acts, NATIONAL CONFERENCE OF STATE LEGISLATURES (May 4, 2017), https://www.ncsl.org/research/civil-and-criminal-justice/state-rfra-statutes.aspx.] The Department must clarify that it will not preempt these laws through its proposed Rule.

<19 8.1 8.4.3 I. The Department Must Revise the Rule to Comply with Federal Laws Including the Religious Freedom Restoration Act.

The federal government must comply with RFRA.[Footnote 4: 42 U.S.C. § 2000bb.] If finalized, the proposed Rule would substantially burden the free exercise of religion, triggering strict scrutiny. The Department will fail this test because it has not shown that its stringent approach satisfies a compelling interest, nor has it drafted the Rule in the least restrictive manner.

A. The proposed Rule would harm millions of Americans from a myriad of faith backgrounds who hold sincere religious beliefs about gender, marriage, and family life.

A bipartisan Congress enacted RFRA to "provide very broad protection for religious liberty" for all Americans living according to their sincerely held religious beliefs, including protection from government penalties or punishment.[Footnote 5: Holt v. Hobbs, 574 U.S. 352, 356 (2015).] Here, the proposed Rule infringes on sincerely held beliefs relating to sexual orientation, gender identity, marital and parental status, and termination of pregnancy. Religious beliefs about these sensitive areas of life, family, and conscience motivate persons of faith who interact with health programs and activities in healthcare (as patients, providers, health educators, and students), and in health insurance (the insured, insurers, brokers, benefits entities).

The proposed Rule fails to assess its negative impact on the religious liberty of people of faith. The Rule constrains religious believers in a wide breadth of roles, including individual healthcare providers in a variety of fields, such as obstetrics/gynecology, pharmacy, psychiatry, psychology/counseling, endocrinology, and surgery. Many institutions also operate according to sincerely held religious beliefs, such as employers, houses of worship, closely held corporations, religious hospitals, and health education institutions, and this Rule infringes on their religious exercise as well.[Footnote 6: Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 706-08 (2014).]

The Department has requested comment on the potential impact of its policy causing "providers with religious and conscience objections leaving the profession, or covered entities existing the market." [Footnote 7: 87 Fed. Reg. 47905.] Looking at hospitals alone, 18.5% of hospitals are religiously affiliated as of 2016; 14.5% of these are Catholic-owned or Catholic-affiliated, and 4.0% are affiliated with other faiths or denominations. [Footnote 8: Maryam Guiahi, Patricia E. Helbin, & Stephanie B. Teal, Patient Views on Religious Institutional Health Care, Public Health, JAMA Netw. Open (2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2757998.] Even if merely a subset of these hospitals were forced to close or reduce their services, that would have a significant impact on patient access to healthcare at a time when the healthcare system is already facing severe shortages. Turning to individual providers, 51.2% of surveyed physicians reported themselves as religious, and 20.7% reported praying with patients. [Footnote 9: Kristin A. Robinson, Meng-Ru Cheng, Patrick D. Hansen, Jicard J. Gray, Religious and Spiritual Beliefs of Physicians, J. Relig. Health (2017),

https://pubmed.ncbi.nlm.nih.gov/27071796/#:~:text=Primary%20care%20physicians%20or%20medical,agnostic%2 C%20and%2011.6%20%25%20atheist.] Again, even if only a portion of these physicians have conscientious objections to participating in gender-transition treatment as the

proposed Rule requires, the proposed Rule will have a significantly detrimental impact on the overall healthcare system as many are forced to withdraw from caring from the patients they seek to serve. According to a 2009 survey of religious medical professionals, 95% agreed with the statement, "I would rather stop practicing medicine altogether than be forced to violate my conscience." [Footnote 10: Van Mol, Andre, Health-Care Reform's Great Expectations and Physician Reality, ANN PHARMACOTHER (2010); 44:1492-5.]

Even if the proposed Rule would violate the consciences of [Italics: only] Christian medical professionals, which is not the case as the next section shows, the Christian Medical & Dental Associations have more than 19,000 members. Most of these members share the organization's position, which affirms "the biblical understanding of humankind as having been created male and female," and that "healthcare professionals should not be forced to violate their conscientious commitment to their patients' health and welfare by being required to accept and participate in harmful gender-transition interventions, especially on the young and vulnerable."[Footnote 11: CMDA Ethics Statement: Transgender Identification, CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS (2021),

file:///Users/kaylatoney/Downloads/Transgender%20Identification%202021%20-%20October%20(1).pdf.] 8.1 8.4.3 19>

<20 8.1 Research on religious beliefs shows that religions from diverse cultures and geographic regions assert—and have asserted for millennia—that sex is an objective, binary category that cannot be changed by self-perception or medical intervention.[Footnote 12: See, e.g., Christopher Yuan, Gender Identity and Sexual Orientation, THE GOSPEL COALITION, https://www.thegospelcoalition.org/essay/gender-identity-and-sexual-orientation/.] If the proposed regulations discussed above are implemented, the Department will be inviting recipients to attack the faith of individuals from numerous religions, including:</p>

- Amish Communities: "In the Bible, marriage is a divinely ordered institution designed to form a permanent union between one man and one woman for one purpose (among others) of procreating or propagating the human race. That was God's order in the first of such unions (Genesis 1:27–28; 2:24; Matthew 19:5). If, in His original creation of humans, God had created two persons of the same sex, there would not be a human race in existence today. The Christian point of view is based solely upon the Bible, the divinely inspired Word of God. A truly Christian standard of ethics is the conduct of divine revelation, not of statistical research nor of public opinion. Homosexuality is an illicit lust forbidden by God. . . In these passages, homosexuality is condemned as a prime example of sin—a sexual perversion. The Christian can neither alter God's viewpoint nor depart from it."[Footnote 13: Lehman Strauss, Homosexuality: The Christian Perspective, MISSION TO AMISH PEOPLE (Nov. 1, 2019), https://www.mapministry.org/articles/2019/11/01/homosexuality-the-christian-perspective.]
- Anglican Church in North America: "Our foundation is the Scriptural truth that God made us male and female in His image—a profound unity with distinction (Genesis 1:27). God established marriage between male and female to fill the earth through procreation (Genesis 1:28)."[Footnote 14: Anglican Church in North America, Sexuality and Identity: A Pastoral Statement from the College of Bishops, Jan. 2021, https://anglicanchurch.net/sexuality-and-identity-a-pastoral-statement-from-the-collegeof-bishops/.]
- Assemblies of God: "Genesis 1:26–31 is the record of God creating, blessing, and commanding humanity as male and female. Humans are created in the 'image of God' as male and female. . . . The biblical recognition of two distinct human sexes, female and male, from the creation of humanity as male and female in Genesis 1:26–27, is affirmed by Jesus in Matthew 19:4 and Mark 10:6. True human identity is what is being realized in relationship with Christ, body and an immaterial nature, which will culminate in the Resurrection.

No account of humanity that asserts the interior life as the true self over against the body is a biblical understanding of humanity." [Footnote 15: Assemblies of God, Transgenderism, Transsexuality, and Gender Identity (Adopted by the General Presbytery in Session August 5-7, 2017), https://ag.org/Beliefs/Position-Papers/Transgenderism-Transsexuality-and-Gender- Identity.] "It should be noted at the outset that there is absolutely no affirmation of changes in sexual identity found anywhere in Scripture. Male and female genders are carefully defined and unconfused. The consistent ideal for sexual experience in the Bible is chastity for those outside a monogamous heterosexual marriage and fidelity for those inside such a marriage." [Footnote 16: Assemblies of God, Homosexuality, Marriage, and Sexual Identity (Aug. 4-5, 2014), https://ag.org/Beliefs/Position-Papers/Homosexuality-Marriage-and-Sexual-Identity.]

- Baha'i: "Baha'u'llah teaches that the soul has no gender, race, or other physically ascribed identities. It is a spiritual reality that transcends all such distinctions. From this vantage point, Baha'is understand that the autonomy and welfare of human beings are not only determined by the laws and constraints of the natural world, but also by an objective spiritual existence that is integrally related to it."[Footnote 17: Baha'is of the United States, What is the Baha'i View Pertaining to Identity? https://www.bahai.us/bahai-teachings- homosexuality/.]
- Buddhism: "Clinging to gender identity and letting conventional ideas about gender dictate one's life thus contradicts all central Buddhist teachings. One would then also have to contend that egolessness is gendered, which would be a self-contradictory, illogical proposition." [Footnote 18: Rita M. Gross, Why Go Beyond Gender?, SHAMBHALIA PUBLICATIONS (March 27, 2018), https://www.shambhala.com/go-beyond-gender-excerpt-buddhism-beyond-gender/.] "Pandaka refers to male tranvestites and [effeminate] homosexuals... The scriptures describe the Buddha as expressing a compassionate attitude towards people who began to show cross-gender characteristics after ordination and to those who, while attracted to members of the same sex, were regarded as being physiologically and behaviourally true to the then prevailing cultural notions of masculinity. However, the Buddha opposed accepting into the sangha those who openly expressed cross-gender features at the time they presented for ordination. Volume Four of the Vinaya recounts a story of a pandaka who violated the clerical vow of celibacy and whose bad example led to a comprehensive ban on the ordination of pandaka." [Footnote 19: Peter A. Jackson, Male Homosexuality and Transgenderism in the Thai Buddhist Tradition, (1993) http://buddhism.lib.ntu.edu.tw/museum/TAIWAN/md/md08-52.htm.]
- Church of God in Christ: "The opening book of the Bible tells us: 'A man will leave his father and his mother and he must cleave to his wife and they must become one flesh' (Genesis 2:24). The Hebrew word 'wife' connotes one who is a female human being. Jesus confirmed that those yoked together in marriage should be 'male and female' (Mafthew 19:4). Therefore, God intended marriage to be a permanent and an intimate bond between a man and a woman. Men and women are designed to complement each other so they may be capable of satisfying each other's emotional, spiritual, and sexual needs and desires."[Footnote 20: General Assembly of the Church of God in Christ, Inc., Marriage: A Proclamation to COGIC Worldwide, https://www.cogic.org/generalassembly/proclamation-on-marriage]
- Church of Jesus Christ of Lafter-day Saints: "Church leaders counsel against elective medical or surgical intervention for the purpose of attempting to transition to the opposite gender of a person's birth sex ('sex reassignment'). Leaders advise that taking these actions will be cause for Church membership restrictions. Leaders also counsel against social transitioning. ... Transgender individuals who do not pursue medical, surgical, or social transition to the opposite gender and are worthy may receive Church callings, temple recommends, and temple ordinances."[Footnote 21: The Church of Jesus Christ of Lafter-Day Saints, What is the Church's Position on Transitioning? https://www.churchofjesuschrist.org/topics/transgender/understanding?lang=eng.]

Confucianism: "Traditional Confucian culture, the common base of social culture in the mainland
of China, Taiwan and Vietnam, is a complex system of moral, social, political, and religious thought
with regard to individual's relationships with others and appropriate conduct. Its core concepts
advocate filial devotion to family and priority of collective interests, self-cultivation of virtue and
[Italics: unequal gender roles.]"[Footnote 22: Ersheng Gao. How does Traditional Confucian Culture
Influence Adolescence in Three Asian Cities?, NATIONAL

18, 2014),

LIBRARY OF MEDICINE (Nov.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4235616/#:~:text=Confucianism%20sees%20sexualit y%20as%20ta boo,of%20marriage%20is%20not%20condoned.] "[T]he biological processes associated with female reproduction are ranked on a hierarchical scale reflecting women's social position that conforms with Confucian gender hierarchies and social mores."[Footnote 23: Megan Pellouchoud, Women's Biological Threat to Confucian Social Order: An Examination of Gender Constructs through an Analysis of Pre-Modern Chinese Literature, OREGON UNDERGROUND RESEARCH JOURNAL (2018),

https://scholarsbank.uoregon.edu/xmlui/bitstream/handle/1794/23514/OURJ\_spring\_2018\_MPellouc houd.pdf?seque nce=1&isAllowed=y.]

- Daoism: "Daoist philosophy... advocated for gender equality. This idea was reinforced in the symbolism of yin-yang by illustrating the complementary, dualistic, interdependent, and equal natures of the male (yang) female (yin) elements. One would not exist without the other and both have been equally important in creating and sustaining life. If one of the components were missing, reality would not be complete." [Footnote 24: Dessie Miller, Celebrating the Feminine: Daoist Connections to Contemporary Feminism in China, Master's Projects and Capstones, University of San Francisco (2017), at 3, https://repository.usfca.edu/cgi/viewcontent.cgi?article=1607&context=capstone#:~:text=Daoism%20 emphasizes% 20gender%20equality%20by,be%20understood%20without%20the%20other.]
- Falun Gong: "With regards to sexual ethics, Falun Gong holds traditional views similar to the
  teachings of Buddhism or Christianity. In short, Falun Gong aims at taking attachments and desires
  lightly, including sexual desire, and stipulates that sexual relations should only occur in the context of
  monogamous, heterosexual marriage." [Footnote 25: Falun Dafa InfoCenter, "Intolerant"?,
  https://faluninfo.net/misconceptions-intolerant/.]
- Jehovah's Witnesses: "Are sexual practices and gender really a matter of personal choice? What does God's Word have to say on these issues? ... According to the Bible book of Genesis, God himself created the differences between males and females." [Footnote 26: Watch Tower Bible And Tract Society of Pennsylvania, The Bible's Viewpoint: Alternative Life-Styles—Does God Approve? (2022), https://wol.jw.org/en/wol/d/r1/lp-e/102003726.]
- Lutheran Church: "[T]ransgenderism cannot be reconciled with Luther's explanation of the first
  article of the Creed. When Lutherans confess that God has made us and all creatures, that he's
  made our bodies and souls, and that it is our duty to thank and praise him for this, we are not merely
  confessing God as our creator. We're also confessing him as our Lord, the one who is both
  responsible for making the universe and who has divine ownership over every atom of his creation,
  including our flesh."[Footnote 27: The Council on Biblical Manhood and Womanhood, A Lutheran
  View of Transgenderism (Nov. 21, 2021), https://cbmw.org/2021/11/21/a-lutheran-view-oftransgenderism/.]
- Orthodox Church of America: "The Bible says 'Male and female He Created them' (Gen. 1:27).
   Our sexuality began with our creation. Since the Fall, however, we have become confused about what it means to be male and female. On one level there are clear biological differences such as reproductive organs, hormones, etc. On the level of social interaction, though, there is a variety of

ways of distinguishing males from females, men from women, and vice versa."[Footnote 28: Orthodox Church of America, "In the Beginning..." Healing our Misconceptions, https://www.oca.org/the- hub/two-become-one/session-2-in-the-beginning-.-.-healing-our-misconceptions.]

- Orthodox Judaism: "Orthodox Judaism generally does not accept that a person can change gender/sex. However, for purposes of public order and propriety, Orthodox rabbis will sometimes accommodate trans people's gender expressions in limited ways."[Footnote 29: Aaron H. Devor, Transgender People and Jewish Law, DE GRUYTER (2016), https://www.degruyter.com/document/doi/10.1515/9783110434392-022/pdf.] "Male homosexual intercourse is forbidden by the Torah for both Jews[Footnote 30: Leviticus 18:22; Leviticus 20:13.] and Gentiles."[Footnote 31: Chaim Rapoport, Judaism and Homosexuality: An Alternate Rabbinic View, 13 Hakirah, the Flatbush Journal of Jewish Law and Thought 29, 30 (citing Sanhedrin 58a (expounding on Genesis 2:24) and Maimonides, Mishneh Torah, Hilkhot Melakhim 9:5), https://hakirah.org/Vol13Rapoport.pdf.] "It is noteworthy, in this context, that whilst the exact meanings of many Biblical commandments have been subject to dispute in the Mishnaic and Talmudic period, there has been absolute unanimity throughout the entire rabbinic tradition as to the unequivocal meaning of the Biblical injunction regarding male homosexual intercourse."[Footnote 32: ld. at 30.] "[W]e have to strive to 'maintain sexual purity' on a universal level and it is 'our obligation... to incorporate the Holiness Code into our everyday civic and communal life." [Footnote 33: Id. at 32.1
- Presbyterian Church in America: "Statement 2: Image of God. We affirm that God created human beings in his image as male and female (Gen. 1:26-27). Likewise, we recognize the goodness of the human body (Gen. 1:31; John 1:14) and the call to glorify God with our bodies (1 Cor. 6:12-20). As a God of order and design, God opposes the confusion of man as woman and woman as man (1 Cor. 11:14-15). While situations involving such confusion can be heartbreaking and complex, men and women should be helped to live in accordance with their biological sex." [Footnote 34: Forty-Seventh General Assembly of the Presbyterian Church in America Ad Interim Committee on Human Sexuality (May 2020), https://pcaga.org/wp-content/uploads/2020/05/AIC-Report-to-48th-GA-5-28-20.pdf.]
- Roman Catholicism: According to Catechism of the Catholic Church, Sexual Identity (No. 2333), "Everyone, man and woman, should acknowledge and accept his sexual identity. Physical, moral, and spiritual difference and complementarity are oriented toward the goods of marriage and the flourishing of family life. The harmony of the couple and of society depends in part on the way in which the complementarity, needs, and mutual support between the sexes are lived out."[Footnote 35: U.S Counsel of Catholic Bishops, Gender Theory/Gender Ideology—Select Teaching Resources (Aug. 7, 2019), https://www.usccb.org/resources/Gender-Ideology-Select-Teaching-Resources\_0.pdf.] "Sexuality, by means of which man and woman give themselves to one another through the acts which are proper and exclusive to spouses, is not something simply biological, but concerns the innermost being of the human person as such."[Footnote 36: Catholic Catechism, No. 2361, https://www.usccb.org/sites/default/files/flipbooks/catechism/569/#zoom=z.]
- Seventh-day Adventist Church: "[T]he desire to change or live as a person of another gender
  may result in biblically inappropriate lifestyle choices. Gender dysphoria may, for instance, result in
  cross-dressing, sex reassignment surgery, and the desire to have a marital relationship with a
  person of the same biological sex. On the other hand, transgender people may suffer silently, living
  a celibate life or being married to a spouse of the opposite sex."[Footnote 37: Seventh-day Adventist
  Church, Statement on Transgenderism, https://www.adventist.org/official- statements/statement-ontransgenderism/.]

- Shi'ah and Sunni Muslims: "Prophet Mohammad (pbuh) has stated that: 'men and women are twin halves of each other' (Bukhari). This narration also brings home the fact that men and women are created from a single source. Furthermore, by using the analogy of twin half, the Prophet (pbuh) has underlined the reciprocal and interdependent nature of men and women's relationships."[Footnote 38: Marriage in Islam, Why Islam? Facts about Islam, https://www.whyislam.org/social-issues/marriage-in-islam/.] "There are fatwas from different Islamic countries which give rulings regarding sex change surgery or gender reconstruction surgery with regard to both the khunsa and the mukhannath (the transsexual). These fatwas generally agree that gender reconstruction surgery for the khunsa is permissible in Islam but prohibited in the case of the mukhannath."[Footnote 39: Ani Amelia Zainuddin, et al, The Islamic Perspectives of Gender-Related Issues in the Management of Patients with Disorders of Sex Development, NATIONAL LIBRARY OF MEDICINE (April 21, 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5272885/.]
- Sikhism: "Although it is true that the 'idea of gender' has changed wildly throughout different times and different cultures, we don't see any specific examples of that type of deconstruction within the span of Sikh history. In fact, as mentioned earlier via the Manji- Pir system and Singh-Kaur, the solidification and acknowledgement of male and female genders is socially built into Sikh institutions. Norms of masculinity and femininity have indeed evolved, but [Italics: this does not mean that such norms did not exist] in fact, traditional Sikh canon conveys the exact opposite."[Footnote 40: Jung Nihang, The Manipulation of Gurbani and the Sikh Gurus for Gender Politics, May 13, 2021, https://jodhsingh.medium.com/the-manipulation-of-gurbani-and-the-sikh-gurus-for-gender-politics-77225b1c9cb7.]
- Southern Baptists: "Man is the special creation of God, made in His own image. He created them male and female as the crowning work of His creation. The gift of gender is thus part of the goodness of God's creation." [Footnote 41: Baptist Faith & Message 2000, https://bfm.sbc.net/bfm2000/#xviii.] "God's design was the creation of two distinct and complementary sexes, male and female (Genesis 1:27; Matthew 19:4; Mark 10:6) which designate the fundamental distinction that God has embedded in the very biology of the human race [G]ender identity is determined by biological sex and not by one's self-perception—a perception which is offen influenced by fallen human nature in ways contrary to God's design (Ephesians 4:17–18). . . . [W]e extend love and compassion to those whose sexual self-understanding is shaped by a distressing conflict between their biological sex and their gender identity [W]e regard our transgender neighbors as image-bearers of Almighty God and therefore condemn acts of abuse or bullying committed against them . . . [W]e oppose efforts to alter one's bodily identity (e.g., cross-sex hormone therapy, gender reassignment surgery) to refashion it to conform with one's perceived gender identity. "[Footnote 42: Southern Baptist Convention, On Transgender Identity, June 1, 2014, https://www.sbc.net/resource-library/resolutions/on-transgender-identity/.] 8.1 20>
- <21 8.1 8.4.3 RFRA and the First Amendment provide robust protection for religious believers who adhere to these faiths and for individuals who do not participate in a specific religious tradition but who hold deep, sincere beliefs about the body, sexuality, marriage, gender, and human life.[Footnote 43: Thomas v. Review Bd. of Ind. Emp't Sec. Div., 450 U.S. 707, 714 (1981).] Even if an individual is not a member of one of these religious groups, religious liberty protections still apply as long as the belief is sincerely held.[Footnote 44: Holt v. Hobbs, 574 U.S. 352, 362 (2015) (finding that even if religious claimant's belief were "idiosyncratic," the "guarantee of the Free Exercise Clause is 'not limited to beliefs which are shared by all of the members of a religious sect.'") (quoting Thomas, 450 U.S. at 714).] The Department would violate both the Free Exercise and Establishment Clauses if they decided that a sincerely held religious objection from an individual of faith is not "legitimate" merely because he or she does not belong to one of the faith traditions listed above. Conscience rights also belong to those who do not identify with a particular religion at all. According to philosopher Edward Tingley, "conscience rights protect those who object to the norm of what even a majority thinks is right," and [t]he claim of wrong needs only to be serious and defensible. In our</p>

context, because moral complicity is prosecutable, physicians and pharmacists have the right to decline participation in or referral for procedures and therapies violating their ethical or religious convictions."[Footnote 45: Van Mol, Andre, Health-Care Reform's Great Expectations and Physician Reality, ANN PHARMACOTHER (2010); 44:1492-5.]

Various religious texts define marriage between a man and woman as a sacred institution. Sacred texts that define beliefs on marriage, sexuality, chastity, and sex as binary (male and female) include the Qu'ran, [Footnote 46: Marriage in Islam, Why Islam? Facts About Islam (March 5, 2015), https://www.whyislam.org/social-issues/marriage-in-islam/; Women are the Twin Halves of Men, Observer News Service, (March 9, 2017), https://kashmirobserver.net/2017/03/09/women-are-the-twin-halves-of-men/.] Ahadith, [Footnote 47: Dr. Sikiru Gbena Eniola, An Islamic Perspective of Sex and Sexuality: A Lesson for Contemporary Muslims, 12 IOSR JOURNAL OF HUMANITIES AND SOCIAL SCIENCE 2 (May-Jun. 2013), at 20-28, https://www.iosrjournals.org/iosr-jhss/papers/Vol12-issue2/C01222028.pdf] Catholic Catechism, [Footnote 48: Catholic Catechism, No. 2361, https://www.usccb.org/sites/default/files/flipbooks/catechism/569/#zoom=z.] the Torah, [Footnote 49: Issues in Jewish Ethics: Homosexuality, JEWISH VIRTUAL LIBRARY, https://www.jewishvirtuallibrary.org/homosexuality-in-judaism.] the Bible, and the Book of Mormon. [Footnote 50: The Church of Jesus Christ of Latter-Day Saints, Chastity, Chaste, https://www.churchofjesuschrist.org/study/scriptures/tg/chastity?lang=eng]

Many religious traditions include beliefs related to bodily integrity and sanctification, and these beliefs have a practical, positive impact on patients' health. "Considerable research suggests that greater general religiousness (e.g., religious affiliation, rates of church attendance, self-rated importance of religion) is tied to lower levels of health compromising behavior and greater endorsement of health protective attitudes and behaviors in the general population." [Footnote 51: Annette Mahoney, Robert A. Carles, Kenneth I. Pargament, Amy Wachholtz, Laura Edwards Leeper, Mary Kaplar & Robin Frutchey, The Sanctification of the Body and Behavioral Health Patterns of College Students, The International Journal for the Psychology of Religion, Vol. 15 No. 3 (2005).] Individuals' religious beliefs make a difference in their health-related choices, too. For example, college students who "viewed their bodies as being a manifestation of God (e.g., My body is a temple of God) and as characterized by sacred qualities (e.g., holy, blessed[,] sacred)" exhibited "greater health protective behaviors, high levels of exercise, greater subjective satisfaction of one's body, less unhealthy eating practices, more disapproval of alcohol consumption and illicit drug use, and less alcohol consumption." [Footnote 52: Id. at 3.]

Many faith traditions hold sincere religious beliefs about sex-segregated facilities for healthcare. For example, research has shown that there is a need for religious cultural competency to understand Muslims' beliefs about sexuality, marriage, and modesty. Because of their religious beliefs, Muslim patients are often deeply uncomfortable interacting with opposite-sex providers in eye contact and physical contact, undergoing physical exams and intimate surgical procedures (such as intrapartum and postpartum care), receiving counseling about sexual health and infertility, and using facilities (such as bathrooms and shared overnight facilities).[Footnote 53: Shahawy S, Deshpande NA, Nour NM, Cross-Cultural Obstetric and Gynecologic Care of Muslim Patients, OBSTET GYNECOL (Nov. 2015); 126(5):969-973; see also ATTUM B, HAFIZ S, MALIK A, SHAMOON Z, CULTURAL COMPETENCE IN THE CARE OF MUSLIM PATIENTS AND THEIR FAMILIES (2022).] 8.1 8.4.3 21>

<2 8.4.2 8.4.3 B. Every court to consider the merits of this Rule's predecessor has found that it violates RFRA.

When the Obama Administration first promulgated its 2016 Rule, which redefined sex discrimination to include gender identity and termination of pregnancy, legal challenges abounded. These lawsuits, brought by concerned religious organizations and individuals, coalesced into three major cases. In all three, multiple courts have repeatedly held that 2016 Rule violated RFRA. By seeking to resurrect the stringent restrictions on medical professionals in its new NPRM, the Department is once again violating RFRA and will face legal consequences for its actions.

In Franciscan Alliance v. Becerra, the Fifth Circuit and Northern District of Texas held multiple times that the 2016 Rule violated RFRA. [Footnote 54; Franciscan All. v. Becerra, 47 F.4th 368 (5th Cir. Aug. 26, 2022).] The Christian Medical and Dental Associations, with over 19,000 healthcare professionals as members, along with two religious hospitals, Franciscan Alliance and Specialty Physicians of Illinois, claimed that the Rule violated RFRA by forcing religious medical providers to perform abortions and gender-reassignment surgeries that violate their sincerely held religious beliefs. The district court agreed, finding the RFRA violation so severe that it merited a permanent injunction, prohibiting the Department from ever enforcing Section 1557 against Franciscan Alliance or the other plaintiffs "in a manner that would require [it] to perform or insure gender-reassignment surgeries or abortions." [Footnote 55: Franciscan All. v. Becerra, 47 F.4th 368, 373 (5th Cir. Aug. 26, 2022).] The Fifth Circuit affirmed and held that Franciscan Alliance's RFRA claim was not moot. Indeed, the court cited the Department's March 2022 Guidance as clear evidence of a credible threat of enforcement against these religious plaintiffs, noting that "HHS has also repeatedly refused to disavow enforcement against Franciscan Alliance" and other religious plaintiffs.[Footnote 56: Id. at 376 (citing HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Mar. 2, 2022), https://perma.cc/LX26-59QR).] This should send a clear signal to the Department that its 2022 NPRM will continue to face judicial sanctions for violating RFRA, because the 2022 NPRM, "if adopted, would reinstate much the same approach as the 2016 Rule." [Footnote 57: Id. at 373.]

This recent holding is consistent with previous opinions in Franciscan Alliance; the Rule violates RFRA. In December 2016, the district court held that the Rule "places substantial pressure on Plaintiffs to perform and cover transitions and abortion procedures," that the government failed to prove its rule advances a compelling interest, and that it failed to consider the "numerous less restrictive means available to provide access and coverage for transition and abortion procedures." [Footnote 58: Franciscan All. v. Burwell, 227 F. Supp. 3d 660, 693 (N.D. Tex. 2016).] In October 2019, the court found once again that "the Rule substantially burdens Private Plaintiffs' religious exercise by making the practice of religion more expensive in the business context," and that it violated RFRA "by expressly prohibiting religious exemptions." [Footnote 59: Franciscan All. v. Azar, 414 F. Supp. 3d 928, 942-44 (N.D. Tex. 2019).] The court made clear that "Defendants have twice failed to demonstrate that applying the Rule to Private Plaintiffs . . . would achieve a compelling governmental interest through the least restrictive means." [Footnote 60: Id.] The Fifth Circuit affirmed and ruled that the district court should consider providing permanent protection, [Footnote 61: Franciscan All. v. Becerra, 843 Fed. App'x 662 (5th Cir. 2021).] and in August 2021, the district court granted that permanent injunction, finding that the Biden Administration's interpretation of Section 1557 is "materially indistinguishable from the 2016 Rule."[Footnote 62: Franciscan All. v. Becerra, 553 F. Supp. 3d 361 (N.D. Tex. 2021).] Thus, ever since they first examined the 2016 Rule, these courts have consistently found that it violates RFRA by imposing a substantial burden on religious healthcare providers and failing to pass strict scrutiny. The 2022 Rule, if enacted, will fare no differently in court.

Indeed, courts are already finding that the Biden Administration's interpretation of Section 1557 likely violates RFRA and the Free Exercise Clause. In late 2021, the Christian Employers Alliance challenged the Biden Administration's new HHS Guidance on Section 1557, alleging that it violates RFRA, the Free Exercise Clause and the Free Speech Clause by compelling them to provide health insurance coverage for gender transition service against their religious beliefs, to affirm gender

transitions, and to forgo maintaining facilities in accordance with their beliefs, [Footnote 63: Christian Employers All. v. EEOC, No. 1:21-cv-195, 2022 WL 1573689, at \*1 (D.N.D. May 16, 2022).] The court found that the plaintiffs, employers who run their businesses and organizations according to their religious beliefs, had standing because they showed a "credible threat" of enforcement given that the Department was promising to put the 2016 Rule "back into effect." [Footnote 64: Christian Employers All., 2022 WL 1573689, at \*5.] The court also found that under the Biden Administration. the Department's current interpretation of Section 1557 "is substantially the same as the 2016 Rule," and that it "characterizes the [plaintiff's] stated beliefs as 'abuse' or 'discrimination.'" [Footnote 65: Id. at \*5, \*7.] The court granted a preliminary injunction shielding Alliance members from enforcement of the Department's new rule and enjoined the Department 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," or "prevents, restricts or compels the Alliance's members' speech on gender identity issues."[Footnote 66: Id. at \*9.] The Department's new rule likely violates RFRA because it imposes a substantial burden in the form of "monetary penalties for [plaintiffs'] refusal to violate religious beliefs," and the government has failed to show a compelling interest in refusing exemptions to these particular claimants.[Footnote 67: Id. at \*8.]

In another round of litigation challenging the 2016 Rule, a coalition of hospital systems affiliated with the Catholic Church and the State of North Dakota brought RFRA and APA challenges which have been successful at every stage so far.[Footnote 68: Religious Sisters of Mercy v. Azar, 513 F. Supp. 3d 1113, 1147–49 (D.N.D. 2021) (order struck down transgender mandate as violating RFRA and APA); see also Catholic Benefits Assoc. v. Burwell, No. 3:16-cv-00432 (D.N.D. 2016) (consolidated with Religious Sisters of Mercy in 2017).] In January 2017, the court in Religious Sisters of Mercy stayed enforcement of the 2016 Rule against the Catholic Plaintiffs, to the extent that it prohibited discrimination on the basis of gender identity and termination of pregnancy.[Footnote 69: Religious Sisters of Mercy v. Burwell, No. 36 Civ. 3:16-cv-386 (D.N.D. Jan. 23, 2017).]

Reaching the merits in January 2021, the court held that implementing Section 1557 according to the Department's 2016 Rule would substantially burden the religious exercise of the nuns, Catholic hospitals, and Catholic University, who all hold sincere religious beliefs about procreation and the sanctity of human life and "believe that performing gender-transition procedures would violate their medical judgment by potentially causing harm to patients." [Footnote 70: Religious Sisters of Mercy, 513 F. Supp. 3d at 1132.] For these religious healthcare providers, "adverse practical consequences abound" if Section 1557 is enforced against them, because "refusal to perform or cover gendertransition procedures would result in the Catholic Plaintiffs losing millions of dollars in federal healthcare funding and incurring civil and criminal liability." [Footnote 71: Id. at 1147.] The court also held that the Department failed to show a compelling interest in "ensuring nondiscriminatory access to healthcare" because this was too "broadly formulated," and "[n]either HHS nor the EEOC has articulated how granting specific exemptions for the Catholic Plaintiffs will harm the asserted interests in preventing discrimination." [Footnote 72: Religious Sisters of Mercy, 513 F. Supp. 3d at 1148.) The court recognized many less restrictive alternatives beyond forcing Catholic providers to violate their beliefs: the Government could assume the cost, the employers could provide subsidies or tax credits to employees, community health centers and hospitals with income-based support could provide the services, or ACA exchanges could expand access without compromising conscientious objectors. [Footnote 73: Id. at 1148-49.] Because the Department failed to show that none of these alternatives would be feasible, it failed strict scrutiny. Thus, the court granted permanent injunctive relief for the Catholic plaintiffs.[Footnote 74: ld. at 1152-53.]

These rulings make clear that both the 2016 Rule and the proposed Rule violate RFRA. If enacted, the proposed Rule will continue to be challenged in court, and judges will continue to enjoin its enforcement against religious healthcare providers who are able to sue—as they should. Yet members of minority faiths may not receive protection from these injunctions. And most healthcare

providers with sincere religious convictions do [Italics: not] work for Catholic hospitals. On the contrary, religious providers give excellent medical care to all patients in a myriad of medical settings, most of which are not religiously affiliated at all. Furthermore, medical providers with individual religious objections that do not necessarily correspond to an official religious institution or denomination remain unprotected by these injunctions.

Finally, the Department's proposed Rule does not address the closures of healthcare facilities, the withdrawal of religious healthcare providers from the marketplace, or the deprivation of federal financial assistance, all of which would have a significant negative impact on patient access to the healthcare sector as a whole. These impacts would especially limit providers' ability to provide equitable care to persons with disabilities, racial minorities, and persons in rural areas that would face significant gaps in care if religious providers were forced to withdraw from the marketplace. The proposed Rule recognizes this issue, yet its requirements would exacerbate it:

There are an increasing number of communities in the United States with limited options to access healthcare from non-religiously affiliated healthcare 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. [Footnote 75: 87 Fed. Reg. 47840.]

Despite this acknowledgement, the Department has not calculated the effects of diminished access to faith-based healthcare providers on low-income and rural Americans. The consequences of the Department's violation of faith-based healthcare providers' rights of conscience would disparately impact rural hospitals and urban hospitals that primarily serve minority populations, and thus the proposed Rule "would in effect devastate access to Catholic medical care and other faith-based care across the board that are the backbone of caring for patients, especially the poor, in our country." [Footnote 76: Louis Brown, Eliminating medical conscience rights threatens human dignity and the freedom to love, THE HILL (Apr. 29, 2022), https://thehill.com/opinion/healthcare/3471359-eliminating-medical-conscience-rights-threatens- human-dignity-and-the-freedom-to-love/.] 8.4.2 8.4.3 2>

<3 2 8.4.2 C. Because these issues are still percolating in the courts, the agency should not erode religious liberty even further at this time.

As the court in Christian Employers Alliance pointed out, the changes between the 2016 Rule and the 2020 Rule have led to "conflicting decisions by separate courts, each holding that HHS must enforce Section 1557 in opposite manners." [Footnote 77: Christian Employers All., 2022 WL 1573689, at \*5 (citing Religious Sisters of Mercy, 513 F. Supp. 3d at 1144 (D.N.D. 2021); Whitman-Walker Clinic, 485 F. Supp. 3d 1 (D.D.C. 2020)).] Drastic policy changes with each new administration have increased confusion and decreased the ability of healthcare providers to rely on stable regulations without fear of negative enforcement against them. This counsels in favor of pausing the proposed Rule at least until the courts can reach a consensus about which version should apply and how exactly it applies.

On October 3, 2022, the court in State of Texas v. EEOC ruled that the Biden Administration's March 2 Guidance[Footnote 78: HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Mar. 2, 2022), https://perma.cc/LX26-59QR.] was "arbitrary and capricious" for several reasons, including that it appears to misstate the law:

By its terms, the March 2 Guidance leaves the reader with the impression that Section 504 generally defines gender dysphoria as a disability—subject to some exceptions—even though the opposite is

true Nor do Defendants explain how HHS and OCR arrived at the March 2 Guidance's conclusion that "denial of ... care solely on the basis of [a patient's] sex assigned at birth or gender identity likely violates Section 1557." Because Defendants appear to misstate the law and do not detail what went into their decision-making, the Court finds the March 2 Guidance arbitrary and capricious.[Footnote 79: State of Texas v. EEOC, No. 74 Civ. 2:21-CV-194-Z (N.D. Tex. Oct. 1, 2022), at 18.]

After the Trump Administration issued the 2020 Rule and after the Supreme Court decided Bostock v. Clayton County, two district courts extended Bostock's reasoning to Title IX as applied through Section 1557, entering injunctions modifying the 2020 Rule and purportedly restoring certain provision of the 2016 Rule. These were APA challenges, not RFRA challenges, and they left undisturbed the consistent holdings that the 2016 Rule violated RFRA. In Walker v. Azar, the court decided to leave the following definitions from the 2016 Rule in effect: 'on the basis of sex,' 'gender identify,' and 'sex stereotyping.'"[Footnote 80: Walker v. Azar, 480 F. Supp. 3d 417, 430 (E.D.N.Y. 2020)] But the court found that the plaintiffs lacked standing to challenge any other portions of the Rule, and it did not address the Title IX religious exemption at all (which the Trump Administration added to the 2020 Rule to protect religious institutions and healthcare providers).

In Whitman-Walker Clinic, Inc. v. HHS, the court preliminarily enjoined the Department from "enforcing 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." [Footnote 81: Whitman-Walker Clinic v. HHS, 485 F. Supp. 3d 1, 64 (D.D.C. 2020).] This opinion went further than Walker v. Azar because it addressed the Title IX religious exemption, finding that it was improperly included in the 2020 Rule. But even this opinion recognized the strength of RFRA in providing religious protections. The court conceded that the Department could incorporate Title IX's religious exemption in the future, as long as it adequately considered the effect on prompt access to care. The court also noted that "nothing in this decision renders religiously affiliated providers devoid of protection. Far from it."[Footnote 82: ld. at 46.] Protections for religious providers include the ACA's clauses ensuring that federal laws protecting conscience still apply. [Footnote 83: "The ACA instructs that no provision '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." Whitman-Walker Clinic, 485 F. Supp. 3d at 46 (quoting 42 U.S.C. § 18023(c)(2)).] "The 2020 Rule, moreover, explicitly acknowledges that Section 1557 is subject to RFRA's protections of religious conscience from government-imposed burdens, protections the Supreme Court has confirmed are 'very broad.'" [Footnote 84: Id. at 46 (citing 45 C.F.R. § 92.6(b) and Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 693 (2014)).] In February 2021, the D.C. Circuit stayed the appeal in light of ongoing agency proceedings. [Footnote 85: Whitman-Walker Clinic, Inc. v. HHS, No. 1886057 Civ. 20-5331 (D.C. Cir. Feb. 18, 2021).]

Several other cases challenging the 2020 Rule are still pending but have been stayed in light of the proposed Rule and the NPRM process.[Footnote 86: See, e.g., Boston All. of Gay, Lesbian, Bisexual & Transgender Youth v. U.S. Dep't of Health & Human Servs., No. 1:20-cv-11297, 2020 WL 3891426 (D. Mass. July 9, 2020); New York v. U.S. Dep't of Health & Human Servs., No. 1:20-cv-05583, 2020 WL 4059929 (S.D.N.Y. July 20, 2020).] Instead of creating more confusion in these cases by changing its policies yet again, the Department should at least retain the robust religious protections from the 2020 Rule. If it does not, overlapping and conflicting injunctions will continue to plague any attempts at enforcement. 2 8.4.2 3>

<4 8.7 D. A flurry of litigation shows that religious providers will be targeted, sued, and prosecuted if they remain true to their consciences and violate the proposed Rule.

While every court to examine the merits of religious plaintiffs' RFRA claims has found in favor of the religious healthcare providers, these providers face a very credible threat of enforcement if the proposed Rule is enacted. Many courts have concluded that categorically declining to perform or insure gender transitions—as many religious healthcare providers must— violates Section 1557 and Title VII, even when the decision to decline is religiously based. And this issue is creating a large amount of costly litigation for hospitals and providers, including religious hospitals and providers:

- Hammons v. Univ. of Md. Sys. Corp., 551 F. Supp. 3d 567, 591 (D. Md. 2021) (Catholic hospital violated Section 1557 when it declined to perform gender-transition procedure because of religious beliefs);
- C.P. ex rel. Pritchard v. Blue Cross Blue Shield of Ill., 536 F.Supp.3d 791, 793-94 (W.D. Wash. 2021) (transgender plaintiff stated claim of sex discrimination under Section 1557 against Catholic employer whose health plan excluded transition procedures because of religious beliefs);
- Conforti v. St. Joseph's Healthcare Sys., No. 2:17-cv-00050, 2019 WL 3847994 (D.N.J. 2019) (transgender plaintiff sued for sex discrimination under Section 1557 against Catholic hospital that declined to schedule gender-transition surgery because of religious beliefs; case settled and was dismissed in 2021)
- Robinson v. Dignity Health, No.16-3035 (N.D. Cal. filed June 6, 2016) (transgender employee sued Catholic hospital whose health insurance plan excluded gender-transition surgery because of religious beliefs; case settled)
- Scott v. St. Louis Univ. Hosp., No. 4:21-cv-01270, 2022 WL 1211092, at \*1, 6 (E.D. Mo. Apr. 25, 2022) (plaintiff stated claim for discrimination under Section 1557 and the ACA, where employer excluded transition procedures for minor child);
- Tovar v. Essentia Health, 342 F.Supp.3d 947, 947, 950 (D. Minn. 2018) (employee denied coverage for minor's gender-transition surgery stated claim for sex discrimination under Section 1557)
- Flack v. Wis. Dep't of Health Servs., 328 F.Supp.3d 931, 934-35, 946-51 (W.D. Wis. 2018) (granting preliminary injunction to transgender plaintiffs because Wisconsin's Medicaid program excluding coverage for transition procedures likely violated Section 1557); but see Hennessy-Waller v. Snyder, 529 F. Supp.3d 1031 (D. Ariz. 2021), aff'd, Doe v. Snyder, 28 F.4th 103 (9th Cir. 2022) (denying preliminary injunction to minor plaintiffs because Arizona's Medicaid program excluding coverage for transition procedures did not likely violated Section 1557, and Bostock was limited to Title VII claims)
- Cruz v. Zucker, 218 F. Supp. 3d 246 (S.D.N.Y. 2016) (finding for transgender plaintiffs who challenged denial of Medicaid coverage for gender dysphoria treatments under Section 1557)
- Prescott v. Rady Children's Hosp.-S.D., 265 F.Supp.3d 1090 (S.D. Cal. 2017) (holding that parent of transgender patient stated claim under Section 1557 for sex discrimination)
- Kadel v. Folwell, 446 F. Supp. 3d 1 (M.D.N.C. Mar. 11, 2020) (transgender plaintiffs challenging state employee health plan which excluded coverage of gender-transition treatments stated claim for sex discrimination under Section 1557 of Affordable Care Act, Title IX, and the Equal Protection Clause)

- Toomey v. Arizona, No. CV-19-00035, 2021 WL 753721 (D. Ariz. 2021) (denying preliminary injunction to transgender employee seeking insurance coverage for gender- transition surgery, because Title VII claims were unlikely to succeed as there was no discrimination based on transgender status)
- Boyden v. Conlin, 341 F. Supp. 3d 979 (W.D. Wis. September 18, 2018) (exclusion of gender transition treatment from insurance coverage for transgender state employees violated Title VII and Section 1557 nondiscrimination provision)

The growing number of cases against healthcare providers, including religious providers whose insurance excludes gender-transition procedures, is telling. Religious individuals and institutions face a credible threat of enforcement, whether from this Department if the proposed Rule is enacted, from continued litigation when they do voice religious objections to providing services that violate their consciences, or—most likely—both. This is all the more reason for the Department to retain the robust religious freedom protections from the 2020 Rule and carefully consider the impact of its decisions on religious healthcare providers. 8.7 4>

<5 8.5 2 II. The Department Must Revise the Rule to Comply with the Constitution.

The Department is bound to comply with the U.S. Constitution, which protects the free exercise of religion, free speech (which includes religious speech), and the Tenth Amendment (which ensures that states who provide religious freedom protections are not commandeered to restrict the rights by the federal government). As currently written, the proposed Rule violates the Free Exercise Clause, the Free Speech Clause, and the Tenth Amendment.

A. The proposed Rule triggers strict scrutiny under the Free Exercise Clause because it is not neutral or generally applicable.

Under the First Amendment, government policies and practices that substantially burden the free exercise of religion are subject to strict scrutiny unless they are neutral and generally applicable. [Footnote 87: See Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah, 508 U.S. 520, 531-32 (1993); Fulton v. City of Philadelphia, 141 S. Ct. 1868, 1877 (2021) ("Government fails to act neutrally when it proceeds in a manner intolerant of religious beliefs or restricts practices because of their religious nature.").] In Obergefell v. Hodges, the Supreme Court recognized that many Americans have sincere religious objections to social movements such as same-sex marriage based on "decent and honorable religious or philosophical premises," and that "neither they nor their beliefs are disparaged here." [Footnote 88: Obergefell v. Hodges, 576 U.S. 644, 672 (2015).] Disparagement of religious beliefs, as the Court recognized in Masterpiece Cakeshop and reiterated in Kennedy v. Bremerton, is a separate Free Exercise Clause violation. When "official expressions of hostility' to religion accompany laws or policies burdening religious exercise . . . the Court has "set aside such policies without further inquiry." [Footnote 89: Kennedy v. Bremerton Sch. Dist. 142 S. Ct. 2407, 2422 n.1 (2022) (quoting Masterpiece Cakeshop, Ltd. v. Colo. Civil Rights Comm'n, 138 S. Ct. 1719, 1732 (2018)).] Notably, religious discrimination triggers the highest level of scrutiny in constitutional law, while gender discrimination triggers only intermediate scrutiny, and there is no clear legal standard on how to evaluate gender identity discrimination. [Footnote 90: Compare Lukumi, 508 U.S. at 546 (applying

"most rigorous form of scrutiny to religious discrimination case), with Nguyen v. U.S., 533 U.S. 53 (2001) (applying intermediate scrutiny to sex discrimination case)]

Here, the proposed Rule is not neutral because the Department singles out religious beliefs on gender transition or gender-affirming care. First, the Department ignored repeated calls for a religious exemption and intentionally removed the religious exemption from Title IX that was included

in the 2020 Rule, rolling back the protections for faith-based providers that the previous administration put in place. President Biden's Executive Order fulfilled a campaign promise to "[g]uarantee" the ACA's "nondiscrimination protections for the LGBTQ+ community" and "reverse" "religious exemptions" for "medical providers" with religious objections or conscience concerns. [Footnote 91: Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation (Jan. 20, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive- order-preventing-and-combating-discrimination-on-basis-of-gender-identity-or-sexual-orientation/.] The intentional removal of the religious exemption from the 2020 Rule sends a message of hostility to religious healthcare providers that they are no longer protected.

Second, the Department has specifically drafted its prohibition on categorical objections to refer to "a provider's belief:" "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 92: 87 Fed. Reg. 47918.] This blanket determination that consistent religious objections can never be a sufficient basis for a healthcare provider's judgment provides no room for nuanced decisions based on conscience. If anything, this approach punishes the providers with the most integrity—providers who take individualized approaches to caring for each patient yet hold consistent religious beliefs that prevent them from approving or participating in gender-transition procedures. While the non-religious provider with an occasional objection to providing gender-transition procedures (that could indeed be rooted in discrimination against a certain patient) gets a free pass, the consistent, religiously committed provider whose conscience does not alter no matter the circumstance is punished because of her religious beliefs.

Contrary to popular narratives, the scholarly literature is not unanimous that gender- affirming care is medically necessary in religious environments, and religious communities who do not affirm a preferred identity do not negatively impact transgender patients' health. In the American Journal of Orthopsychiatry, health professionals wrote: "We did not find support for our hypothesis that exposure to non-affirming religious settings - operationalized as individuals with affiliation with nonaffirming religious settings versus those who never attend religious services - predicts more depressive symptoms and worse psychological well-being."[Footnote 93: David M. Barnes and Ilan H. Meyer, Religious affiliation, internalized homophobia, and mental health in lesbians, gay men, and bisexuals, 82(4) AM J ORTHOPSYCHIATRY 505 (Oct. 2012).] On the contrary, "it is the moral and religious convictions of religious sisters and Catholic healthcare workers that drive them to love and care for underserved African American communities," as one example of a minority population who uniquely relies on and benefits from faith-based healthcare. [Footnote 94: Louis Brown, "Eliminating medical conscience rights threatens human dignity and the freedom to love," The Hill (Apr. 29, 2022), https://thehill.com/opinion/healthcare/3471359-eliminating-medical-conscience-rightsthreatens- human-dignity-and-the-freedom-to-love/.] Instead of recognizing this importance and allowing for religious providers to serve patients according to their consciences and convictions, the proposed Rule perpetuates a stereotype that religious Americans are bigots. That message of hostility violates the Free Exercise Clause. 8.5 2 5>

<6 8.5 8.4.1 B. The Department's mechanism for granting individualized exemptions triggers strict scrutiny under the Free Exercise Clause and Supreme Court jurisprudence.

Under the First Amendment, a government policy or practice is not neutral and generally applicable when it provides exemptions or when it otherwise treats secular conduct more favorably than religious exercise. According to the unanimous Supreme Court in Fulton v. City of Philadelphia, "A law is not generally applicable if it invites the government to consider the particular reasons for a person's conduct by providing a mechanism for individualized exemptions." [Footnote 95: See Fulton v. City of Philadelphia, 141 S. Ct. 1868, 1877 (2021).] The Court has also held that regulations

"trigger strict scrutiny under the Free Exercise Clause, whenever they treat [Italics: any] comparable secular activity more favorably than religious exercise." [Footnote 96: Tandon v. Newsom, 141 S. Ct. 1294, 1296 (2021).]

Here, the proposed Rule triggers strict scrutiny because it allows for providers to decline gender-transition services based on secular medical judgment while removing the religious exemption that protected providers with conscientious objections. The NPRM claims that it is not requiring issuers to "cover all services related to gender-affirming care for transgender individuals—or all medically necessary services generally."[Footnote 97: 87 Fed. Reg. 47824, 47874 (Aug. 4, 2022).] On the contrary, "[i]ssuers retain flexibility in designing their benefit packages, and this proposed rule would not require issuers to cover any particular benefit or to cover all medically necessary services."[Footnote 98: 87 Fed. Reg. 47874.] The proposed Rule "does not compel a provider to prescribe a specific treatment that the provider decides not to offer after making a nondiscriminatory bona fide treatment decision."[Footnote 99: 87 Fed. Reg. 47867.] The Rule gives two examples, both of which show a willingness to make secular exceptions but not religious ones:

- "[A] family practice covered by the rule would not be required to provide transition-related surgery where surgical care is not within its normal area of practice.
- Nor would the proposed rule 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."[Footnote 100: 87 Fed. Reg. 47867.]?

This allowance for flexibility and exemptions seems logical and well-warranted. But it triggers strict scrutiny under Fulton by not allowing any flexibility to providers with religious objections based on belief. [Footnote 101: Fulton, 141 S. Ct. at 1877.] Further, it is completely up to the Department's discretion to decide what is a "legitimate, nondiscriminatory reason for denying or limiting" a service, and the Department makes clear that "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. "[Footnote 102: 87 Fed. Reg. 47867.] This example that the proposed Rule includes makes clear that religious objections would not be considered legitimate:

"[A] gynecological surgeon may be in violation of the rule if they accept a referral for a hysterectomy but later refuse to perform the surgery upon learning the patient is a transgender man. If OCR were to receive a complaint in a case such as this, it would evaluate whether the provider had a legitimate basis for concluding that the surgery would not be clinically appropriate for the patient. If the surgeon invokes such a justification, OCR would make a determination as to whether the reason was a pretext for discrimination." [Footnote 103: 87 Fed. Reg. 47867.]?

Thus, the proposed Rule's supposed "flexibility" does not apply to providers with religious objections. [Footnote 104: 87 Fed. Reg. 47867.] If doctors are unwilling to participate in gender-transition procedures because they consistently disagree on religious grounds rather than medical judgment, those are considered "categorical exclusions" and a "pretext for discrimination." [Footnote 105: 87 Fed. Reg. 47867.] This policy treats secular activity such as the exercise of independent medical judgment more favorably than religious reasons for declining to participate in controversial medical procedures, and such unequal treatment triggers strict scrutiny under Tandon v. Newsomm. [Footnote 106: Tandon, 141 S. Ct. at 1296.] 8.5 8.4.1 6>

<7 8.4.1 8.2 C. The Department's proposed scheme for evaluating religious exemption requests is inadequate and problematic for several reasons.

As the Department has requested comments on its proposed scheme for requesting religious exemptions and "invite[s] comments from covered entities controlled by or affiliated with religious organizations [and] providers employed by such entities," [Footnote 107: 87 Fed. Reg. 47841.] we raise several concerns as civil rights attorneys who represent religious organizations and religious healthcare providers.

The Department's scheme for requesting religious exemptions in the proposed Rule is problematic for several reasons. First, it forces religious entities to expose themselves to potential sanctions in order to even request an exemption. Unlike the broader religious exemption that the 2020 Rule incorporated from Title IX, which recognizes the robust protections belonging to religious entities by the very nature of their identity under the First Amendment and RFRA, this scheme requires entities to ask, "Mother, may I?" in a way that puts their operations at risk. The very act of requesting an exemption would expose a religious hospital or healthcare provider to potential targeting by an agency that has repeatedly proven itself a bully to religious entities. Under Secretary Becerra, the Department 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 108: Rachel N. Morrison, HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate in Health Care, THE FEDERALIST SOCIETY (Sept. 8, 2022), https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed- nondiscrimination-regulations-imposetransgender-mandate-in-health-care-1.] Religious institutions who request an exemption will lose their privacy and anonymity, which may in turn have a chilling effect on their provision of healthcare services. Some institutions may experience pressure to reduce or eliminate their services altogether rather than expose themselves to targeting by the Department. This would only exacerbate the problems the Department already recognizes: that a lack of religious exemptions "could also result in providers with religious and conscience objections leaving the profession, or covered entities exiting the market."[Footnote 109: 87 Fed. Reg. 47905.]

Second, the scheme contains no guarantee of adequate review or opportunity to appeal. The procedural process is unclear. Who will evaluate claims? Will the Conscience and Religious Freedom Division be involved? If so, this should be stated explicitly in the regulation. Also, the Department under Secretary Becerra has characterized a general goal of nondiscrimination as a compelling interest, so there is no guarantee that religious exemption requests will receive adequate review and case-by-case consideration. Further, if an exemption request is denied, there is no appeal process available.

Third, the proposed Rule still violates RFRA despite its purported religious exemption scheme. The Department's vague promises to consider RFRA are not adequate protection for the religious liberties of healthcare providers and organizations with conscientious objections. As the Fifth Circuit recently held in Franciscan Alliance:

In Speech First, Inc. v. Fenves the defendant vaguely promised to not enforce the challenged policies "contrary to the First Amendment"—similar to HHS's promise to "comply with the Religious Freedom Restoration Act . . . and all other legal requirements." We held that the plaintiffs had standing to bring suit because they were within the "class whose [conduct] is arguably restricted," and the defendant's promise was so vague that the scope of liability was both "unknown by the [defendant] and unknowable to those regulated by it."[Footnote 110: Franciscan All., 47 F.4th at 377.]

So too here. The Department's promise to consider religious exemption requests is vague with no guarantee of due process, appeal, or unbiased decisionmaking. The scope of liability for religious

institutions and healthcare providers remains both "unknown" and "unknowable"—exactly what the Fifth Circuit found showed a credible threat of enforcement that gave religious plaintiffs standing to sue

For all these reasons, the Department should reinstate the portion of the 2020 Rule that incorporated Title IX's broad religious exemption. This is logical because the Department is already using Title IX to interpret Section 1557, and it would provide much more clarity, notice, and assurance to religious entities and providers that their beliefs will be respected. This would also save the Department time and money from not having to review individual requests, and it would reduce the need for costly litigation because religious entities would have robust protection without having to expose themselves publicly to potential sanction and discrimination. 8.4.1 8.2 7>

<22 8.1 12.1.14 D. The proposed Rule will fail strict scrutiny because the Department lacks a compelling interest and has ignored a host of less restrictive alternatives.

The Department cannot pass muster by asserting a "broadly formulated interest" in preventing discrimination on the basis of gender identity, or increasing access to healthcare for transgender individuals, especially given the increasingly diverse and competitive marketplace with a myriad of options for health insurance and healthcare providers. On the contrary, the Supreme Court requires courts to "scrutinize the asserted harm of granting specific exemptions to particular religious claimants and to look to the marginal interest in enforcing the challenged government action in that particular context." [Footnote 111: Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418, 431 (2006).] This means that to pass strict scrutiny, the Department must show a compelling interest in denying religious exemptions to each particular religious provider with an objection to providing gender-transition procedures. As the court in Religious Sisters of Mercy made clear, it has not done so: "Neither HHS nor the EEOC has articulated how granting specific exemptions for the Catholic Plaintiffs will harm the asserted interests in preventing discrimination." [Footnote 112: Religious Sisters of Mercy, 513 F. Supp. 3d at 1148]

The "flexibility" [Footnote 113: 87 Fed. Reg. 47874.] in the application of the proposed Rule undermines the Department's attempt to show it has a compelling interest such that its "nondiscrimination policies can brook no departures." [Footnote 114: Fulton, 141 S. Ct. at 1882.] The proposed Rule allows for several non-religious exceptions: 1) if a provider gives a "legitimate, non-discriminatory reason" for declining a treatment; 2) if a provider makes a "nondiscriminatory bona fide treatment decision;" 3) if gender-transition procedures are outside a clinic's normal area of practice, or 4) if a pediatrician concludes that social transition would be a better next step than puberty blockers for a minor patient. [Footnote 115: 87 Fed. Reg. 47867.] All these exceptions undermine the Department's assertion that non-discriminatory access to gender-transition procedures is such a compelling interest that no exceptions can be made for religious providers or institutions. 8.1 12.1.14 22>

<23 12.1.14 8.1 Not only does the Department fail to assert a compelling interest for its proposed Rule, it also ignores the contributions of religious healthcare providers and the many benefits of religion for patient health. For example, studies show the dramatic benefits of religious coping and the role of faith-based and spiritual support during physical and mental illness. According to a Mayo Clinic publication, "most studies have shown that religious involvement and spirituality are associated with better health outcomes, including greater longevity, coping skills, and health-related quality of life (even during terminal illness) and less anxiety, depression, and suicide. Several studies have shown that addressing the spiritual needs of the patient may enhance recovery from illness."[Footnote 116: Paul S. Mueller, M.D., David J. Plevak, M.D. and Teresa A. Rummans, Religious Involvement, Spirituality, and Medicine: Implications for Clinical Practice, 76 MAYO CLINIC PROC. 1225, 1235 (2001), https://www.mayoclinicproceedings.org/article/S0025-</p>

6196(11)62799-7/pdf.] Furthermore, scholars have identified "a number of facets of religious involvement that are uniquely linked with health outcomes. For example, investigators increasingly recognize the importance of church-based social support for health and well-being, particularly for African Americans." [Footnote 117: Christopher G. Ellison, Reed T. DeAngelis, and Metin Güven, Does Religious Involvement Mitigate the Effects of Major Discrimination on the Mental Health of African Americas? RELIGION AND MENTAL HEALTH OUTCOMES (Sept. 2017).] On the whole, religious attendance increases longevity by improving and maintaining good health behaviors, mental health, and social relationships. [Footnote 118: Chatters, Linda M., Religion and health: Public health research and practice, ANNUAL REVIEW OF PUBLIC HEALTH, 21, 335–367, https://www.annualreviews.org/doi/pdf/10.1146/annurev.publhealth.21.1.335.]

Religious healthcare providers are uniquely equipped to address not only the physical but also the spiritual needs of patients who desire a faith perspective. According to the World Health Organization, "spirituality is an important dimension of patients' quality of life." [Footnote 119: Anne L. Dalle Ave and Daniel P. Sulmasy, Health Care Professionals' Spirituality and COVID-19, JAMA 2021; 326(16): 1577-1578, https://jamanetwork.com/journals/jama/fullarticle/2785147#nav.] And "the value of spirituality is not . . . solely as a means of reducing clinicians' distress or promoting better healthcare outcomes, but should be considered as intrinsically valuable."[Footnote 120: Id.] Thus, ousting religious healthcare providers from the field ignores the needs of LGBTQ patients with faith commitments, who often find themselves caught between conflicting pressures and norms and would value the perspective of a religious healthcare provider to assist them in sorting through that process. For example, among individuals who identified as LGBT and Christian, "[r]eligiosity was associated with higher levels of eudaimonic well-being and lower levels of depression, anxiety, and stress."[Footnote 121: Shilpa Boppana, The impact of religiosity on the psychological well of LGBT Christians, JOURNAL OF GAY & LESBIAN MENTAL HEALTH, 23:4 (2019), 412-426] For patients with gender dysphoria, the mental health benefits of a diversity of religious support and healthcare providers should be recognized. A study on body dysmorphia found that the positive body image of "[w]omen in the Religious group increased significantly compared to Control women (who declined) in how they felt about their appearance and looks. Women in the Spiritual condition improved marginally compared to the Control condition." [Footnote 122: Boyatzis, Chris J., et al., Experimental Evidence that Theistic-Religious Body Affirmations Improve Women's Body Image, 46(4) JOURNAL FOR THE SCIENTIFIC STUDY OF RELIGION 553-564 (2007).] Analyzing the links between religion, gender, and body image, scholars reported:

A recent review concluded that in normal non-diagnosed women, religiosity and body image are often linked in positive, healthy ways (Boyatzis and Quinlan 2008). For example, healthier body image is positively associated with women's self-rated importance of religion (Joughin et al. 1992), worship attendance and self-rated religiosity (Mahoney et al. 2005), intrinsic orientation (Forthun et al. 2003; Smith et al. 2003), and religious wellbeing (i.e., a close relationship with God).[Footnote 123: Kristin J. Joman and Chris J. Boyatzis, Body Image in Older Adults: Links with Religion and Gender, J ADULT DEV (2009) 16:230-238.]

Many religious healthcare providers seek to bridge the gap between patients' physical health and spiritual health in ways that benefit both individuals and communities as a whole. For example, the Catholic Health Association makes its mission clear: "As part of the Catholic Health Ministry, we honor the dignity of every person, and we are committed to the common good. We strive always to act in a way that is consistent with our identity and to serve all persons with care and compassion." [Footnote 124: Amy Wilson-Stronks, et al., Faith-Based Health Care and the LGBT Community: Opportunities and Barriers for Equitable Care, TANENBAUM, https://tanenbaum.org/wp-content/uploads/2020/05/Faith-Based-Health-Care-LGBTQ.pdf.] 12.1.14 8.1 23>

<24 8.1 8.4.2 8.2 12.1.14 In sum, faith-based providers help to advance many important interests relating to public health, yet the Department ignores all this and focuses only on a generalized interest in "nondiscriminatory access to healthcare," which is not enough to pass muster under the First Amendment.[Footnote 125: Religious Sisters of Mercy, 513 F. Supp. 3d at 1148.]

The proposed Rule will also fail strict scrutiny because the Department has not chosen the least restrictive means to fulfill its interest. On the contrary, the Department's approach is maximally restrictive to religious healthcare institutions and providers. In Religious Sisters of Mercy, the court recognized many less restrictive alternatives beyond forcing Catholic providers to violate their beliefs: the Government could assume the cost, the employers could provide subsidies or tax credits to employees, community health centers and hospitals with income-based support could provide the services, or ACA exchanges could expand access without compromising conscientious objectors.[Footnote 126: Id. at 1148–49.] The court in Franciscan Alliance listed similar alternatives: "examples of other less restrictive means the government could use to ensure access to transition procedures and abortions include[e] assisting individuals seeking such procedures by finding healthcare providers who offer those services and then assuming the cost."[Footnote 127: Franciscan All., Inc. v. Azar, 414 F. Supp. 3d 928, 943 (N.D. Tex. 2019).]

Incorporating the religious exemption from Title IX would be the most straightforward less-restrictive-means for the Department to accomplish its interests. Another option, given the other exemptions that the proposed Rule allows, is that the Rule could recognize sincere objections based on religious beliefs as one of the legitimate, non-discriminatory reasons for declining to participate or recommend a gender-transition procedure. The Department has not shown that it has considered these alternatives, or that none of them would be feasible. Thus, the proposed Rule fails strict scrutiny, 8.1 8.4.2 8.2 12.1.14 24>

<9 8.4.2 8.4.3 E. Bostock recognizes and affirms the robust religious protections in the Constitution, RFRA, and Title VII.

The proposed Rule relies heavily on Bostock v. Clayton County, inappropriately seeking to import the Court's analysis of a Title VII claim into the context of healthcare provision. [Footnote 128: 87 Fed. Reg. 47829-47830.] Yet both the majority and the dissent in Bostock specifically spelled out the many legal and constitutional protections for religion which apply over and above its interpretation of Title VII. As the majority explained, the Court is "deeply concerned with preserving the promise of the free exercise of religion enshrined in our Constitution; that guarantee lies at the heart of our pluralistic society." [Footnote 129: Bostock, 140 S. Ct. at 1754.] The Court highlighted three doctrines that protect religious liberty, particularly in the context of sex discrimination claims:

- Title VII's religious organization exemption, which allows religious organizations to employ individuals "of a particular religion";
- The ministerial exception under the First Amendment, which "can bar the application of employment discrimination laws 'to claims concerning the employment relationship between a religious institution and its ministers";
- The Religious Freedom Restoration Act (RFRA), which the Court described as a "super statute, displacing the normal operation of other federal laws," that "might supersede Title VII's commands in appropriate cases." [Footnote 130: Id.]

Because it is constitutionally and statutorily required and since the Department is relying on Bostock in the Proposed Rule, the Department must recognize the important protections for religious exercise under the First Amendment and RFRA. The Department must also recognize that the Court

in Bostock was not seeking to resolve potential conflicts over sex discrimination claims and religious liberties, but was instead warning lower courts and government actors to recognize the limits of its holding and take additional care to respect religious liberty when these difficult questions arise. Lower courts have taken note; in Christian Employers Alliance, the court found that "Bostock specifically notes, however, the Supreme Court was 'deeply concerned' with preserving the free exercise of religion and specifically pointed to the Religious Freedom Restoration Act and the First Amendment, noting that this was an issue for future cases, as none of the employers had brought the issue before the Court."[Footnote 131: Christian Employers All., 2022 WL 1573689, at \*3.]

F. Bostock does not apply to Section 1557 or require the reinterpretation of "sex discrimination" to include sexual orientation and gender identity.

The Department's attempt to apply the Title VII analysis in Bostock to the wholly separate context of healthcare in Section 1557 is legally problematic and has harmful consequences for religious healthcare providers. Multiple courts have already recognized that Title IX and Title VII are inherently different in the ways that they refer to "sex." Unlike Bostock, Section 1557 "does not employ the terms 'sex,' 'sexual orientation,' or 'gender identity." Instead, Section 1557 expressly incorporates Title IX, which prohibits discrimination 'on the basis of sex." [Footnote 132: Neese v. Becerra, No. 2:21-cv-00163-Z, 2022 WL 1265925, at \*14 (N.D. Tex. Apr. 26, 2022).] The court in Neese v. Becerra held:

Bostock's Title VII analysis does not control the Title IX and Section 1557 analysis with the ease, precision, and force envisioned in Defendants' Motion. Though courts [Italics: generally] apply the legal standards used in Title VII cases to decide Title IX cases . . . Title IX and Section 1557 are not identical to Title VII in every material instance.[Footnote 133: Id. at \*13.]

One of the key differences is that Title IX refers to "sex" in a binary way that does not include "sexual orientation" or "gender identity." Indeed, Congress has attempted to add these terms to Title IX multiple times, but each attempt has failed.[Footnote 134: See, e.g., H.R. 1652, 113th Cong. (2013); S. 439, 114th Cong. (2015).] Notably, Section 1557 is linked only to Title IX, not Title VII or the Court's interpretation of it in Bostock.

Further, Bostock itself expressly limited the extent of its holding to Title VII cases, not cases involving other regulations or statutes:

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.[Footnote 135: Bostock, 140 S. Ct. at 1753.]

The court in Religious Sisters of Mercy recognized the explicit limitations of Bostock with regard to Section 1557:

The Court warned that its decision did not "prejudge" any "other federal or state laws that prohibit sex discrimination." [Bostock, 140 S. Ct.] at 1753. Indeed, a dissent from Justice Alito went so far as to identify Section 1557 as having the potential to "emerge as an intense battleground under the Court's holding." Id. at

1781 (Alito, J., dissenting). And the Court separately expressed continued commitment to safeguarding employers' religious convictions. Id. at 1753-54 (majority opinion). Referencing the

RFRA by name, the Court categorized it as "a kind of super statute" that "might supersede Title VII's commands in appropriate cases." [Footnote 136: Religious Sisters of Mercy, 513 F. Supp. 3d at 1129–30 (quoting Bostock, 140 S. Ct. at 1754).]

On October 3, 2022, the court in State of Texas v. EEOC agreed that Bostock includes these important limitations: "Justice Gorsuch expressly stated Bostock did not decide "future cases" affecting religion and arising under Title VII's religious-employer exemption, the Religious Freedom Restoration Act, or the "ministerial exception" defined in Hosanna-Tabor." [Footnote 137: State of Texas v. EEOC, No. 74 Civ. 2:21-CV-194-Z (N.D. Tex. Oct. 1, 2022), at 8.]

There are many other key differences between Bostock and the Section 1557 context. Employment cases are fundamentally different from healthcare provision, where life-and-death decisions are made and religious healthcare providers' consciences are uniquely constrained because of the physical, emotional, and spiritual impact of their actions affecting patients' lives. Also, Bostock only considered clients who were consenting adults, not minors with gender dysphoria. 8.4.2 8.4.3 9>

<10 2 7.6.10 III. The Department Needs to Clarify Whether It Will Respect Existing State Laws that Protect Religious Liberty.

The Department should not rescind language in current Section 92.6(a) which prohibits the Department from "supersed[ing] State laws that provide additional protections against discrimination on any basis described in § 92.2 of this part." [Footnote 138: 45 C.F.R. § 92.6.] This language is written by Congress and is relevant to the interpretation of Section 1557. Unlike the Affordable Care Act, which is limited in its application, the Constitution preempts all federal statutes, and RFRA is a "super statute, displacing the normal operation of other federal laws." [Footnote 139: Bostock, 140 S. Ct. at 1754.]

In addition, proposed 45 C.F.R § 92.206(c) restricts protections under state law by stating that "a provider's compliance with a state or local law that reflects a similar judgment" that "gender transition or other gender-affirming care can never be beneficial for such individuals," "is not a sufficient basis for a judgment that a health service is not clinically appropriate."[Footnote 140: 87 Fed. Reg. 47918.] Not only does this provision improperly constrain the independent medical judgment of healthcare providers, but it also seeks to preempt state law on important issues of conscience where states have, in many cases, already acted to protect religious freedom in the medical context.

The proposed Rule's statement on preemption is vague and unclear as to how it would apply to state laws protecting conscience rights. The Rule "explicitly provides that it is not to be construed to supersede State or local laws that provide additional protections against discrimination on any basis articulated under the regulation." [Footnote 141: 87 Fed. Reg. 47907.] But the Rule does not define whether state laws protecting religious freedom and conscience rights for medical providers would fall under the category of "protections against discrimination." [Footnote 142: Id.]

Every state has some form of religious freedom or conscience law in place. [Footnote 143: New Hampshire and Vermont do not have specific statutes protecting medical rights of conscience, but they both have constitutional provisions and nondiscrimination laws that apply. Sarah M. Estelle, Religious Liberty in the States 2022, CENTER FOR RELIGION, CULTURE, AND DEMOCRACY (Sept. 2022), https://religiouslibertyinthestates.s3.us-east-

2.amazonaws.com/Religious\_Liberty\_in\_the\_States\_Report-2022.pdf.] Indeed, 23 states have enacted versions of the Religious Freedom Restoration Act, which apply the strict scrutiny test to government attempts to regulate conscience.[Footnote 144: Id., State Religious Freedom Restoration Acts, National Conference of State Legislatures (May 4, 2017),

https://www.ncsl.org/research/civil-and-criminal-justice/state-rfra-statutes.aspx.] The Department

needs to clarify that it will respect these applicable, binding state religious freedom protections for individuals, which address their conscience objections specifically to procedures of abortion, sterilization, and contraception in the healthcare context. Further, the Rule must state that it will not preempt the following state laws:

- Alabama:[Footnote 145: Id. at 20.]
- o Religious Freedom Restoration Act: Ala. Const. Am. 622
- o Health Care Rights of Conscience Act: Ala. Code § 22-21B-4
- ? Open-ended conscience provision, abortion and sterilization exemptions for individual providers, civil and criminal immunity, and preclusion of government action for providers with conscience objections to abortion or sterilization
- Alaska:[Footnote 146: Id. at 21.]
- o Abortions: Alaska Stat. § 18.16.010(b)
- ? Abortion exemption with civil immunity for individual providers, private and public hospitals; not limited in medical emergencies
- Arizona:[Footnote 147: Id. at 22.]
- o Religious Freedom Restoration Act: Ariz. Rev. Stat. § 41-1493.01
- Exemption from participating in abortion: Ariz. Rev. Stat. § 36-2154
- ? Abortion exemption for individual providers, private and public hospitals; not limited in medical emergencies
- Arkansas:[Footnote 148: Id. at 23.]
- o Religious Freedom Restoration Act: 2015 SB 975
- o Exemption from participating in abortion: Ark. Code Ann. § 20-16-601(a)
- o Arkansas Human Heartbeat Protection Act: Ark. Code Ann. § 20-16-301-305
- ? Abortion exemption from civil liability for individual providers, private and public hospitals, with protection from government consequences; not limited in medical emergencies
- ? Sterilization exemption from civil liability for individuals and private hospitals
- ? Contraceptive exemption from civil liability for individuals and private hospitals
- California:[Footnote 149: Estelle, Religious Liberty in the States 2022, CENTER FOR RELIGION, CULTURE, AND DEMOCRACY, at 24.]
- Exemption from participating in abortion: CA Health & Safety § 123420
- ? Abortion exemption from civil liability for individual providers and private hospitals; not limited in medical emergencies
- Exemption for dispensing drugs: CA Bus. & Prof. § 733(b)(3)
- ? Contraceptive exemption for individuals
- Colorado:[Footnote 150: Id. at 25.]
- o Limitations on sterilization: Colo. Rev. Stat. § 25.5-10-235(2)
- ? Sterilization exemption from civil and criminal liability for individuals and private and public hospitals
- o Contraceptive exemption: Colo. Rev. Stat. § 25-6-102(9)
- ? Contraceptive exemption from civil and criminal liability for individuals and private hospitals
- Connecticut:[Footnote 151: Id. at 26.]
- o Religious Freedom Restoration Act: Conn. Gen. Stat. § 52-571b
- Exemption from participating in abortion: Conn. Agencies Regs. § 19-13-D54(f)
- ? Abortion exemption for individuals, not limited in medical emergencies

- Delaware:[Footnote 152: ld. at 27.]
- o Medical Practice Act: 24 Del. Laws § 1791
- ? Abortion exemption from civil liability for individuals, private and public hospitals, with protection from government consequences; not limited in medical emergencies
- Florida:[Footnote 153: ld. at 28.]
- o Religious Freedom Restoration Act: Fla. Stat. § 761.01, et seq.
- o Exemption from participating in termination procedure: Fla. Stat. § 390.0111(8)
- ? Abortion exemption from civil liability for individuals, private and public hospitals; not limited in medical emergencies
- ? Sterilization exemption from civil liability for individuals.
- Exemption from prescribing contraceptives: Fla. Stat. §381.0051(5)
- ? Contraceptive exemption from civil liability for individuals
- Georgia:[Footnote 154: ld. at 29.]
- o Performance of sterilization procedures: Ga. Code Ann. § 31-20-6
- ? Sterilization exemption from civil liability for individuals, private and public hospitals
- o Objections to providing abortion-related services: Ga. Code Ann. § 16-12-142
- ? Abortion exemption from civil liability for individuals, private and public hospitals; not limited in medical emergencies
- Hawaii:[Footnote 155: Estelle, Religious Liberty in the States 2022, CENTER FOR RELIGION, CULTURE, AND DEMOCRACY, at 30.]
- o Intentional termination of pregnancy: Haw. Rev. Stat. § 453-16(e)
- ? Abortion exemption from civil liability for individuals, private and public hospitals; not limited in medical emergencies
- Idaho:[Footnote 156: Id. at 31.]
- o Religious Freedom Restoration Act: Idaho Code § 73-402
- Exemption from performing abortions: Idaho Code § 18-612
- ? Abortion exemption from civil and criminal liability for individuals, private and public hospitals, with protection from government consequences
- Exemption from participating in sterilization: Idaho Code §39-3915
- ? Sterilization exemption from civil liability for individuals, private and public hospitals
- Illinois:[Footnote 157: Id. at 32.]
- o Religious Freedom Restoration Act: 775 III. Comp. Stat. § 35/1, et seq.
- Health Care Right of Conscience Act: 745 III. Comp. Stat. § 70/1-70/4
- ? Abortion exemption from civil and criminal liability for individuals, private and public hospitals, with protection from government consequences
- ? Sterilization exemption from civil and criminal liability for individuals, private and public hospitals, with protection from government consequences
- ? Contraceptive exemption from civil and criminal liability for individuals, private and public hospitals, with protection from government consequences
- Indiana:[Footnote 158: Id. at 33.]
- o Religious Freedom Restoration Act: 2015 SB 101, enacted March 26, 2015; 2015 SB 50, enacted April 2, 2015
- o Mandatory participation in abortion: Ind. Code § 16-34-1-4
- ? Abortion exemption for individuals and private hospitals, not limited in medical emergencies

- lowa[Footnote 159: ld. at 34.]
- o Abortions: Iowa Code § 146.1-146.3
- ? Abortion exemption from civil liability for individuals and private hospitals, with protection from government consequences
- Kansas:[Footnote 160: Id. at 35.]
- o Religious Freedom Restoration Act: Kan. Stat. Ann. § 60-5301, et seq.
- o Kan. Stat. Ann. §§ 65-443, 65-444, 65-446, 65-447
- ? Abortion exemption from civil liability for individuals and private and public hospitals, not limited in medical emergencies
- ? Sterilization exemption from civil and criminal liability for individuals, private and public hospitals
- Kentucky:[Footnote 161: Estelle, Religious Liberty in the States 2022, CENTER FOR RELIGION, CULTURE, AND DEMOCRACY, at 36.]
- o Religious Freedom Restoration Act: Ky. Rev. Stat. Ann. § 446.350
- o Abortions: Ky. Rev. Stat. Ann. § 311.800
- ? Abortion exemption from civil liability for individuals and private hospitals, with protection from government consequences; not limited in medical emergencies; public hospitals not permitted to perform abortions except to save life of mother
- ? Sterilization exemption for individuals
- Louisiana:[Footnote 162: Id. at 37.]
- Religious Freedom Restoration Act: La. Rev. Stat. § 13:5231, et seq.
- o Abortion; Discrimination against certain persons: La. Stat. Ann. § 40:1061.2
- Abortion; Discrimination against hospitals, clinics, etc.: La. Stat. Ann. § 40:1061.3
- ? Abortion exemption from civil and criminal liability for individuals and private and public hospitals, with protection from government consequences
- Maine:[Footnote 163: Id. at 38.]
- Immunity and employment protection: Me. Stat. tit. 22, §1591
- Discrimination for abstaining from performing abortions: Me. Stat. tit. 22, § 1592
- ? Abortion exemption from civil liability for individuals and private and public hospitals, with protection from government consequences; not limited in medical emergencies
- o Due process in sterilization: Me. Stat. tit. 34-B, § 7016(1)
- ? Sterilization exemption from civil and criminal liability for individuals and private and public hospitals
- o Family planning services: Me. Stat. tit. 22, § 1903(4)
- ? Contraceptive exemption from criminal liability for individuals and private hospitals
- Maryland:[Footnote 164: Id. at 39.]
- o Md. Code Ann., Health-Gen. § 20-214(a)
- ? Abortion exemption from civil liability for individuals and private and public hospitals, with protection from government consequences
- o Md. Code Ann., Health-Gen. § 20-214(b)
- ? Sterilization exemption from civil liability for individuals and private and public hospitals, with protection from government consequences
- Massachusetts:[Footnote 165: ld. at 40.]
- o Mass. Gen. Laws § 4.1.272.21B, § 1.16.112.12I
- ? Abortion exemption from civil liability for individuals and private hospitals, with protection from government consequences; not limited in medical emergencies
- ? Sterilization exemption from civil liability for individuals and private hospitals, with protection from

government consequences

- ? Contraceptive exemption for private hospitals, with protection from government consequences
- Michigan: [Footnote 166: Estelle, Religious Liberty in the States 2022, CENTER FOR RELIGION, CULTURE, AND DEMOCRACY, at 41.]
- o Mich. Comp. Laws §§ 333.20181-20182
- ? Abortion exemption from civil and criminal liability for individuals and private and public hospitals; not limited in medical emergencies
- Minnesota:[Footnote 167: ld. at 42.]
- o Minn. Stat. § 145.414(a)
- ? Abortion exemption for individuals and private and public hospitals, with protection from government consequences; not limited in medical emergencies
- Mississippi:[Footnote 168: Id. at 43]
- o Religious Freedom Restoration Act: Miss. Code § 11-61-1
- o Abortion: Miss. Code Ann. §§ 41-107-5, -7, -9
- ? Abortion exemption from civil and criminal liability for individuals and private and public hospitals, with protection from government consequences; not limited in medical emergencies
- ? Sterilization exemption from civil and criminal liability for individuals and private and public hospitals, with protection from government consequences
- ? Contraceptive exemption from civil and criminal liability for individuals and private and public hospitals, with protection from government consequences
- o General conscience provision: Miss. Code Ann. § 41-41-215(5)
- ? Providers or institutions may decline to comply with an instruction or health-care decision for reasons of conscience
- o Protection from discrimination for persons declining to participate in gender- transition procedures: Miss. Code Ann. § 11-62-5(1)(a)
- o Definition of religious organization: Miss. Code Ann. § 11-62-17(4)(c)
- Missouri:[Footnote 169: Id. at 44.]
- o Religious Freedom Restoration Act: Mo. Rev. Stat. §1.302 o RSMo. § 197.032,
- ? Abortion exemption from civil liability for individuals and private and public hospitals, with protection from government consequences; not limited in medical emergencies
- Montana:[Footnote 170: Estelle, Religious Liberty in the States 2022, CENTER FOR RELIGION, CULTURE, AND DEMOCRACY, at 45.]
- o Religious Freedom Restoration Act: Mont. Code Ann. § 27-33-101, et seq.
- Exemption from participation in abortion: Mont. Code Ann. § 50-20-111
- ? Abortion exemption from civil liability for individuals and private hospitals, with protection from government consequences; not limited in medical emergencies
- ? Sterilization exemption from civil liability for individuals and private hospitals, with protection from government consequences
- Nebraska:[Footnote 171: Id. at 46.]
- o Neb. Rev. Stat. §§ 28-337, -338
- ? Abortion exemption from civil liability for individuals and private and public hospitals; not limited in medical emergencies

- Nevada:[Footnote 172: Id. at 47.]
- Unlawful to require participation in abortion: Nev. Rev. Stat. § 632.475
- ? Abortion exemption from civil liability for individuals and private hospitals
- New Hampshire: [Footnote 173: Id. at 48.]
- o NH Law Against Discrimination: N.H. Rev. Stat. Ann. § 420-C:5:
- ? Prohibits discrimination from healthcare insurers toward providers on the basis of religion and other protected classes
- o Exemption for religious organizations: N.H. Rev. Stat. Ann. § 354-A:18:
- ? Protects ability of religious institutions or organizations to make selections of admission or hiring based on religious belief
- New Jersey:[Footnote 174: Id. at 49.]
- o N.J. Rev. Stat. § 2A:65A-1, A-2
- ? Abortion exemption from civil and criminal liability for individuals and private and public hospitals; not limited in medical emergencies
- ? Sterilization exemption from civil and criminal liability for individuals and private and public hospitals
- ? Contraceptive exemption from criminal liability
- New Mexico:[Footnote 175: Id. at 50.]
- o Religious Freedom Restoration Act: N.M. Stat. Ann. § 28-22-1, et seg.
- o General conscience provision: N.M. Stat. Ann. §§ 24-7A-7(E), -9(A)
- ? Providers or institutions may decline to comply with an instruction or health-care decision for reasons of conscience.
- ? Abortion exemption from civil and criminal liability for individuals and private and public hospitals; not limited in medical emergencies
- ? Sterilization exemption from civil and criminal liability for individuals and private and public hospitals
- ? Contraceptive exemption from criminal liability
- New York: [Footnote 176: Estelle, Religious Liberty in the States 2022, CENTER FOR RELIGION, CULTURE, AND DEMOCRACY, at 51.]
- o N.Y. Civ. Rights Law §79-I; N.Y. Comp. Codes R & Regs. tit. 10, §405.9(b)(10)
- ? Abortion exemption from civil liability for individuals and private and public hospitals; not limited in medical emergencies
- North Carolina: (Footnote 177: Id. at 52)
- o N.C. Gen. Stat. §§ 14-45.1(e)-(f)
- ? Abortion exemption from civil liability for individuals and private and public hospitals; not limited in medical emergencies
- North Dakota:[Footnote 178: ld. at 53.]
- o N.D. Cent. Code § 23-16-14
- ? Abortion exemption for individuals and private and public hospitals; not limited in medical emergencies
- Ohio:[Footnote 179: Id. at 54.]
- o Ohio Rev. Code Ann. § 4731.91
- ? Abortion exemption from civil liability for individuals and private and public hospitals; not limited in medical emergencies

- Oklahoma:[Footnote 180: Id. at 55.]
- o Religious Freedom Restoration Act: Okla. Stat. tit. 51, § 251, et seq.
- o Okla. Stat. tit. 63 § 1-741
- ? Abortion exemption from civil liability for individuals and private hospitals; not limited in medical emergencies
- Oregon:[Footnote 181: Id. at 56.]
- o Or. Rev. Stat. § 435.485, 435.475, , §106.305(8)
- ? Abortion exemption from civil liability for individuals and private hospitals; not limited in medical emergencies
- o Or. Rev. Stat. § 435.225
- ? Contraceptive and family planning exemption for state employees
- Pennsylvania:[Footnote 182: Id. at 57.]
- o Religious Freedom Restoration Act: Pa. Stat. tit. 71, § 2403
- o 16 Pa. Code § 51.41(a), 16 §51.31(b)
- ? Abortion exemption from civil liability for individuals and private hospitals, with protection from government consequences
- ? Sterilization exemption from civil liability for individuals and private hospitals, with protection from government consequences
- Rhode Island:[Footnote 183: Id. at 58.]
- Religious Freedom Restoration Act: R.I. Gen. Laws § 42-80.1-1, et seq.
- o 23 R.I. Gen, Laws § 17-11
- ? Abortion exemption from civil liability for individuals; not limited in medical emergencies
- ? Sterilization exemption from civil liability for individuals
- South Carolina: [Footnote 184: Estelle, Religious Liberty in the States 2022, CENTER FOR RELIGION, CULTURE, AND DEMOCRACY, at 59.]
- Religious Freedom Restoration Act: S.C. Code § 1-32-10, et seq.
- o S.C. Code Ann. § 44-41-50
- ? Abortion exemption from civil liability for individuals and private hospitals
- South Dakota:[Footnote 185: Id. at 60.]
- Religious Freedom Restoration Act: SB 124 (passed in March 2021)
- o S.D. Codified Laws § 34-23A-11, -12, -13, -14
- ? Abortion exemption from civil liability for individuals and private and public hospitals; not limited in medical emergencies
- Tennessee:[Footnote 186: Id. at 61.]
- o Religious Freedom Restoration Act: § Tenn. Code 4-1-407
- o Tenn. Code Ann. § 39-15-204, -205
- ? Abortion exemption for individuals and private and public hospitals; not limited in medical emergencies
- ? Sterilization exemption from civil liability for individuals and private hospitals
- o Tenn. Code Ann. § 68-34-104(5)
- ? Contraceptive exemption from civil liability for individuals and private hospitals
- Texas:[Footnote 187: Id. at 62.]
- Religious Freedom Restoration Act: Tex. Civ. Prac. & Remedies Code § 110.001, et seq.

- o Tex. OCC § 103.001, § 103.004
- ? Abortion exemption for individuals and private hospitals
- Utah:[Footnote 188: Id. at 63.]
- o Utah Code Ann. § 76-7-306(2),-(3)
- ? Abortion exemption from civil liability for individuals and private and public hospitals; not limited in medical emergencies
- Vermont:[Footnote 189: Id. at 64.]
- o Constitution of the State of Vermont, Art. 3:
- ? "That all persons have a natural and unalienable right, to worship Almighty God, according to the dictates of their own consciences and understandings, as in their opinion shall be regulated by the word of God... nor can any person be justly deprived or abridged of any civil right as a citizen, on account of religious sentiments, or peculia[r] mode of religious worship; and that no authority can, or ought to be vested in, or assumed by, any power whatever, that shall in any case interfere with, or in any manner control the rights of conscience, in the free exercise of religious worship."
- Virginia:[Footnote 190: Estelle, Religious Liberty in the States 2022, CENTER FOR RELIGION, CULTURE, AND DEMOCRACY, at 65.]
- o Religious Freedom Restoration Act: Va. Code § 57-2.02
- o Va. Code Ann. § 18.2-75
- ? Abortion exemption from civil liability for individuals and private and public hospitals; not limited in medical emergencies
- Washington:[Footnote 191: Id. at 66.]
- o Wash. Rev. Code § 9.02.150, § 48.43.065(2)(a)
- ? Abortion exemption for individuals and private and public hospitals; not limited in medical emergencies
- ? Sterilization exemption for individuals and private and public hospitals
- West Virginia:[Footnote 192: Id. at 67.]
- o W. Va. Code § 16-2F-7
- ? Abortion exemption for individuals; not limited in medical emergencies
- o W. Va. Code § 16-11-1
- ? Sterilization exemption for individuals and private and public hospitals
- o W. Va. Code § 16-2B-4
- ? Contraceptive exemption for state employees
- Wisconsin:[Footnote 193: Id. at 68.]
- o Wis. Stat. § 253.09(1),
- ? Abortion exemption from civil liability for individuals and private and public hospitals; not limited in medical emergencies
- ? Sterilization exemption from civil liability for individuals and private and public hospitals o Wis. Stat. § 253.075
- ? Contraceptive and family planning exemption for state employees
- Wyoming:[Footnote 194: Id. at 69.]
- o Wyo. Stat. Ann. § 35-6-106
- ? Abortion exemption from civil liability for individuals and private hospitals; not limited in medical emergencies
- o Wyo. Stat. Ann. § 42-5-101(d)
- ? Contraceptive exemption for individuals

The Department is bound by the Tenth Amendment to respect these state laws, which were enacted before the 2022 Rule was proposed or introduced. The Department must clarify that it is not seeking to preempt these robust protections. 2 7.6.10 10>

<11 8.4.3 2 The Department should also retain the religious freedom and conscience laws listed in the 2020 Rule.[Footnote 195: 45 C.F.R. § 92.6(b).] Many additional healthcare conscience statutes included in the current Rule apply in the healthcare context because they address health insurance, pregnancy conditions, Medicaid and other funded programs. These provisions include:

- Section 1553 of the Patient Protection and Affordable Care Act (42 U.S.C. § 18113) providing assisted suicide exemptions
- Section 1441 of the Affordable Care Act on exemption to Individual mandate of health insurance (42 U.S.C. § 18081)
- Section 1303 of the Patient Protection and Affordable Care Act (42 U.S.C. § 18023)
- The Coats-Snowe Amendment (42 U.S.C. § 238n)
- The Church Amendments (42 U.S.C. § 300a-7)
- The Religious Freedom Restoration Act (42 U.S.C. § 2000bb et seq.)
- The Weldon Amendment (Consolidated Appropriations Act, 2019, Pub. L. 115-245, Div.

B sec. 209 and sec. 506(d) (Sept. 28, 2018)),

Medicare counseling referral 42 U.S.C. 42 U.S.C. § 1395w–22(j)(3)(B)

- Section 1311 certificates of exemption (42 U.S.C. § 18031)
- Advance Directives exemptions (42 U.S.C. § 14406)
- 42 U.S.C. § 1396u-2(b)(3)(B) Medicaid counseling referral exemption
- 22 U.S.C. § 7631 PEPFAR exemption
- 42 U.S.C. § 290bb-36 Mental Health Suicide Program Exemptions
- 42 U.S.C. § 280g-1(d) Children Hearing and Screening
- 42 U.S.C. § 5106i Child Abuse Prevention and Treatment Act
- 42 U.S.C. § 1396s Pediatric Vaccine Non-Preemption of State

The current Section 92.6(b) clarifies which conscience and religious freedom laws apply. [Footnote 196: Id.] The Department's language from the 2020 Rule properly interpreted the scope of the agency's authority not to invalidate by imposing or requiring the departure or contradiction of legal standards, and it listed nine federal statutes which are not contradicted by or superseded by Section 1557. This list included several protections for religious liberty: the Coats-Snowe Amendment, the Church Amendments, and RFRA. This provision also included a catchall provision for "any related, successor, or similar Federal laws and regulations." [Footnote 197: 87 Fed. Reg. 37205.] The new proposed Rule improperly removes this provision, which makes it insufficient and vague because it fails to identify any particular statutes or explain how they should interact with Section 1557. 8.4.3 2 11>

<12 5.3.1 The Department should remove the "lesser standard" provision in proposed Section 92.3, because the statutory language does not use the term "lesser standard" or adopt that rule of construction.[Footnote 198: 87 Fed. Reg. 47911.] Restricting the Department's authority to "limit" the rights, remedies, procedures, or legal standards is not the same as the agency's proposals to "expand" the rights beyond the bounds of the limited discretionary authority given to the Office for Civil Rights and its Director. When Congress has defined a legal standard, the agency may not take a limited interpretation below the lowest bound, because that would be illegal. The agency does not have the authority to impose a ratchet in one direction. The only "additional protections" are limited to those provided in "State laws," which are detailed above. This rule of construction is again a restriction on the Department's authority to preempt state law. It would be unreasonable to interpret this restriction on power of the federal government as a grant of [Italics: additional] authority to the agency over states by redefining bases of discrimination. It should also be noted that the statutory provision protecting the "rights" of "individuals aggrieved" expressly includes victims of [Italics:</p>

religious] discrimination.[Footnote 199: 87 Fed. Reg. 47841; see 18 U.S.C. § 18116(a) referring to 42 U.S.C. § 2000e-2, which expressly prohibits discrimination on the basis of religion.] 5.3.1 12>

<13 2 IV. The Department Must Comply with the Affordable Care Act.

The only legal "authority" that the Department relies on for this regulatory action is 42 U.S.C. § 18116 (Section 1557), so the Department is bound by principles of textualism to adhere to this text as written by Congress, and not depart from it in exercising legislative power instead of its administrative power under the Constitution. Part (b) is a rule of construction which restricts the Department's interpretative authority under Section 1557, and does not delegate authority to the agency to "invalidate" rights, remedies, procedures, or legal standards.

The proposed Rule violates Section 1554 of the Affordable Care Act, 42 U.S.C. § 18114, which prevents the Secretary from promulgating 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 200: 42 U.S.C. § 18114.]

The proposed Rule would violate these provisions by restricting the ability of healthcare providers to provide full disclosure about the potential risks and ethical problems with certain forms of treatment, violating the ethical standards of healthcare professionals with religious or philosophical objections to participating in gender-transition procedures, and impeding timely access to healthcare by driving some religious providers out of the market altogether. 2 13>

<14 12.1.2 A. The proposed Rule violates the ACA by dramatically expanding the scope of covered entities.

The Department has dramatically expanded the number of covered entities to include individuals and entities never before under the Department's scope of authority under Section 1557 or the underlying statutes. For example, the proposed Rule adds recipients of pass-through funding, advance tax credit, cost-sharing entities, Section 1332 waivers, Medicare reimbursements, Medicaid, and fee-for-service CHIP programs.

The Department does not calculate the number of new entities that would be added as "covered entities" under Section 1557 by its broadened scope. The Department makes the vague claim that "the costs of the proposed rule are small relative to the revenue of covered entities . . . and because even the smallest affected entities would be unlikely to face a significant impact," but the Department does not provide any more detail to prove this claim.[Footnote 201: 87 Fed. Reg. 47899.]

The Department cannot certify that the proposed Rule will not have a significant economic impact on a substantial number of small entities. The Department has violated the Civil Rights Restoration Act by not limiting its covered entities to those principally engaged in healthcare. The interpretation of this statute is overbroad and will burden providers who are newly covered by this regulation. 12.1.2 14>

<15 6.2.3 6.2.4 6.2.5 6.2.6 B. The proposed Rule conflicts with the ACA by defining "protected class" differently.

The proposed Rule's interpretation of sex as non-binary is in direct conflict with the ACA, which uses binary terminology such as "he or she" in employment nondiscrimination provisions. [Footnote 202: Section 1558, Affordable Care Act, 29 U.S.C. § 218C.] The drafters of the ACA did not use terminology to include other pronouns of other gender identities than male or female, more than two genders, or protected genders under civil rights of the ACA. Section 1557 must be interpreted consistently with the ACA.

The drafting of the proposed Rule is confusing and inconsistent because of its addition of new protected classes related to gender identity and sexual orientation. In the preamble, the Department adds additional protected bases to Section 1557, but such definitions do not appear in the rule text or the underlying statutes. Sometimes the Department uses the term "sex" but other times it uses different terminology. That inconsistency makes the rule difficult to understand and, if enacted, difficult to apply and enforce.

In proposed Section 92.101(a)(2), the Department identifies additional protected classes to include "sex stereotypes," "sex characteristics," "intersex traits," "sexual orientation," "gender identity," "pregnancy," and pregnancy "related conditions." [Footnote 203: 87 Fed. Reg. 47858.] And the Department also adds a catchall "not limited to." The preamble also lists "nonbinary," "gender nonconforming" "genderqueer" and "genderfluid", "transgender," and "LGBT+." [Footnote 204: 87 Fed. Reg. 47858.] In the preamble, the agency also provides a definition of "+": "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 205: 87 Fed. Reg. 47831, n.77.] Yet none of these terms appear anywhere in the enacted rule text of Section 1557, or in Bostock, on which the Department attempts to rely. In Bostock, the only term the Court used is "transgender," and the Court expressly did not create "one catchall protected class covering all conduct correlating to 'sexual orientation' and 'gender identity." [Footnote 206: Bostock, 140 S. Ct. at 1737; State of Texas v. EEOC, No. 74 Civ. 2:21-CV-194-Z (N.D. Tex. Oct. 1, 2022), at 6.] When defining "transgender" in the preamble (but not the rule text), the Department adds additional undefined terms that are confusing: "nonbinary, gendergueer, or gender nonconforming." [Footnote 207: 87 Fed. Reg. 47831, n.75.] These terms differ from the language used in other portions of the ACA. The Department needs to provide further definitions, or at the very least, explain the reasons for its changes in language. 6.2.3 6.2.4 6.2.5 6.2.6 15>

<16 5.7.2 8.1 C. The proposed Rule includes new mandatory conduct requirements that unconstitutionally impose on religious liberty.

The proposed Nondiscrimination Policy in Section 92.8(b) is problematic because it requires all covered entities to implement written nondiscrimination policies that impact a variety of areas.[Footnote 208: 87 Fed. Reg. 47914.] Religious individuals and organizations have robust rights to free speech which are protected by the First Amendment as well as federal and state laws. The nondiscrimination policy regarding "pregnancy, sexual orientation, gender identity, and sex characteristics" unconstitutionally constrains freedom of speech about these topics and freedom of association with a group or religion that takes a position on these issues.[Footnote 209: 87 Fed. Reg. 47914.] 5.7.2 8.1 16>

<17 8.1 6.2.1 If the proposed Rule is enacted, religious organizations, which have been expressly exempted under Title IX regarding issues such as sex-segregated facilities and are exempt under Title III of the ADA, will have to adopt new policies that may affect their faith-based internal decisions regarding single-sex facilities.

The Department tries to distinguish the Title IX exemptions and their applicability in healthcare versus education by making claims about how individuals make choices related to healthcare. They elevate secular considerations of "availability, convenience, urgency, geography, cost, insurance network restrictions." [Footnote 210: 87 Fed. Reg. 47840.] This ignores important choices based on religion and ethics, especially in African American communities which rely more heavily on faith-based healthcare options. [Footnote 211: Louis Brown, Eliminating medical conscience rights threatens human dignity and the freedom to love, THE HILL (Apr. 29, 2022), https://thehill.com/opinion/healthcare/3471359-eliminating-medical-conscience-rights-threatens-human-dignity-and-the-freedom-to-love/.] Contrary to the agency's contention in its preamble that the choice of healthcare providers is "unrelated to the question of whether the healthcare provider is controlled by or affiliated with a religious organization," [Footnote 212: 87 Fed. Reg. 47840.] many persons of faith specifically choose healthcare providers who share their faith. Similarly, many religious Americans choose to work for employers who provide benefits consistent with their faith, or intentionally pursue training on sexual or medical health at religiously affiliated healthcare institutions.

Members of religious orders, such as the Little Sisters of the Poor and the Religious Sisters of Mercy, take vows of membership in single-sex religious communities or houses of worship. Many of these organizations provide health insurance for their employees or others. These organizations and their members often have deeply held religious commitments to celibacy or consecrated single life, abiding by sincerely held beliefs and tenets regarding human sexuality, marriage, abortion, homosexual conduct, contraception, and sterilization.[Footnote 213: See, e.g., Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania, 140 S. Ct. 2367, 2375–76 (2020) (The Little Sisters "are an international congregation of Roman Catholic religious [women]" who have operated homes for the elderly poor in the United States since 1868. They feel called by their faith to care for their elderly residents regardless of "faith, finances, or frailty." Consistent with their Catholic faith, the Little Sisters hold the religious conviction "that deliberately avoiding reproduction through medical means is immoral."); see also Forms of Consecrated Life, U.S. CONFERENCE OF CATHOLIC BISHOPS, https://www.usccb.org/beliefs-and- teachings/vocations/consecrated-life/forms-of-consecrated-life.] 8.1 6.2.1 17>

<18 5.6.1 8.1 In proposed Section 92.7, the Department is also coercing covered entities to designate a Section 1557 coordinator to administer policies on sexual orientation, gender identity, and termination of pregnancy. However, this implicates the authority to hire co-religionists, which is robustly protected under constitutional law and Title VII.[Footnote 214: Our Lady of Guadalupe Sch. v. Morrissey-Berru, 140 S. Ct. 2049 (2020); Hosanna-Tabor Evangelical Lutheran Church and Sch. v. EEOC, 565 U.S. 171 (2002).] Many religious organizations require their employees to abide by statements of faith or religious codes of conduct, and this ability is critical to ensure the effective operation of the organization and preservation of its sincere religious identity. Requiring religious organizations to hire Section 1557 coordinators who may have fundamentally different beliefs and viewpoints would compromise these core religious liberties. 5.6.1 8.1 18>

In sum, the proposed Rule violates RFRA, the First Amendment, the ACA, and it causes conflict with state laws and federal court decisions. We urge the Department to reconsider its proposed Rule and protect religious liberty for healthcare providers, institutions, and the millions of Americans who choose and rely on faith-based medical care.

Sincerely,

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U.S. Department of Health and Human Services Office for Civil Rights Attention: 1557 NPRM (RIN 0945–AA17) Hubert H. Humphrey Building, Room 509F 200 Independence Avenue SW Washington, DC 20201

RE: Department of Health and Human Services, Nondiscrimination in Health Programs and Activities, Proposed Rule HHS-OS-2022-0012-0001, RIN 0945-AA17 (August 4, 2022)

The National Center for Transgender Equality and the Transgender Law Center (collectively "the Protect Trans Health coalition" or "Protect Trans Health") write in response to the Department of Health and Human Services' ("HHS" or "the Department") and the Office for Civil Rights' ("OCR") (collectively "the agency") proposed rule changes on "Nondiscrimination in Health Programs and Activities," pursuant to Section 1557 of the Affordable Care Act ("ACA").1 We strongly support HHS' efforts to ensure broad, robust, and clear protections to prohibit discrimination in health care. This rulemaking is especially important in light of rampant, concerted, and escalating efforts to strip transgender people of self-determination and bodily autonomy across the country. The last few years have seen an onslaught of bills and extra-legal policies that target and criminalize healthcare for transgender and nonbinary people, as well as people who may become pregnant, leaving people terrified to seek healthcare and providers reluctant to provide it, unsure of legal responsibilities and prohibitions. This threat has escalated in the wake of the Supreme Court's devastating decision in Dobbs v. Jackson Women's Health Organization.<sup>2</sup> Providers and patients need clarity, now more than ever, and we are grateful for HHS' efforts to bring the rule's language into alignment with Section 1557's intent. We also recommend strengthening the proposed rule further to advance the purpose of Section 1557 and increase access to affirming, safe, and supportive healthcare for all people living in the United States.

Founded in 2003, the National Center for Transgender Equality ("NCTE") works to improve the lives of the nearly two million transgender people in the United States and their families through sound public policy, public education, and groundbreaking research. NCTE has worked with countless health and human service providers as well as local, state, and federal agencies on policies to ensure equal access to vital health and human services. In 2015, NCTE conducted the U.S. Transgender Survey, the largest

<sup>1 42</sup> U.S.C. § 18116.

<sup>2 142</sup> S. Ct. 2228 (2022).

survey to date of transgender people, with nearly 28,000 respondents from all 50 states and the U.S. territories.<sup>3</sup>

Transgender Law Center ("TLC") is the largest national trans-led organization advocating self-determination for all people. Grounded in legal expertise and committed to racial justice, TLC employs a variety of community-driven strategies to keep transgender and gender nonconforming people alive, thriving, and fighting for liberation. TLC believes in justice and liberation for all trans people, and that means change that starts with the people most impacted by the systems we fight — including trans people in prison, Black and brown trans migrants, Black trans women, trans people living with HIV, and trans youth. In addition to bringing strategic litigation to advance legal protections for transgender and nonbinary people, TLC's Legal Information Helpdesk provides legal information to anyone who submits an inquiry about laws and policies that affect transgender people across many areas, including employment, health care, housing, civil rights, immigration, prisoners' rights, and identity document changes.

Founded in 2003, Transgender Legal Defense and Education Fund ("TLDEF") is a 501(c)(3) nonprofit whose mission is to end discrimination and achieve equality for transgender people, particularly those in our must vulnerable communities. Our strategies include pathbreaking transgender rights cases and amicus curiae briefs regarding key issues of employment, health care, education, and public accommodations. Through our Trans Health Project, TLDEF takes a comprehensive, systematic approach to expanding access to transgender-related health care by educating affected individuals about their legal rights; cultivating a robust movement to achieve health care equity; expanding enforcement of existing legal protections; and driving clinical policy changes among insurance carriers. Through this work, TLDEF has gained first-hand experience assisting transgender people who have experienced discrimination in the U.S. healthcare system, particularly through discriminatory health insurance denials, which we bring to bear in this Comment.

The Protect Trans Health coalition first formed in 2019, when the prior presidential administration threatened to gut nondiscrimination protections for transgender and nonbinary people. NCTE and TLC then launched a campaign to raise awareness about the harmful impact of the regulations introduced in 2019 and finalized in 2020 that attempted to reverse the robust interpretation of Section 1557 and encourage the public to submit comments opposing it. That rulemaking has been challenged, and enjoined in large part, in several ongoing lawsuits, including one litigated by TLC and TLDEF along with others. Protect Trans Health has again come together in 2022, now co-led by our partners at TLDEF and supported by 140 additional organizations, to solicit public comment in response to this proposed rule through our website portal available at protecttranshealth.org.

We offer the following recommendations based on our organizations' experience and the stories shared with us by thousands of community members.

Executive Summary of Protect Trans Health's Recommendations:

<sup>&</sup>lt;sup>3</sup> Sandy E. James *et al.*, "The Report of the 2015 U.S. Transgender Survey" (Washington: National Center for Transgender Equality, 2016) (hereinafter "James, USTS"), *available at* <a href="https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf">https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf</a>.

The Protect Trans Health coalition **supports the overwhelming majority** of HHS' proposals in its Notice of Proposed Rulemaking<sup>4</sup> ("proposed rule" or "NPRM"). In particular, we support the agency's interpretation of discrimination on the basis of sex including explicitly including gender identity and sex stereotypes, sex characteristics including intersex traits, and pregnancy or related conditions. The proposed rule correctly acknowledges that discrimination "on the basis of sex" or "because of sex" includes discrimination based on gender identity consistent with the U.S. Supreme Court's holding in *Bostock v. Clayton County* and is consistent with the vast majority of jurisprudence regarding sex discrimination under Title VII, Title IX, and in other contexts, including the interpretation of Section 1557.5

We make the following recommendations to strengthen the proposed rules and to increase their effectiveness in eliminating discrimination:

- HHS should work with other federal agencies, including the Department of Justice, to extend the
  protections outlined in the proposed rule to other non-health programs and activities through a
  separate rulemaking.
- The definition of prohibited sex discrimination in § 92.101 of the proposed rule should be used uniformly throughout the rule.
- Covered entities requesting religious exemptions should be required to provide notice of
  exemptions in their notices of non-discrimination or, in the alternative, the Office for Civil Rights
  should publish a periodic list of covered entities claiming religious exemptions, so that patients
  have advance notice when choosing medical providers or insurance plans.
- Because discrimination can occur on multiple axes of identity at once, language should be added
  that expressly addresses intersectionality, making it clear that individuals may bring complaints
  of discrimination on the basis of multiple protected bases in a single complaint.
- Discrimination on the basis of sex necessarily includes "transgender status" (including nonbinary status), as well as the other categories of discrimination already described in the proposed rule.
   Language should be added further clarifying that discrimination on these bases is also prohibited.
- It is crucial in light of the Supreme Court's recent decision in Dobbs v. Jackson Women's Health
  Organization that language be added to the rule clarifying that discrimination on the basis of
  pregnancy or related conditions includes discrimination on the basis of pregnancy termination.
- The language in § 92.207(b)(4) should be modified to clarify that the provision applies to any denial of gender-affirming care, as well abortion and reproductive health services.
- Language should be added to § 92.207 clarifying prohibited forms of pregnancy-related discrimination.

#### Structure of the Comment

In addition to providing specific comments on the proposed rulemaking, this comment also provides critical context for our recommendations. Part I outlines the need for the proposed rulemaking, first addressing in Part I.A. how discrimination against transgender people results in negative health outcomes, then explaining in Part I.B. how the proposed rulemaking will resolve legal confusion arising

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<sup>&</sup>lt;sup>4</sup> Nondiscrimination in Health Programs and Activities, 87 FR 47824, (proposed Aug. 4, 2022), (hereinafter "NPRM).

<sup>5</sup> See Part I.B, infra.

from years of litigation around the regulation promulgated in 2016 ("the 2016 Rule")<sup>6</sup>, the 2020 rule ("Rollback Rule")<sup>7</sup>, and judicial decisions not in line with the Supreme Court's decision in *Bostock v*. *Clayton County*. Recognizing the significant disinformation that exists around gender-affirming healthcare – as well as the extent to which such disinformation is likely to appear in comments opposed to the draft rule, Part II then addresses the medical science regarding gender-affirming healthcare, including the fact major health professional associations – including the American Medical Association, the Endocrine Society, the American Psychiatric Association, the American Psychological Association, the American College of Physicians, the American Osteopathic Association, and the American College of Obstetrics and Gynecology – endorse gender-affirming care or call for its coverage by insurance. Finally, Part III provides commentary on the proposed rule itself, offering recommendations on how it can be drafted to even more effectively protect transgender people.

#### The return of explicit nondiscrimination protections for transgender and nonbinary people under Section 1557 is sound public policy and supported by law

Access to comprehensive, inclusive, and affirming health care is of vital importance for transgender and nonbinary people across the United States. Research demonstrates that transgender and nonbinary people experience high rates of psychological distress and suicidality, family rejection, homelessness, substance use, and violence as a result of pervasive discrimination and inequities.<sup>8</sup>

While being transgender or nonbinary need not and should not be a barrier to well-being, the fact remains that transgender and nonbinary people today suffer disparately poor health outcomes linked with inequitable access to healthcare and health insurance. Transgender and nonbinary people face discriminatory treatment when seeking treatment from providers across the health care delivery system: from nurses and doctors to intake coordinators and insurers. And far too many transgender people

<sup>&</sup>lt;sup>6</sup> See Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (May 18, 2016) (codified at 45 C.F.R. § 92 (2019)).

<sup>&</sup>lt;sup>7</sup> See Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2020).

<sup>8</sup> A. Jess Williams et al., A systematic review and meta-analysis of victimisation and mental health prevalence among LGBTQ+ young people with experiences of self-harm and suicide, 16 PLoS ONE e0245268 at 11 (2021), available at <a href="https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0245268">https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0245268</a>; Andrew Yockey et al, Past-Year Suicidal Ideation Among Transgender Individuals in the United States, 26 ARCHIVES OF SUICIDE RESEARCH 70 (2022), available at <a href="https://www.tandfonline.com/doi/abs/10.1080/13811118.2020.1803165?journalCode=usui20">https://www.tandfonline.com/doi/abs/10.1080/13811118.2020.1803165?journalCode=usui20</a>; James, USTS, supra note 3 at 5. See also Nat'l Acads. Of Scis. Engineering and Medicine, Understanding the Health and Wellbeing of LGBTQI+ Populations (2020) at 317-318 (concluding that transgender and LGBQI people experience health disparities "driven by social forces, such as racism, sexism, and xenophobia"), available at <a href="https://www.nap.edu/read/25877/chapter/1">https://www.nap.edu/read/25877/chapter/1</a>; Nat'l Acads. Of Scis. Engineering and Medicine, Understanding the Health and Wellbeing of LGBTQI+ Populations (2020) at 317-18 (concluding that transgender and LGBQI people experience health disparities "driven by social forces, such as stigma, prejudice, and discrimination" that may be "compounded by intersecting stressors, such as racism, sexism, and xenophobia"), available at <a href="https://www.nap.edu/read/25877/chapter/1">https://www.nap.edu/read/25877/chapter/1</a>.

<sup>9</sup> James, USTS, supra note 3, at 93-98.

<sup>&</sup>lt;sup>10</sup> James, USTS, supra note 3, at 5, 92-103.; Caroline Medina et al., Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities (2022), available at <a href="https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/">https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/</a> (Noting that in 2021 alone, 37% of transgender people avoided needed medical and 41% preventative screenings care because of previously experienced discrimination).

postpone or forgo both preventive and urgently needed medical care due to experiences of discrimination.

As transgender led organizations that work on a national and local level, we are intimately familiar with the pervasive discrimination experienced by transgender and nonbinary people within healthcare settings. We also witness how access to affirming and comprehensive healthcare can vastly improve the lives of our diverse communities. Therefore, we write in support of full, explicit textual protections for transgender and nonbinary people in Section 1557.

A. Transgender people face heightened discrimination in access to healthcare and health insurance and are disproportionately reliant on programs funded by the Department of Health and Human Services

Due to longstanding and pervasive social stigma, many transgender people have struggled to get access to any and all medically necessary care—including not only gender-affirming care or that recommended to treat gender dysphoria,<sup>11</sup> but also medical care for unrelated conditions. Numerous studies have documented the widespread and pervasive discrimination experienced by transgender people in the health care system.<sup>12</sup> In 2015, NCTE conducted the U.S. Transgender Survey ("USTS"), which examined the experiences of transgender people in the United States, with 27,715 respondents from all fifty states, the District of Columbia, American Samoa, Guam, Puerto Rico, and U.S. military bases overseas.<sup>13</sup> The USTS found that in just the year prior to taking the survey, one-third (33%) of respondents who saw any health care provider during that year were turned away because of being transgender, denied treatment, physically or sexually assaulted in a health care setting, or faced another form of mistreatment or discrimination due to being transgender.<sup>14</sup>

endocrine systems, deriving from an atypical interaction of sex hormones and the developing brain, which results in a person being born with circulating hormones and primary/secondary sex characteristics inconsistent with the person's gender identity, characterized by clinically significant distress associated with one's assigned sex at birth. See Ferdinand J.O. Boucher and Tudor I. Chinnah, Gender Dysphoria: A Review Investigating the Relationship Between Genetic Influences and Brain Development, 11 Adolescent Health & Med. Therapeutics 89, 90 (2020), available at <a href="https://www.dovepress.com/gender-dysphoria-a-review-investigating-the-relationship-between-genet-peer-reviewed-fulltext-article-AHMT">https://www.dovepress.com/gender-dysphoria-a-review-investigating-the-relationship-between-genet-peer-reviewed-fulltext-article-AHMT</a>. See also American Psychiatric Association, Diagnostic & Statistical Manual Of Mental Disorders (5th ed. 2022). This text revision updated the text in its definition of "gender dysphoria" to use culturally-sensitive language, e.g., "desired gender" was changed to "experienced gender," "cross-sex medical procedure" was updated to "gender affirming medical procedure," "cross-sex hormone treatment to "gender affirming hormone treatment," "natal male" to "individual assigned male at birth" and "natal female" to "individual assigned female at birth". Moreover, "differences in sex development" was noted to be an alternate term for "disorders of sex development."

<sup>&</sup>lt;sup>12</sup> See Janis Renner et al., Barriers to Accessing Health Care in Rural Regions by Transgender, Non-Binary, and Gender Diverse People: A Case-Based Scoping Review, 12 FRONTIERS IN ENDOCRINOLOGY at 2 (2021), available at <a href="https://www.frontiersin.org/articles/10.3389/fendo.2021.717821">https://www.frontiersin.org/articles/10.3389/fendo.2021.717821</a>; Neena K. Aggarwal et al., Health and Health Care Access Barriers Among Transgender Women Engaged in Sex Work: A Synthesis of U.S.-Based Studies Published 2005-2019, 8 LGBT HEALTH 11 (2021), available at <a href="https://www.liebertpub.com/doi/10.1089/lgbt.2019.0243">https://www.liebertpub.com/doi/10.1089/lgbt.2019.0243</a>; Michelle Teti et al., A Qualitative Scoping Review of Transgender and Gender Non-conforming People's Physical Healthcare Experiences and Needs, 9 FRONTIERS IN PUBLIC HEALTH at 18-19 (2021), available at

https://www.frontiersin.org/articles/10.3389/fpubh.2021.598455 (last visited Sep 28, 2022).

<sup>13</sup> James, USTS, supra note 3, at 21.

<sup>&</sup>lt;sup>14</sup> James, USTS, supra note 3, at 96-97.

Experiences with discrimination were common across a wide range of health providers and services. For example, in the year prior to taking the survey:

- Nearly one-quarter (22%) of respondents who visited a drug or alcohol treatment program where staff thought or knew they were transgender were denied equal treatment or service, verbally harassed, or physically assaulted there due to being transgender;<sup>15</sup>
- One in seven (14%) respondents who resided in or visited a nursing home or extended care
  facility where staff thought or knew they were transgender were denied equal treatment or
  service, verbally harassed, or physically assaulted there due to being transgender;<sup>16</sup> and,
- One-quarter (25%) of respondents experienced a problem with their health insurance related to being transgender. This included being denied coverage for medical treatments for gender dysphoria as well as being denied coverage for unrelated preventive screenings, primary care, or other medical treatment simply because they are transgender.<sup>17</sup>

Similarly, a nationally representative 2022 study found that out of those who had visited a doctor or health care provider in the previous year, one in five transgender or nonbinary respondents reported that a healthcare provider refused to document evidence of gender dysphoria or readiness to provide gender affirming care.<sup>18</sup>

Transgender and nonbinary people also experience disparities in accessing reproductive and sexual health care. Several studies have found that transgender men eligible for cervical cancer screenings are less likely to receive them than cisgender women.<sup>19</sup> The 2015 USTS also found that transgender people faced barriers to reproductive and sexual health screenings and treatment, and received this care at lower rates. Among respondents assigned female at birth, only 27% report a Pap smear in the previous year, compared with 43% in the U.S. adult population.<sup>20</sup> In the previous year, more than one in eight (13%) of those who sought coverage for services typically considered to be gender-specific (such as Pap smears, prostate exams, and mammograms), were denied because of being transgender.<sup>21</sup> A recent qualitative study including interviews with transgender and nonbinary patients found that the most common barriers for accessing contraception and abortion related care are health insurance denials, limited knowledge of healthcare providers, lack of affirming service provision, and previous experiences with discrimination.<sup>22</sup> Studies indicate that this gap leads to increased risks for poor health outcomes for

<sup>15</sup> James, USTS, supra note 3, at 216.

<sup>&</sup>lt;sup>16</sup> James, USTS, supra note 3, at 219.

<sup>&</sup>lt;sup>17</sup> James, USTS, supra note 3, at 95.

<sup>18</sup> Medina, supra note 10.

<sup>&</sup>lt;sup>19</sup> Kayla C. Hatos, A Literature Review of Cervical Cancer Screening in Transgender Men, 22 NURSING FOR WOMEN'S HEALTH 52, 55 (2018), available at

https://www.sciencedirect.com/science/article/pii/S1751485117303380?via%3Dihub. See also Sarah M. Peitzmeier, et al. Pap Test Use Is Lower Among Female-to-Male Patients Than Non-Transgender Women, 47 Am. J. PREV. MED. 808 (2014), available at https://www.ajpmonline.org/article/S0749-3797(14)00398-5/fulltext.

<sup>20</sup> James, USTS, supra note 3, at 102.

<sup>&</sup>lt;sup>21</sup> James, USTS, supra note 3, at 96.

<sup>&</sup>lt;sup>22</sup> Laura Fix et al., Stakeholder Perceptions and Experiences Regarding Access to Contraception and Abortion for Transgender, Non-Binary, and Gender-Expansive Individuals Assigned Female at Birth in the U.S., 49 ARCH SEX BEHAV 2683 at 2689-2690 (2020).

transgender people and their families.<sup>23</sup> These are a few examples of how transgender and nonbinary people experience discrimination outside of gender affirming specific care. Yet, they illustrate the importance of comprehensively addressing discrimination against transgender and nonbinary people across all forms of healthcare.

## 1. Transgender people who face intersectional systemic inequities face even more discrimination in access to healthcare and health insurance

We support the agency's proposed uniform enforcement mechanism at proposed section 92.304(a) and (b) as transgender and nonbinary people with marginalized intersecting identities face compounding impacts of discrimination based on these identities, such as racism, ageism, ableism and other forms of discrimination. Thus, transgender and nonbinary people should have the ability to bring complaints of discrimination on the basis of multiple identities in a single complaint, have their complaints considered as a whole as part of a single investigation, and be subject to a single uniform standard, as the proposed rule provides.

Transgender people of color face higher discrimination rates than both their white transgender peers and their cisgender peers of color. While one-third (33%) of respondents to the USTS who had seen a provider in the past year reported having at least one negative experience with a doctor or other health care provider related to being transgender, that rate increased to 50% for American Indian respondents, 40% among Middle Eastern respondents and 38% among multiracial respondents. Transgender people of color also report higher discrimination in emergency rooms, with doctors and hospitals, and when seeking services of ambulances and emergency medical technicians (EMTs), all of which, once again, leads to lower health care utilization and places transgender people of color at higher risk of chronic health conditions.<sup>24</sup> A recent qualitative study looking at health outcomes of transgender people of color found that transgender people of color are often faced with transphobic and racist stereotypes when accessing health care.<sup>25</sup> For example, respondents noted that healthcare providers made negative

<sup>&</sup>lt;sup>23</sup> See e.g., Monica Hahn et al., Providing Patient-Centered Perinatal Care for Transgender Men and Gender-Diverse Individuals: A Collaborative Multidisciplinary Team Approach, 134(5) Obstetrics & Gynecology 959, 963 (2019), available at

https://journals.lww.com/greenjournal/Fulltext/2019/11000/Providing\_Patient\_Centered\_Perinatal\_Care\_for.9.
aspx; Jennifer Hoffmann & Ashlee Bergin, Contraception, Abortion and More: Understanding Health Disparities for
LBGTQ Patients in their Own Words, 133 Obstetrics & Gynecology Suppl. 1 at 76S (2019), available at
https://journals.lww.com/greenjournal/Abstract/2019/05001/Contraception,\_Abortion\_and\_More\_\_Understand
ing.262.aspx; Stacey L. Williams & Abbey K. Mann, Sexual and Gender Minority Health Disparities as a Social Issue:
How Stigma and Intergroup Relations Can Explain and Reduce Health Disparities, 73(3) J. Social Issues 450 (2017),
available at https://spssi.onlinelibrary.wiley.com/doi/abs/10.1111/josi.12225; Lucy Stackpool-Moore et al, Linking
Sexual and Reproductive Health and Rights and HIV Services for Young People: The Link Up Project, 60(2) J. Adol.
HEalth at S3, S3-S4 (2017), available at https://www.jahonline.org/article/S1054-139X(16)30861-8/fulltext; Kelly
Walker, Megan Arbour & Justin Waryold, Educational Strategies to Help Students Provide Respectful Sexual and
Reproductive Health Care for Lesbian, Gay, Bisexual, and Transgender Persons, 61(6) J. MIDWIFERY & WOMEN'S HEALTH
737 (2016), available at https://onlinelibrary.wiley.com/doi/10.1111/jmwh.12506.

<sup>&</sup>lt;sup>24</sup> See Shanna K. Kattari et al, Racial and ethnic differences in experiences of discrimination in accessing health services among transgender people in the United States, 16 INT'L J. TRANSGENDERISM 68 (2015), available at <a href="https://www.tandfonline.com/doi/full/10.1080/15532739.2015.1064336">https://www.tandfonline.com/doi/full/10.1080/15532739.2015.1064336</a>.

<sup>&</sup>lt;sup>25</sup> Susanna D. Howard *et al.*, *Healthcare Experiences of Transgender People of Color*, 34 J. Gen. Intern. Med. 2068, at 2072 (2019), *available at* <a href="https://link.springer.com/article/10.1007/s11606-019-05179-0">https://link.springer.com/article/10.1007/s11606-019-05179-0</a>.

assumptions about their education, their resources, or their professions, all of which damaged their relationship with their healthcare provider.<sup>26</sup>

Further, transgender people with disabilities experience significant barriers to accessing appropriate care. A 2022 study found that transgender people with disabilities are four times more likely to be unable to see a doctor as needed, three times more likely to be unable to get prescription medication as needed or see a specialist, and more than two and half times more likely to report having at least one unmet healthcare need compared to cisgender people with disabilities.<sup>27</sup> The 2015 USTS found that transgender respondents with disabilities were more likely to report at least one negative experience with a health provider in the past year compared to respondents who did not identify as having a disability. These findings are particularly important given that transgender adults in are substantially more likely to have a disability, as defined by the American Community Survey (ACS), than the general U.S. population. About four in ten (39%) USTS respondents had a disability, nearly three times the rate in the adult population.<sup>28</sup> This rate is even higher among people of color; for example, the rate reached 55% among American Indian and Alaska Native respondents.<sup>29</sup>

As a population, transgender and nonbinary people are at a greater risk for contracting HIV.<sup>30</sup> Of the total respondents in the USTS, 1.4% were living with HIV, which is nearly five times the rate in the U.S. population.<sup>31</sup> However, there are significant differences by race and gender among respondents. Transgender women are more than ten times as likely as transgender men to be living with HIV, at 3.4 percent. The rate among Black respondents was substantially higher at 6.7 percent, and the rate for Black transgender women was a staggering 19%.<sup>32</sup> American Indian (4.6%) and Latina (4.4%) transgender women reported notably higher rates as well – more than three times as likely as the overall sample to be living with HIV.<sup>33</sup>

Transgender people living with HIV experience unique forms of healthcare discrimination and stigma, leading to even further healthcare avoidance. A needs assessment survey of transgender people living with HIV in the United States found that 41% of respondents had gone six months or longer without medical care since their HIV diagnosis.<sup>34</sup> Transgender people with HIV who were previously incarcerated or detained (51%) were significantly more likely to have gone without medical care for

<sup>26</sup> Id.

<sup>&</sup>lt;sup>27</sup> Abigail Mulcahy et al, Gender Identity, Disability, and Unmet Healthcare Needs among Disabled People Living in the Community in the United States, 19 INT. J. ENVIRON. RES. PUBLIC HEALTH 2588, at 10 (2022), available at <a href="https://www.mdpi.com/1660-4601/19/5/2588">https://www.mdpi.com/1660-4601/19/5/2588</a>.

<sup>28</sup> James, USTS, supra note 3, at 57.

<sup>29</sup> Id.

<sup>&</sup>lt;sup>30</sup> See Centers for Disease Control and Prevention, HIV and Transgender People (2022), available at <a href="https://www.cdc.gov/hiv/group/gender/transgender/index.html">https://www.cdc.gov/hiv/group/gender/transgender/index.html</a>; Stefan D. Baral et al, Worldwide Burden of HIV in Transgender Women: A Systematic Review and Meta-Analysis, 13(3) LANCET INFECTIOUS DISEASES 214, 217-18 (2013), available at <a href="https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(12)70315-8/fulltext">https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(12)70315-8/fulltext</a>; Jamie M. Grant et al., Injustice at Every Turn: A Report of the National Transgender Discrimination Survey at 80 (2011); Sari L. Reisner et al, Global Health Burden and Needs of Transgender Populations: A Review, 388 LANCET INFECTIOUS DISEASES 412, 427 (2016), available at <a href="https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)00684-X/fulltext">https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)00684-X/fulltext</a>.

<sup>31</sup> James, USTS, supra note 3, at 122-123.

<sup>32</sup> James, USTS, supra note 3, at 122-123.

<sup>33</sup> James, USTS, supra note 3, at 122-23.

<sup>&</sup>lt;sup>34</sup> Cecilia Chung, et al., Positively Trans: Initial report of a national needs assessment of transgender and gender non-conforming people living with HIV at 7, (2016), available at <a href="http://transgenderlawcenter.org/wp-content/uploads/2016/02/PositivelyTrans-2015-7-border-FINAL.pdf">http://transgenderlawcenter.org/wp-content/uploads/2016/02/PositivelyTrans-2015-7-border-FINAL.pdf</a>

more than 6 months those never detained (35%).<sup>35</sup> The most common reason respondents reported for going without healthcare for more than 6 months was previous or anticipated discrimination by a healthcare provider (29%).<sup>36</sup>

The Administration on Aging has reported that LGBT older Americans are less likely than their non-LGBT counterparts to receive screenings, diagnoses and treatment for important medical problems.<sup>37</sup> In part because of fear of discriminatory treatment, more than one in five (22%) of LGBT older adults chose not to disclose their LGBT status to physicians;<sup>38</sup> while this may serve to protect them from discrimination because of their sexual orientation or gender identity, it may also negatively impact the care they receive because their physician may not know to provide certain screenings. Further, due to high levels of family rejection and poverty, transgender older adults are more likely to be eligible for, and to need assistance from, federally-funded Medicare and Medicaid programs that support older Americans.

Above are a few examples of the ways that transgender and nonbinary people experience multiple forms of discrimination at once or in tandem, demonstrating the need to be able file a single complaint encompassing, which will be evaluated as a whole under a uniform standard. We further strongly support the proposed rules' explicit inclusion of Medicare Part B under the definition of Federal Financial Assistance to further clarify that transgender older adults are fully and explicitly protected from discrimination.

# 2. Transgender people are disproportionately reliant on HHS-funded healthcare programs due to the effects of systemic discrimination

We strongly support the NPRM's expansion of nondiscrimination rules to "[e]very health program or activity, any part of which receives Federal financial assistance," as well as to "[e]very health program or activity administered by [HHS]" or a Title I entity.<sup>39</sup> This is particularly needed given that transgender people are more likely to be eligible for, and to need assistance from, care from safety-net providers funded by HHS grants. Research suggests that transgender people are much more likely than the general population to rely on safety-net providers such as Federally Qualified Health Centers, Community Health Centers, Title X clinics, or hospital emergency rooms. For example, a major national survey found that while 60% of transgender adults primarily received health care through a private doctor's office, 24% relied on a community health center or free clinic, 4% on the Veterans Health Administration, 2% on other providers, and 4% on hospital emergency rooms.<sup>40</sup> Additionally, there are an estimated 152,000 transgender adults covered by Medicaid.<sup>41</sup> Further, transgender Medicare beneficiaries suffer disproportionately worse health, evidenced by a higher number of chronic conditions than their

<sup>35</sup> Id at 7.

<sup>36</sup> Id. at 8.

<sup>&</sup>lt;sup>37</sup> See Administration for Community Living, Long-term Care Considerations for LGBT Adults (last modified Mar. 16, 2022), available at <a href="https://acl.gov/ltc/basic-needs/pathfinder/long-term-care-considerations-lgbt-adults">https://acl.gov/ltc/basic-needs/pathfinder/long-term-care-considerations-lgbt-adults</a>.

<sup>38</sup> Id.

<sup>39</sup> NPRM, supra note 4, at § 92.2.

<sup>40</sup> Grant, supra note 30, at 73.

<sup>&</sup>lt;sup>41</sup> Christy Mallory & William Tentindo, MEDICAID COVERAGE FOR GENDER-AFFIRMING CARE at 22 (2019), available at <a href="https://williamsinstitute.law.ucla.edu/wp-content/uploads/Medicaid-Gender-Care-Oct-2019.pdf">https://williamsinstitute.law.ucla.edu/wp-content/uploads/Medicaid-Gender-Care-Oct-2019.pdf</a>.

cisgender peers.<sup>42</sup> These healthcare differentials are even worse for transgender individuals who are marginalized along multiple axes of identity.<sup>43</sup> Given that transgender and nonbinary people experience discrimination across many facets of their lives and likely across a variety of federally funded programs, it's critical that HHS work with other federal departments to enforce section 1557 across all HHS funded healthcare programs.

## B. The Consensus Among Courts is That Sex Discrimination Necessarily Encompasses Discrimination Against Transgender People

The ACA contains a landmark civil rights provision prohibiting discrimination in federally funded healthcare and health insurance. Section 1557<sup>44</sup> incorporates the antidiscrimination provisions of several civil rights statutes, including Title IX of the Education Amendments of 1972 ("Title IX"),<sup>45</sup> which prohibits discrimination "on the basis of sex." Federal jurisprudence interpreting statutes that prohibit sex discrimination is therefore instructive for defining protections under the ACA. The proposed rule correctly acknowledges that discrimination "on the basis of sex" or "because of sex" includes discrimination based on gender identity consistent with the U.S. Supreme Court's holding in *Bostock v. Clayton County.*<sup>46</sup> The proposed rule is consistent with the vast majority of jurisprudence regarding sex discrimination under Title VII, Title IX, and in other contexts, including the interpretation of Section 1557.

### 1. The proposed rule is consistent with federal jurisprudence regarding sex discrimination

a. The proposed rule is consistent with Supreme Court precedent

Prior to *Bostock*, the overwhelming consensus of federal courts held that employers could not discriminate against transgender employees under Title VII of the Civil Rights Act of 1964 ("Title VII")<sup>47</sup> because of the employee's failure to conform to sex stereotypes or gender norms. Three decades ago, the Supreme Court held in *Price Waterhouse v. Hopkins* that Title VII's proscription of discrimination "because of . . . sex" prohibited employers from taking adverse employment actions based on an employee's failure to conform to sex stereotypes.<sup>48</sup> *Oncale v. Sundowner Offshore Services, Inc.*, lent further support to this interpretation by holding that Title VII not only prohibits the types of sex discrimination that Congress specifically considered when enacting it but also that the statute can "go beyond the principal evil [Title VII sought to address] to cover reasonably comparable evils," 49 holding that same sex harassment violates Title VII. <sup>50</sup>

<sup>&</sup>lt;sup>42</sup> Christina N. Dragon et al, *Transgender Medicare Beneficiaries and Chronic Conditions: Exploring Fee-for-Service Claims Data*, 4(6) LGBT HEALTH 404, 404 (2017), *available at* <a href="https://psycnet.apa.org/record/2017-55484-006">https://psycnet.apa.org/record/2017-55484-006</a>. ("[Transgender Medicare Beneficiaries] under age 65 show an already heavy chronic disease burden which will only be exacerbated with age.")

<sup>43</sup> See Part I.A.1, supra.

<sup>44 42</sup> U.S.C. § 18116.

<sup>45 20</sup> U.S.C. § 1681.

<sup>&</sup>lt;sup>46</sup> 140 S. Ct. 1731 at 1737-38, 1743-45, 1753 (2020) (using Title VII's phrase "because of . . . sex" and Title IX's phrase "on the basis of sex" interchangeably).

<sup>47 42</sup> U.S.C. § 2000e-2(a)(1).

<sup>48</sup> Price Waterhouse v. Hopkins, 490 U.S. 228, 240 (1989).

<sup>49</sup> Oncale v. Sundowner Offshore Servs., Inc., 523 U.S. 75, 79 (1998).

<sup>50</sup> Id. at 78.

Federal courts that considered the interplay between Title VII and discrimination against transgender people prior to *Bostock* easily found that such discrimination unlawfully relies on the same gender-based considerations prohibited by the Supreme Court's holdings in *Price Waterhouse* and *Oncale*. Following those decisions, federal appellate courts overwhelmingly agreed that discrimination based on transgender status and sex stereotypes is unlawful under the definition of "sex." District courts across the country have also held that a transgender person can bring claims under Title VII when alleging discrimination due to nonconformity with sex stereotypes. According to the Eleventh Circuit in *Glenn v. Brumby*, Title VII's protections against sex discrimination "are afforded to everyone, [therefore] they cannot be denied to a transgender individual." The analysis cannot and should not change just because the plaintiff alleging discrimination is transgender. After all, "[b]y definition, a transgender individual does not conform to the sex-based stereotypes of the sex that he or she was assigned at birth." Set

In *Bostock*, the Supreme Court affirmed this precedent by holding that sex discrimination under Title VII necessarily includes discrimination on the basis of transgender status. The Court explained that "[s]ex plays a necessary and undisguisable role in the decision" to fire "an individual for being [...] transgender" because the employer "fires that person for traits or actions it would not have questioned in members of a different sex."<sup>55</sup> As such, the Court held that "transgender status [is] inextricably bound up with sex."<sup>56</sup> Although *Bostock* was decided within the context of employment discrimination under Title VII, its reasoning is applicable to all sex discrimination laws because any discrimination based on gender identity turns on the sex of the targeted person.<sup>57</sup> Moreover, *Bostock* affirmed that discrimination based on gender identity can exist even when adverse action is not exclusively based on sex. So long as sex is a but-for cause of discrimination — that is, if changing the sex of the individual would yield a different result — a statutory prohibition against sex discrimination has been violated.<sup>58</sup>

Since Bostock, federal appeals courts have rightfully overturned lower court decisions that conflict with the Supreme Court's holding, affirming that gender identity is necessarily a protected basis under Title

<sup>&</sup>lt;sup>51</sup> See, e.g., Smith v. City of Salem, Ohio, 378 F.3d 566, 575 (6th Cir. 2004) (holding that discrimination against transgender people "is no different from the discrimination directed against Ann Hopkins in *Price Waterhouse*, who, in sex-stereotypical terms, did not act like a woman"); see also EEOC v. R.G. & G.R. Harris Funeral Homes, Inc., 884 F.3d 560, 572 (6th Cir. 2018); Chavez v. Credit Nation Auto Sales, LLC, 641 F. App'x 883, 884 (11th Cir. 2016); Glenn v. Brumby, 663 F.3d 1312, 1316 (11th Cir. 2011); Barnes v. City of Cincinnati, 401 F.3d 729, 741 (6th Cir. 2005). The Tenth Circuit also left open an avenue for a transgender employee to bring a claim for discrimination under Title VII where that employee faced adverse action based on perceived nonconformity to sex stereotypes. See Etsitty v. Utah Transit Auth., 502 F.3d 1215, 1224 (10th Cir. 2007).

<sup>&</sup>lt;sup>52</sup> See, e.g., EEOC v. A&E Tire, Inc., 325 F. Supp. 3d 1129, 1135 (D. Colo. 2018); Parker v. Strawser Constr., Inc., 307 F. Supp. 3d 744, 755–60 (S.D. Ohio 2018); Roberts v. Clark Cnty. Sch. Dist., 215 F. Supp. 3d 1001, 1014 (D. Nev. 2016); Fabian v. Hosp. of Cent. Conn., 172 F. Supp. 3d 509, 527 (D. Conn. 2016); Finkle v. Howard Cnty., 12 F. Supp. 3d 780, 788 (D. Md. 2014); Lopez v. River Oaks Imaging & Diagnostic Grp., Inc., 542 F. Supp. 2d 653, 660 (S.D. Tex. 2008); Schroer v. Billington, 577 F. Supp. 2d 293, 305 (D.D.C. 2008); Mitchell v. Axcan Scandipharm, No. Civ. A 05–243, 2006 WL 456173, at \*2 (W.D. Pa. Feb. 17, 2006); Kastl v. Maricopa Cnty. Cmty. Coll. Dist., No. Civ. 02–1531, 2004 WL 2008954, at \*2–3 (D. Ariz. June 3, 2004); Tronetti v. Healthnet Lakeshore Hosp., No. 03–cv–0375E, 2003 WL 22757935, at \*4 (W.D.N.Y. Sept. 26, 2003).

<sup>53</sup> Glenn, 663 F.3d at 1319.

<sup>54</sup> Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ., 858 F.3d 1034, 1048 (7th Cir. 2017).

<sup>55 140</sup> S. Ct. at 1737.

<sup>56</sup> Id. at 1742.

<sup>&</sup>lt;sup>57</sup> See id. at 1741 (holding that "it is impossible to discriminate against a person for being [...] transgender without discriminating against that individual based on sex").

<sup>58</sup> See id.

VII's prohibition against sex discrimination.<sup>59</sup> As such, *Bostock* overturned erroneous lower court decisions that misconstrued gender identity as outside the purview of Title VII's protections.

#### b. The proposed rule is consistent with Title IX precedent

The proposed rule is consistent with jurisprudence regarding sex discrimination under Title IX, including the prior precedent affirmed by *Bostock*. Courts have generally construed Title IX's antidiscrimination provision consistently with Title VII.<sup>60</sup> Moreover, Justice Alito's dissent in *Bostock* anticipated that the Court's ruling would be "virtually certain to have far-reaching consequences" because "[o]ver 100 federal statutes prohibit discrimination because of sex," namely Title IX and the ACA.<sup>61</sup> That foresight was correct. In *Grimm v. Gloucester County School Board*, the Fourth Circuit applied *Bostock's* reasoning in the context of Title IX, holding that a school board's policy that precluded a transgender plaintiff from using a restroom aligned with his gender identity violated Title IX by discriminating "on the basis of sex" since the plaintiff's sex was a "but-for cause for the Board's actions."<sup>62</sup>

# c. The proposed rule's inclusion of gender identity correctly interprets 1557's prohibition against discrimination based on sex

The proposed rule is consistent with jurisprudence regarding Section 1557. Since the ACA explicitly incorporates Title IX and because Title VII is instructive for determining Title IX's protections, "Bostock is [...] the appropriate test to determine whether a policy discriminates in violation of the ACA." Even prior to Bostock, courts have rightfully upheld that the plain and unambiguous language of Section 1557 prohibits discrimination against transgender people because they are transgender.

<sup>62</sup> 972 F.3d 586, 616 (4th Cir. 2020); see also Adams v. Sch. Bd. of St. Johns Cnty., 968 F.3d 1286, 1305 (11th Cir. 2020) (petition for rehearing en banc granted, 9 F.4th 1369 (11th Cir. 2021)).

<sup>&</sup>lt;sup>59</sup> See, e.g., Tudor v. Se. Okla. State Univ., 13 F.4th 1019, 1028 (10th Cir. 2021) (holding that discrimination based on transgender status was sex discrimination prohibited by Title VII, invalidating the defendant's reliance on overruled precedent that held otherwise); Roberts v. Glenn Indus. Grp., Inc., 998 F.3d 111, 121 (4th Cir. 2021) (holding that Bostock permitted an employee to establish sexual harassment claims under Title VII "where the plaintiff was perceived as not conforming to traditional male stereotypes").

<sup>&</sup>lt;sup>60</sup> See, e.g., Doe v. Snyder, 28 F.4th 103, 113–14 (9th Cir. 2022); Emeldi v. Univ of Or., 698 F.3d 715, 725 (9th Cir. 2012) ("[T]he Supreme Court has often 'looked to its Title VII interpretations of discrimination in illuminating Title IX'" (quoting Olmstead v. L.C. ex rel. Zimring, 527 U.S. 581, 616 n.1 (1999) (Thomas, J., dissenting))); Franklin v. Gwinnett Cnty. Pub. Sch., 503 U.S. 60, 75 (1992) ("Congress surely did not intend for federal moneys to be expended to support the intentional actions it sought by statute to proscribe.").

<sup>61 140</sup> S. Ct. at 1778-82 (Alito, J., dissenting).

<sup>&</sup>lt;sup>63</sup> Kadel v. Folwell, No. 1:19CV272, 2022 WL 3226731, at \*29 (M.D.N.C. Aug. 10, 2022); see also Hammons v. Univ. of Md. Med. Sys. Corp., 551 F. Supp. 3d 567, 590 (D. Md. 2021).

<sup>&</sup>lt;sup>64</sup> See Rumble v. Fairview Health Servs., No. 14-cv-2037, 2015 WL 1197415, at \*26 (D. Minn. March 16, 2015) (holding that if a plaintiff's subpar medical treatment "was because of . . . transgender status, then . . . [the conduct] serves as a basis for Plaintiff's Section 1557 claim"); Prescott v. Rady Child.'s Hosp.-San Diego, 265 F. Supp. 3d 1090, 1100 (S.D. Cal. 2017) (denying a children's psychiatric hospital's motion to dismiss, finding that its employees' repeated misgendering of a transgender patient in the hospital's care made out a cognizable claim for sex discrimination under the ACA); Tovar v. Essentia Health, 342 F. Supp. 3d 947, 953 (D. Minn. 2018) (on remand, 857 F3d 771, 779 (8th Cir 2017)) (denying a motion to dismiss by an employer and an administrator of the employer's health insurance plan by finding that the plan's exclusion of gender affirming care could constitute sex discrimination under the ACA); Flack v. Wis. Dep't of Health Servs., 395 F. Supp. 3d 1001, 1015, 1022 (W.D. Wis. 2019) (granting summary

In the wake of *Bostock*, courts have overwhelmingly affirmed that the Section 1557 protects gender identity and rebuked the Rollback Rule that repealed a definition of discrimination on the basis of sex that explicitly and correctly included "gender identity." <sup>65</sup> Courts have held that HHS acted "arbitrarily and capriciously" and "contrary to law" in enacting the Rollback Rule by disregarding the clear mandate under *Bostock*. <sup>66</sup> In *BAGLY v. United States Department of Health and Human Services*, the court held that the plaintiffs pled a "plausible inference that anti-transgender animus was a motivating factor in the decision to promulgate" the Rollback Rule. <sup>67</sup> In *Doe v. Snyder*, the Ninth Circuit ruled that a district court acted erroneously by narrowly construing *Bostock* as only applicable to Title VII claims. <sup>68</sup> As such, the proposed rule correctly interprets that Section 1557 forbids discrimination based on gender identity.

The proposed rule's interpretation of discrimination on the basis of sex is necessary to reflect the purpose of the ACA and judicial consensus, and to reduce confusion

Congress enacted the ACA in 2010 to expand healthcare access and remove significant barriers to insurance coverage.<sup>69</sup> In 2016, HHS issued the 2016 Rule, which interpreted Section 1557's civil rights protections.<sup>70</sup> The 2016 Rule defined discrimination "on the basis of sex" as including "discrimination on the basis of . . . sex stereotyping, and gender identity."<sup>71</sup> It also prohibited categorical coverage exclusions for gender affirming care and required covered entities to "treat individuals consistent with their gender identity" in accordance with the majority of precedent regarding sex discrimination.<sup>72</sup> However, on June 19, 2020, four days after *Bostock* was decided, HHS promulgated the Rollback Rule that repealed this definition, sowing confusion and uncertainty regarding the status of the ACA's civil rights protections for gender identity and sexual orientation.<sup>73</sup> By removing the 2016 Rule's definition of "on the basis of sex," the Rollback Rule disregarded *Bostock* and the weight of applicable federal case law and threatened to arbitrarily and unlawfully strip statutorily-guaranteed healthcare rights from transgender and nonbinary people. Indeed, the Rollback Rule was subsequently enjoined by multiple federal courts on precisely this basis.<sup>74</sup>

judgment to plaintiffs—a class of transgender patients who were Medicaid recipients—and permanently enjoining the challenged exclusion of gender-affirming care as a violation of Section 1557); *Boyden v. Conlin*, 341 F. Supp. 3d 979, 997 (W.D. Wis. 2018) (granting summary judgment to transgender state employees by holding that the state's exclusion of gender affirming care from insurance coverage violated Section 1557).

<sup>&</sup>lt;sup>65</sup> See Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2020).

<sup>&</sup>lt;sup>66</sup> See, e.g., Walker v. Azar, 480 F. Supp. 3d 417, 420, 429 (E.D.N.Y. 2020); Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health and Hum. Servs., 485 F. Supp. 3d 1, 42 (D.D.C. 2020).

<sup>67 557</sup> F. Supp. 3d 224, 246 (D. Mass. 2021).

<sup>68 28</sup> F.4th at 113-14.

<sup>&</sup>lt;sup>69</sup> Congressional Budget Office, Letter to the Hon. Nancy Pelosi (Mar. 18, 2010), available at <a href="https://www.cbo.gov/sites/default/files/hr4872\_0.pdf">https://www.cbo.gov/sites/default/files/hr4872\_0.pdf</a>.

<sup>70</sup> See Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375 (May 18, 2016).

<sup>71</sup> Id. at 31,467.

<sup>72</sup> Id. at 31,471-72.

<sup>&</sup>lt;sup>73</sup> See, e.g., First Amended Complaint at ¶¶ 208-209, BAGLY v. United States Department of Health and Human Services, 557 F. Supp. 3d 224, 246 (D. Mass. 2021) (No. 1:20-cv-11297-PBS).

<sup>&</sup>lt;sup>74</sup> See, e.g., BAGLY v. U.S. Dep't of Health and Human Services, 557 F. Supp. 3d 224 (D. Mass. 2021); Walker v. Azar, No. 20-CV-2834 (E.D.N.Y. Aug. 17, 2020); Whitman-Walker Clinic, Inc. v. Department of Health and Human Services, No. 20-1630 (D.D.C. Sept. 2, 2020).

In promulgating the Rollback Rule, HHS erroneously relied<sup>75</sup> on an outlying district court decision in *Franciscan Alliance, Inc. v. Burwell.*<sup>76</sup> In *Franciscan Alliance*, the court misconstrued Section 1557 by interpreting that Title IX's "prohibition of sex discrimination unambiguously prevented discrimination on the basis of the biological differences between males and females," which it found was a "separate and distinct [basis] of discrimination" from gender identity.<sup>77</sup> The court then issued a preliminary injunction against enforcing the 2016 Rule's prohibition of gender identity discrimination.<sup>78</sup> Plaintiffs have since been granted a permanent injunction.<sup>79</sup> The *Franciscan Alliance* decision, however, was issued nearly four years before the Supreme Court's contrary decision in *Bostock* – a case that HHS failed to even mention in the Rollback Rule, despite it having been decided a mere four days prior.<sup>80</sup>

Similarly, in *Religious Sisters of Mercy v. Azar*, a case that is currently pending before the Eighth Circuit Court of Appeals, the Biden-Harris administration has appealed a decision by the district court of North Dakota to permanently enjoin HHS from "interpreting or enforcing Section 1557 of the ACA . . . in a manner that would require [the plaintiffs] to preform or provide insurance coverage for gender-transition procedures." 81

But while Franciscan Alliance and Religious Sisters of Mercy are likely to be pointed to by opponents of the proposed rules, it is crucial to emphasize that the two decisions are outliers and are inconsistent with the decisions of the majority of courts that have considered regulations under Section 1557.82 The two cases reflect an outdated understanding of discrimination on the basis of sex, an understanding that has been put firmly to rest not only in Bostock itself, but in the string of court decisions that have enjoined the Rollback Rule.

The outlying decisions in *Franciscan Alliance* and *Religious Sisters of Mercy* do, however, put into sharp relief why the proposed regulations are so important. Due to the confusion sown by these outlying cases, it is critical that HHS provide clear guidance of the correct interpretation of 1557's prohibition against discrimination on the basis of sex. The vast majority of federal case law suggests that the *Franciscan Alliance* and *Religious Sisters of Mercy* decisions misinterpret the plain meaning of Section 1557's prohibition on sex discrimination and should be superseded by *Bostock*, which made clear that "it is impossible to discriminate against a person for being [...] transgender without discriminating against that individual based on sex."83 This is critical for the public to understand their rights as patients, as evidenced by the experiences of transgender and nonbinary people who forgo necessary care due to fear of discrimination, as well as for regulated entities to understand their obligations under 1557.

The proposed rule is also necessary to bring HHS policy and public understanding of the law in line with actions taken by the Biden-Harris administration since January 2021. In light of the *Bostock* decision,

<sup>79</sup> Franciscan All. v. Becerra, No. 21-11174, 2022 WL 3700044, at \*1 (5th Cir. Aug. 26, 2022).

<sup>&</sup>lt;sup>75</sup> Nondiscrimination in Health and Health Education Programs or Activities, 84 Fed. Reg. 27,846, 27,848 (June 19, 2019).

<sup>&</sup>lt;sup>76</sup> 227 F. Supp. 3d 660 (N.D. Tex. 2016).

<sup>77 227</sup> F. Supp. 3d at 688-89.

<sup>78</sup> Id. at 696.

<sup>80</sup> See Nondiscrimination in Health and Health Education Programs or Activities, 84 Fed. Reg. 27,846.

<sup>81</sup> Religious Sisters of Mercy v. Azar, 513 F. Supp. 3d 1113, 1153 (D.N.D. 2021).

<sup>&</sup>lt;sup>82</sup> See, e.g., BAGLY v. U.S. Dep't of Health and Human Services, 557 F. Supp. 3d 224 (D. Mass. 2021); Walker v. Azar, No. 20-CV-2834 (E.D.N.Y. Aug. 17, 2020); Whitman-Walker Clinic, Inc. v. Department of Health and Human Services, No. 20-1630 (D.D.C. Sept. 2, 2020).

<sup>83</sup> See 140 S. Ct. at 1741.

on January 20, 2021, President Biden signed Executive Order 13988, which affirmed that federal antidiscrimination laws prohibiting sex discrimination necessarily "prohibit discrimination on the basis of gender identity [...] so long as the laws do not contain sufficient indications to the contrary."84 That order directed federal agencies to review all "existing orders, regulations, guidance documents, policies, programs, or other agency actions" that implement antidiscrimination provisions on the basis of sex and extend those protections to gender identity.85 In compliance with Executive Order 13988, HHS issued a notification in May of 2021 affirming that it would "interpret and enforce Section 1557's prohibition on the basis of sex to include: [...] discrimination on the basis of gender identity."86 In March of 2022, HHS' Office for Civil Rights released further notice affirming that Section 1557 prohibits discrimination based on gender identity, including restrictions to gender-affirming care. 87 Three lawsuits are currently pending in Tennessee, Texas, and North Dakota that seek to invalidate HHS's May 2021 notification, and the Attorney General of Texas has filed a lawsuit challenging the March 2022 guidance. This litigation poses further risk of confusion regarding the scope and effect of Section 1557's protections.

Taken together, the 2016 Rule, its repeal by the Rollback Rule, cross-cutting lower court decisions enjoining both rules at least in part, Executive Order 13988, subsequent notifications by HHS, and pending lawsuits challenging those notifications have introduced significant uncertainty into what implementing regulations are actually in force, confusing what should be a straightforward application of Section 1557's prohibition on discrimination on the basis of sex. More than three decades of federal court decisions, culminating in Bostock, have affirmed that gender identity discrimination is necessarily encompassed by federal civil rights prohibitions against sex discrimination, including Section 1557. We commend the proposed rule for rectifying past errors in the interpretation of the law and for seeking to implement Section 1557 in accordance with the overwhelming consensus of federal jurisprudence.

#### II. Gender-affirming Healthcare is Supported by Every Major Medical Association and Backed by Extensive Scientific Study88

We strongly support the agency's proposed prohibitions against the denial of gender-affirming care in 92.206 and 92.207.89 Contrary to the misinformed arguments of anti-trans advocacy efforts,90 gender

85 Id. at 7023-24.

<sup>84</sup> Exec. Order No. 13988, 86 Fed. Reg. 7023 (January 20, 2021).

<sup>86</sup> Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, 86 Fed. Reg. 27,984 (May 25, 2021).

<sup>87</sup> U.S. Department of Health and Human Services Office of Civil Rights. HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy, (2022).

<sup>88</sup> The authors include Section II. to respond to the misinformed arguments advanced by anti-trans activists that are not supported by science.

<sup>89</sup> See proposed rule section 92.206(b)(4) ("a covered entity must not Deny or limit health services sought for purpose of gender transition or other gender-affirming care [...] based on a patient's assigned sex at birth, gender identity or gender otherwise recorded"; and section 92.206(c) ("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"); and 92.207(b)(4) (prohibiting categorical exclusions of gender affirming care).

<sup>90</sup> See Kellan E. Baker et al., Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review, 5 J ENDOCR. Soc. bvab011 (2021).; Jeremy A. Wernick et al., A Systematic Review of the Psychological Benefits of Gender-Affirming Surgery, 46 UROL. CLIN. NORTH AM. 475 (2019); Taciana Silveira Passos, Marina Sá Teixeira & Marcos Antonio Almeida-Santos, Quality of Life After Gender Affirmation Surgery: a Systematic Review and Network Meta-analysis, 17 SEX RES. SOC. POLICY 252 (2020).

affirming healthcare is safe, effective, scientifically supported, and medically necessary. Genderaffirming care, which encompasses a broad range of safe and scientifically-supported treatments and resources, such as counseling, laser hair removal, voice training, puberty suppression, hormone replacement therapy, and more, is critical to transgender and nonbinary people's physical, mental, and social health needs and well-being.

## A. Comprehensive gender-affirming healthcare is endorsed by every major medical association

Transgender and nonbinary people work with their doctors to determine the best treatments for them, considering their personal, medical, and social needs. Medical associations that endorse comprehensive gender-affirming health care for transgender people include the American Academy of Pediatrics ("AAP"),<sup>93</sup> Endocrine Society,<sup>94</sup> Pediatric Endocrine Society ("PES"),<sup>95</sup> American Medical Association ("AMA"),<sup>96</sup> American Psychiatric Association ("APA"),<sup>97</sup> American Academy of Child and Adolescent Psychiatry ("AACAP"),<sup>98</sup> the American College of Osteopathic Pediatricians ("ACOP"),<sup>99</sup> the National Association of Pediatric Nurse Practitioners ("NAPNAP"),<sup>100</sup> the American College of Obstetricians and

<u>2018-Discrimination-Against-Transgender-and-Gender-Diverse-Individuals.pdf.</u>

<sup>&</sup>lt;sup>91</sup> See, e.g., Ivy H. Gardner, Joshua D. Safer, Progress on the Road to Better Medical Care for Transgender Patients, 20(6) CURRENT OPIN. ENDOCRINOLOGY DIABETES & OBES. 553 (2013), available at <a href="https://journals.lww.com/co-endocrinology/Abstract/2013/12000/Progress on the road to better medical care for.9.aspx;">https://journals.lww.com/co-endocrinology/Abstract/2013/12000/Progress on the road to better medical care for.9.aspx;</a> Sari L. Reisner, Asa Radix & Madeline B. Deutsch, Integrated and Gender-Affirming Transgender Clinical Care and Research, 72 Suppl 3 J. ACQUIR. IMMUNE DEFIC. SYNDR. S235 (2016).

<sup>&</sup>lt;sup>92</sup> See, e.g., University of California San Francisco, Voice and Speech Therapy | Gender Affirming Health Program (last visited Sept. 28, 2022), available at <a href="https://transcare.ucsf.edu/voice-and-speech-therapy%09">https://transcare.ucsf.edu/voice-and-speech-therapy%09</a>; Eli Coleman et al., Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, 23 INT'L J. OF TRANSGENDER HEALTH S1 (2022).

<sup>&</sup>lt;sup>93</sup> See Jason Rafferty, Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents, 142 14 (2018).

<sup>&</sup>lt;sup>94</sup> See Endocrine Society, *Transgender Health: An Endocrine Society Position Statement* (Dec. 16, 2020), available at .https://www.endocrine.org/advocacy/position-statements/transgender-health.

<sup>&</sup>lt;sup>95</sup> See Pediatric Endocrine Society, Transgender Care: Introduction to Health for Transgender Youth (July 17, 2020), available at .https://pedsendo.org/patient-resource/transgender-care/.

<sup>\*</sup> See American Medical Association, Issue brief: Health insurance coverage for gender-affirming care of transgender patients at 5 (2019), available at .https://www.ama-assn.org/system/files/2019-03/transgender-coverage-issue-brief.pdf.

<sup>%</sup> See Jack Drescher & Eric Yarbrough, American Psychiatric Association, Position Statement on Discrimination Against Transgender and Gender Diverse Individuals at 2 (2018), available at .https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Position-

<sup>\*\*</sup> See AACAP, Transgender and Gender Diverse Youth (2020), available at .https://www.aacap.org/AACAP/Families\_and\_Youth/Facts\_for\_Families/FFF-Guide/transgender-and-gender-diverse-youth-122.aspx.

<sup>\*\*</sup> See American College of Osteopathic Pediatricians, ACOP Statement Against Anti-Transgender Health Laws in State Legislation (Apr. 27, 2021), available at . <a href="https://acopeds.org/acop-statement-against-anti-transgender-health-laws-in-state-legislation/">https://acopeds.org/acop-statement-against-anti-transgender-health-laws-in-state-legislation/</a>.

<sup>&</sup>lt;sup>100</sup> See National Association of Pediatric Nurse Practitioners et al., NAPNAP Position Statement on Health Risks and Needs of Lesbian, Gay, Bisexual, Transgender, and Questioning Youth, 33 J. Ped. Health Care A12 (2019).

Gynecologists ("ACOG"),<sup>101</sup> and the World Professional Association for Transgender Health ("WPATH").<sup>102</sup> These strong endorsements from medical associations provide strong support for proposed rule section 92.207(b)(4), which expressly prohibits covered entities from categorically limiting coverage for gender-affirming care regardless of medical necessity or medical advice.

#### B. Puberty blockers and gender-affirming hormone therapy are non-experimental and are proven safe for both adults and adolescents

Similarly, the draft rules – particularly rules 92.206 and 92.207 – are strongly supported by the evidence surrounding two well-studied gender-affirming treatments, Gonadotropin-releasing hormone analogs (GnRH) and gender-affirming hormone therapy (GAH). GnRH is a standard treatment among transgender adolescents, as it temporarily prevents further pubertal progression. GnRH treatments have long been used to treat early onset puberty, also known as central precocious puberty (CPP). GAH involves using cross-sex hormones to develop secondary sex characteristics in alignment with a patient's gender identity.

The use of GnRH for nearly three decades to treat both CPP and with transgender patients demonstrates that the effects are reversible. Extant evidence indicates that GnRHs and GAH are safe for transgender youth and adults. <sup>105</sup> A 2022 review of current pharmacological treatments for transgender adolescents published in a peer-reviewed journal found that (GnRH) is well tolerated by youth. <sup>106</sup> Research has also found no significant risk between treatment with GAH and cardiovascular disease, decrease in cognitive abilities, or hormone-related tumors. <sup>107</sup>

The impact of GnRH on bone mineral density (BMD) is of particular interest for researchers and medical providers as peak bone mass and density are established during puberty. A recent review published by authors from multiple endocrinology societies found no significant differences in BMD among youth who later stopped taking GnRH and completed puberty compared to those treated with GnRH. Researchers suggest that medical providers monitor BMD among transgender youth treated with GnRH and suggest increasing calcium and weight-bearing exercise. In terms of the impact of GAH on bone density, a longitudinal study in the Netherlands looked at the effects of long-term hormone use over ten

<sup>&</sup>lt;sup>101</sup> See American College of Obstetricians and Gynecologists Committee on Gynecologic Practice and Committee on Health Care for Underserved Women, Committee Opinion Number 823: Health Care for Transgender and Gender Diverse Individuals (2021), available at .
https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals.
102 Coleman, supra note 92.

<sup>&</sup>lt;sup>103</sup> Id.; Claudia Geist et al., Pediatric Research and Health Care for Transgender and Gender Diverse Adolescents and Young Adults: Improving (Biopsychosocial) Health Outcomes, 21 ACAD. PEDIATR. 32 at 35 (2021).

<sup>&</sup>lt;sup>104</sup> See Kanthi Bangalore Krishna et al., Use of Gonadotropin-Releasing Hormone Analogs in Children: Update by an International Consortium, 16.

<sup>&</sup>lt;sup>105</sup> See Michele A O'Connell et al., Approach to the Patient: Pharmacological Management of Trans and Gender-Diverse Adolescents, 107 J. CLINICAL ENDOCRINOLOGY & METABOLISM 241 (2022).

<sup>&</sup>lt;sup>106</sup> Sebastian E E Schagen et al., Bone Development in Transgender Adolescents Treated With GnRH Analogues and Subsequent Gender-Affirming Hormones, 105 J. CLINICAL ENDOCRINOLOGY & METABOLISM e4252 at 4255-4257 (2020). <sup>107</sup> Thomas McFarlane, Jeffrey D. Zajac & Ada S. Cheung, Gender-affirming hormone therapy and the risk of sex hormone-dependent tumours in transgender individuals – A systematic review, 89 CLINICAL ENDOCRINOLOGY 700 at 707 (2018).; Maria A Karalexi, Gender-affirming hormone treatment and cognitive function in transgender young adults\_a systematic review and meta-analysis, 9 (2020) at 3; O'Connell, supra note 105 at 249.

<sup>108</sup> See Krishna, supra note 104.

<sup>109</sup> O'Connell, supra note 105 at 250.

years among 1,254 transgender people and found no impact on BMD.<sup>110</sup> Thus, the overall body of research demonstrates that GnRH and GAH are safe to use relative to BMD.

Another area of interest is the impact of GnRH and gender-affirming hormone treatment (GAH) on transgender people's fertility. Research on youth who use GnRH to treat CPP and later go on complete puberty has shown little impact on their future fertility potential.<sup>111</sup> For those who continue with GAH, current research suggests that the effects on ovarian tissue and functions are reversible with breaks in treatment.112

One study looked at the effects of testosterone treatment on ovarian reserve through measurement of Serum anti-Müllerian Hormone (AMH) after three months and 12 months of treatment and found that AMH levels slightly decreased but remained within the normal range. 113 Additionally, they looked at cross-sectional data for transgender men who had received therapy for an average of 35 months and found similar results.114

In alignment with best practices for any treatment that might impact long-term fertility, researchers suggest that medical providers have conversations with their transgender patients about potential fertility preservations and other reproductive health care, further illustrating the importance of safe and holistic clinical practices for transgender people. 115

> C. The Proposed Rule appropriately prohibits limiting access to gender-affirming healthcare as such care increases the social and mental wellbeing of transgender people

The current evidence demonstrates that gender-affirming care is safe with minimal risk of long-term health implications. At the same time, there is overwhelming evidence demonstrating that access to gender-affirming care substantially improves transgender people's overall social and mental well-being. A 2018 systematic review of peer reviewed literature identified more than 50 articles demonstrating that gender-affirming care improves the overall wellbeing of transgender people. 116 A more recent peer reviewed literature review looked at more than 50 articles and found that gender-affirming surgery is associated with reduced rates of suicide attempts, anxiety, depression, and symptoms of gender

<sup>111</sup> See Krishna, supra note 104.

<sup>110</sup> Chantal M Wiepjes et al., Bone Safety During the First Ten Years of Gender-Affirming Hormonal Treatment in Transwomen and Transmen, 34 J. BONE & MINERAL RES. 447 (2019) at 451.

<sup>112</sup> Allison C Mayhew & Veronica Gomez-Lobo, Fertility Options for the Transgender and Gender Nonbinary Patient, 105 J. CLINICAL ENDOCRINOLOGY & METABOLISM 3335 (2020) at 3340.

<sup>113</sup> I. Yaish et al., Functional ovarian reserve in transgender men receiving testosterone therapy; evidence for preserved anti-Müllerian hormone and antral follicle count under prolonged treatment, 36 HUM. REPROD. 2753 at 2756 (2021). 114 Id at 2757.

<sup>115</sup> Mayhew, supra note 112 at 3342.

<sup>116</sup> See Cornell University Public Policy Research Portal, What does the scholarly research say about the effect of gender transition on transgender well-being?, WHAT WE KNOW, https://whatweknow.inequality.cornell.edu/topics/lgbtequality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/.

dysphoria.<sup>117</sup> Further, gender-affirming surgery is associated with higher levels of life satisfaction, happiness, and quality of life.<sup>118</sup>

<sup>117</sup> See Jaime Swan et al., Mental health and quality of life outcomes of gender-affirming surgery: A systematic literature review, J. GAY & LESBIAN MENTAL HEALTH (2022), DOI: 10.1080/19359705.2021.2016537.

The potential of healthcare regret is not something unique to gender-affirming care. Indeed, it is a subject that medical ethicists have addressed more broadly in debates on informed consent and whether treatments should be given to or withheld from patients. See, e.g., Paddy McQueen, The Role of Regret in Medical Decision-making, 20 ETHICAL THEORY & MORAL PRACTICE 1051 (2017), available at https://link.springer.com/article/10.1007/s10677-017-9844-8. According to medical ethicists, some rate of regret is inevitable, but that does not mean that care should be withheld in all cases, as doing so can result in much lower overall wellbeing among potential patients. Id. at 1062. Moreover, blanket denials based on potential regret constitute "a significant affront to one's autonomy and dignity .... This is especially the case given the importance that bodily autonomy has for a person's sense of self-control and dignity." Id. As such, regret in healthcare cannot be understood in a vacuum, but rather must be understood as part of a broader analysis of whether care is effective, and must be assessed in conjunction with other factors such as the severity of the condition treated, the success rate of treatment, and the degree of success. A key purpose of Section 1557 is to ensure that the provision of healthcare is not impaired by discrimination on the basis of sex, including discrimination on the basis of gender identity or transgender status. Where a covered entity considers potential regret only in context of sex-based care, while disregarding concerns over regret for care that is not sex-based, the entity is committing sex discrimination. Likewise, depriving people of the ability to provide or withhold informed consent for healthcare is sex discrimination when it is done only for care that is sex-based. Section 1557 must be applied to ensure regret is not treated any differently in the context of gender-affirming care than in any other context.

When viewed through this lens, arguments about regret as a reason for denying gender-affirming care on a wide scale fall apart. Research has demonstrated that very few transgender people who undergo gender-affirming treatments later experience regret. A retrospective study of the experiences of 6,793 transgender people who received gender-affirming care at a clinic in the Netherlands found that the regret rate was less than 1% among those who received treatment as adults and no cases of regret among those who received care before the age of 18. Chantal M. Wiepjes et al., The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets, 15 J. SEX. MED. 582 (2018). Another study looking specifically at transgender men's experience with chest reconstruction found that rates of regret were close to zero and that those who had surgery experienced significantly less symptoms of chest dysphoria than those who had not yet had surgery. Johanna Olson-Kennedy et al., Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts, 172(5) JAMA PEDIATRICS 431 (2018). https://doi.org/10.1001/jamapediatrics.2017.5440. A systematic review that pooled together the experiences of 7,928 transgender patients across 27 studies found that the pooled prevalence of regret after gender-affirming surgeries was less than 1%. Valeria P. Bustos et al., Regret after Gender-affirmation Surgery: A Systematic Review and Metaanalysis of Prevalence, 9 PLAST. RECONSTR. SURG. GLOB. OPEN e3477 (2021). The most common reasons for regret were related to difficulties with social acceptance, thus highlighting the importance of inclusive and affirming social environments. Id.

<sup>&</sup>lt;sup>119</sup> Potential regret must not detract from nondiscrimination protections. There is no sound medical or policy reasoning for denying someone access to affirming and lifesaving healthcare under the guise of potential regret later in life. The narrative of possible regret is a distraction used to promote discriminatory beliefs and misinformation about transgender and nonbinary people. These narratives provide no legal basis to undermine protections against discrimination, especially as research demonstrates significant positive outcomes from access to gender-affirming healthcare outlined in detail above.

Research has also demonstrated that gender-affirming care has positive psychosocial impacts on transgender youth, which is vital given their exorbitantly high rates of suicidal ideation, depression, anxiety, and lower quality of life. A 2020 systematic review of the treatment of transgender youth with GnRHs found that delaying puberty is associated with increased positive mental health outcomes. <sup>120</sup> A 2022 study looking at the mental health outcomes of 104 transgender youth in Seattle after receiving care for one year observed a 60% decrease in depressive symptoms and a 73% decrease in suicidal ideation. <sup>121</sup> A 2020 cross-sectional study found that transgender people who received pubertal suppression were significantly less likely to experience suicidal ideation later in life than those who wanted treatment but didn't receive it. <sup>122</sup> Similarly, another study found that transgender people who accessed GAH were significantly less likely to experience suicidal ideation than transgender people who had never received GAH. <sup>123</sup> Further, they found that those who received GAH during adolescence had lower odds of suicidal ideation than those who started to receive GAH in adulthood. <sup>124</sup> Therefore, ensuring that transgender youth have access to comprehensive and inclusive medical care is essential to reducing high rates of mental health disparities.

## D. Conclusion: Gender-affirming healthcare is well-supported by medical and scientific evidence

Over the last twenty years, there have been vast improvements in research on gender-affirming care. 125 Currently, there is a well-established body of evidence demonstrating that comprehensive, affirming care is safe and should be made to accessible to all transgender and nonbinary people. 126 As noted previously, transgender and nonbinary people experience high rates of poor psychosocial and medical health outcomes. Yet, this is not inevitable and can be addressed through ensuring they have access to inclusive, caring, and safe healthcare, which should be the goal for all healthcare services no matter the patient's gender identity.

Thus, any categorical exclusions of gender-affirming care are not based on the scientific evidence which clearly and continuously demonstrates that these treatments are safe and necessary for transgender youth and adults, but rather are discriminatory in nature. The undersigned organizations are grateful to see that the proposed rule is consistent with current science and recognized accessible and inclusive

While critics of the proposed rules will no doubt cite this as evidence against provisions in 92.206, 92.207, and elsewhere guaranteeing access to gender-affirming care, HHS must not use the fact that a very small number of individuals later regret their decision to seek gender-affirming healthcare as justification to deny rights to the vast majority of transgender people who benefit significantly from access to such care.

<sup>&</sup>lt;sup>120</sup> Jack L. Turban et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145 PEDIATRICS e20191725 at 5 (2020).

<sup>&</sup>lt;sup>121</sup> Diana M. Tordoff et al., Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care, 5 JAMA NETW OPEN e220978 (2022) at 6.; see, also 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 (2022).

<sup>122</sup> Jack L. Turban et al., Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults, 17 PLOS ONE e0261039 at 5 (2022).

<sup>123</sup> Turban, Pubertal Suppression, supra note 120 at 5.

<sup>&</sup>lt;sup>124</sup> Id at 5.

<sup>&</sup>lt;sup>125</sup> See Asa Radix and Andrew M. Davis, Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons, JAMA 318 (15): 1491 (2017). https://doi.org/10.1001/jama.2017.13540.

<sup>&</sup>lt;sup>126</sup> See David A. Klein et al, Caring for Transgender and Gender-Diverse Persons: What Clinicians Should Know, 98 Am. Fam. Physician 645 (2018).

gender-affirming health care as necessary medical care by proscribing covered providers from refusing to provide it.

#### III. Comments on the proposed rulemaking

As noted above, the Protect Trans Health coalition supports the overwhelming majority of HHS' proposals in the proposed rule. Below, we offer comment both where we believe the proposed rule can be improved in the final rulemaking, as well as to address questions raised by HHS in the NPRM.

#### A. Subpart A: General Provisions 1. Application (§ 92.2)

The Protect Trans Health coalition strongly supports the restoration of regulatory language expressly applying Section 1557 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 insurance coverage of health care. We also support the omission of Title IX's religious exemption in the education context, 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 people 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.

# a. Nondiscrimination protections should be extended to other non-health programs and activities of the agency in a separate rulemaking<sup>127</sup>

In the NPRM, HHS asks for comment as to whether these nondiscrimination protections should be extended to other non-health programs and activities of the agency. We strongly encourage the adoption of such protections for these other programs in separate rulemaking and urge HHS to make those protections equally as robust as and consistent with those proposed here for health programs and activities to ensure correct enforcement of the law and to avoid confusion.

Given the significant confusion regarding the state of regulations implementing Section 1557 following the issuance of injunctions against both the 2016 Rule and the Rollback Rule, however, we believe it is crucial to finalize the proposed rule as expeditiously as possible. As such, we request that extension of

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<sup>&</sup>lt;sup>127</sup> The authors do not support delaying finalization of this rule to achieve this but rather to do so in a separate rulemaking.

nondiscrimination protections to other HHS programs be handled through a separate rulemaking process, so as not to delay finalization of the present rules.

Because discrimination causes significant harm and many people obtain health care services and coverage from other federal agencies, regulations enforcing the protections of Section 1557 should be expressly extended to health programs and activities administered by or receiving federal funding from agencies other than HHS. We encourage HHS to work with the Department of Justice and other agencies that administer such programs to develop a common rule to implement Section 1557. 128 Such a rule would make it clear that the ACA's nondiscrimination protections do extend to health programs and activities outside of HHS, assisting both covered entities as well as program participants and beneficiaries and promoting consistent enforcement.

#### 2. Policies and Procedures (§ 92.8)

We support the requirement that covered entities develop and implement written policies and procedures to ensure compliance with this rule, and that the procedural requirements apply across all covered nondiscrimination bases.

We note that the description of prohibited sex discrimination in this section differs from the language of section 92.101. While the differences are not extensive, for the sake of clarity it would be preferable to use consistent language throughout the rule; the more expansive definition in 92.101 should be used here in 92.8, as well as elsewhere.

#### 3. Notice of Nondiscrimination (§ 92.10)

We strongly support the notice requirements in section 92.10 and the Department's attempt to strike a balance so that covered entities are not overly burdened but that program participants and beneficiaries are aware of their rights.

We note that the description of prohibited sex discrimination in this section differs from the language of section 92.101. While the differences are not extensive, for the sake of clarity it would be preferable to use consistent language throughout the rule; the more expansive definition in 92.101 should be used.

HHS should include in the notice requirement that any entity receiving a religious exemption include the existence and scope of such exemption in its required notices

We ask that HHS include in the notice requirement that any entity receiving a religious exemption under proposed section 92.302 include the existence and scope of such exemption in its required notices. It would be misleading and inaccurate to require entities to tell participants and beneficiaries and the public generally that the entity does not discriminate if the entity does in fact discriminate in certain circumstances and has been granted permission to do so. We also request that the Office for Civil Rights publish on a periodic basis a list of entities that have been granted exemptions under section

<sup>128</sup> See Mem. from the U.S. Dep't of Justice to the Fed. Agency Civil Rights Dirs. and Gen. Counsels 2 (March 26, 2021) at 2 ("After considering the text of Title IX, Supreme Court caselaw, and developing jurisprudence in this area, the Division has determined that the best reading of Title IX's prohibition on discrimination 'on the basis of sex' is that it includes discrimination on the basis of gender identity and sexual orientation."), available at <a href="https://www.justice.gov/crt/page/file/1383026/download">https://www.justice.gov/crt/page/file/1383026/download</a>.

92.302, so that participants and beneficiaries have sufficient advance notice of any claimed exemptions prior to seeking care or services.

#### B. Subpart B – Nondiscrimination Provisions

#### 1. 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, an issue we addressed *supra* in I.A.1. While a common complaint procedure is established by 92.304(b), we recommend including 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, **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).

We also applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. As explained *supra* in Part I.B, federal case law – including the Supreme Court's decisions in *Price Waterhouse v. Hopkins* and *Bostock v. Clayton County* – makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity, including transgender status. It is essential that this rule track those decisions to provide assurance to participants, beneficiaries and enrollees and notice to covered entities that these bases are unequivocally included. We also support the explicit inclusion of discrimination based on sex characteristics, including intersex traits, as such discrimination is inherently sex-based.

We 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.<sup>129</sup> 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 as the Department of Education's Title IX regulations prohibit discrimination related to "termination of pregnancy or recovery therefrom." <sup>130</sup> 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. It is critical the agency explicitly state that the prohibition against discrimination on the basis of sex prohibits denials of care based on

<sup>&</sup>lt;sup>129</sup> 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). <sup>130</sup> 34 C.F.R. § 106.40(b)(1).

abortion history, refusals to provide information, resources and referrals for contraceptive or abortion care, <sup>131</sup> or limit access to medications that can be prescribed to terminate 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, including termination of pregnancy; sexual orientation; transgender status; and gender identity.

# C. Subpart C – Specific Applications to Health Programs and Activities 1. 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 in I.A. It importantly clarifies – particularly at 92.206(c) – 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.

#### a. Inconsistent State Law or Policy (§ 92.206(c))

Over the past two years, we have seen a number of states adopt laws and policies designed to limit access to gender-affirming care. At the time of this submission, at least three states have enacted legislation to prohibit gender-affirming care for transgender youths;<sup>132</sup> at least a dozen more states considered similar legislation during their 2022 legislative sessions.<sup>133</sup> In addition, at least two states have attempted to limit access to gender-affirming care through administrative action.

On February 22, 2022, Texas Governor Greg Abbott issued a directive to the Texas Department of Family and Protective Services instructing DFPS to treat the provision of gender-affirming care to minors as child abuse and directing the agency "to conduct a prompt and thorough investigation of any reported instances of these abusive procedures in the State of Texas." <sup>134</sup> The letter further claimed that medical providers, teachers, and even members of the general public faced "criminal penalties for failure to

<sup>&</sup>lt;sup>131</sup> For example, many Indigenous individuals rely on the Indian Health Service for health care, but IHS facilities often fail to provide information to patients about abortion care or counseling about pregnancy options.

<sup>132</sup> See Alabama Act No. 2022-289 (April 7, 2022), available at <a href="https://arc-sos.state.al.us/ucp/L0926536.AI1.pdf">https://arc-sos.state.al.us/ucp/L0926536.AI1.pdf</a>; Arizona Senate Bill 1138 (March 30, 2022), codified at ARIZ. REV. STAT. § 32-3230, available at <a href="https://www.azleg.gov/legtext/55leg/2R/laws/0104.pdf">https://www.azleg.gov/legtext/55leg/2R/laws/0104.pdf</a>; Arkansas Act No. 626 (April 13, 2021) (passed over governor's veto), available at

https://www.arkleg.state.ar.us/Bills/Detail?id=HB1570&ddBienniumSession=2021%2F2021R.

<sup>&</sup>lt;sup>133</sup> See Lindsey Dawson et al, Youth Access to Gender Affirming Care: The Federal and State Policy Landscape, KAISER FAMILY FOUNDATION (June 1, 2022), available at <a href="https://www.kff.org/other/issue-brief/youth-access-to-gender-affirming-care-the-federal-and-state-policy-landscape/">https://www.kff.org/other/issue-brief/youth-access-to-gender-affirming-care-the-federal-and-state-policy-landscape/</a>.

<sup>&</sup>lt;sup>134</sup> Letter from Governor Greg Abbott to Commissioner Jaime Masters, Texas Department of Family and Protective Services (Feb. 22, 2022) at 1, available at <a href="https://gov.texas.gov/uploads/files/press/O-MastersJaime202202221358.pdf">https://gov.texas.gov/uploads/files/press/O-MastersJaime202202221358.pdf</a>.

report such child abuse."135 Governor Abbott's directive was based not on affirmative legislation, but rather upon an opinion of Texas Attorney General Ken Paxton issued four days previously. 136

Unsurprisingly, families of transgender minors quickly filed suit, seeking an injunction against enforcement of the February 22 directive. On March 11, the District Court of Travis County issued a statewide temporary injunction, finding "a substantial likelihood that Plaintiffs will prevail after a trial on the merits because the Governor's directive is ultra vires, beyond the scope of his authority, and unconstitutional."137 On May 13, the Texas Supreme Court partially reversed the order on interlocutory appeal, limiting the District Court's injunction only to the named plaintiffs. 138

The Texas Supreme Court decision did, however, call into question whether the February 22 directive was binding in the first place:

[W]e are directed to no source of law obligating DFPS to base its investigatory decisions on the Governor's letter or the Attorney General's Opinion. The Governor and the Attorney General were certainly well within their rights to state their legal and policy views on this topic, but DFPS was not compelled by law to follow them. 139

At the time of writing, litigation surrounding the February 22 directive continues, with no statewide injunction in place to protect the vast majority of Texas families with transgender children.

Meanwhile, the State of Florida has also been waging its own administrative campaign against genderaffirming care. On April 20, 2022, the Florida Department of Health issued a press release entitled "Treatment of Gender Dysphoria for Children and Adolescents," in which the Department concluded that gender-affirming care for minors was experimental, that neither puberty blockers nor hormone therapy should be prescribed to anyone under 18, that gender-affirming surgeries should not be made available to minors, and even that "[s]ocial gender transition should not be a treatment option for children and adolescents."140 The press release was issued in response to - and refutation of - an HHS Office of Population Affairs fact sheet, "Gender-Affirming Care and Young People," which had been issued in March 2022.141

While the April 20 press release itself had no legally-binding effect, it was only the first of several administrative steps taken by Florida to severely limit access to gender-affirming care for both adults

135 Id.

<sup>136</sup> Attorney General Ken Paxton, Opinion No. KP-0401 (Feb. 18, 2022), available at https://gov.texas.gov/uploads/files/press/O-MastersJaime202202221358.pdf.

<sup>137</sup> Doe v. Abbott, No. D-1-GN-22-000977 at 2 (Dist. Ct. Travis Cnty., Mar. 11, 2022) (order granting preliminary injunction), available at https://www.lambdalegal.org/in-court/legal-docs/abbott\_tx\_20220311\_order-grantingtemporary-injunction.

<sup>138</sup> In re Abbott, No. 22-0229 (Tex. Sup. Ct. May 13, 2022), available at https://www.txcourts.gov/media/1454197/220229.pdf. 139 Id at 4-5.

<sup>140</sup> Florida Dep't of Health, Press Release: Treatment of Gender Dysphoria for Children and Adolescents (April 20, 2022), available at https://www.floridahealth.gov/\_documents/newsroom/press-releases/2022/04/20220420-genderdysphoria-guidance.pdf.

<sup>141</sup> Dep'of Health and Human Services Office of Population Affairs, Gender-Affirming Care and Young People (March 2022), available at https://opa.hhs.gov/sites/default/files/2022-03/gender-affirming-care-young-people-march-2022.pdf.

and minors. Following a rushed administrative review, 142 on August 10 the Florida Agency for Health Care Administration published a final rule prohibiting the state Medicaid program from providing coverage for gender dysphoria, effective August 21, 2022.143 While the state's alleged concerns focused on gender-affirming treatments for transgender adolescents, the final Medicaid rule went significantly further, eliminating coverage not only for adolescents, but also for adult transgender people. Litigation challenging the Medicaid exclusion is currently pending in the Northern District of Florida. 144

Not content to simply eliminate Medicaid funding for gender-affirming care, on August 5 the Florida Board of Medicine voted to initiate rulemaking to set the standard of care for gender dysphoria 145 in contravention of long-standing standards of care for gender-affirming healthcare based in science and endorsed by major medical organizations.<sup>146</sup> At the time of writing, the Board of Medicine is still considering rulemaking. Should the Board of Medicine adopt rules barring physicians licensed in Florida from providing care for gender dysphoria, those rules would squarely contravene the requirements of 92.206(c), as well as the recommendations of every major medical organization and undermine access to medically necessary health care for transgender young people in the state.

As these events demonstrate, not only is there is a serious risk that states will adopt laws, regulations, and executive orders to limit or outright prohibit access to gender-affirming healthcare for transgender and nonbinary people, but also transgender and nonbinary people are already unable to access needed care because of these hostile efforts.<sup>147</sup> While we understand that the majority of these state policies would be barred by 92.206(c), we suggest including preamble language to make this clear. We further strongly encourage the Office for Civil Rights to apply forcefully the tools available to it (in

<sup>142</sup> See Letter from Simone Marstiller to Tom Wallace (Apr. 20, 2022) (instructing Florida Agency for Health Care Administration to consider whether gender-affirming treatments for minors were consistent with generallyaccepted professional medical standards), available at

https://www.ahca.myflorida.com/letkidsbekids/docs/AHCA\_GAPMS\_June\_2022\_Attachment\_A.pdf; Florida Medicaid, Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria, (June, 2022) (finding that puberty blockers, cross-sex hormones, and "sex reassignment surgery" are experimental, despite contrary endorsement by American Academy of Pediatrics and other medical organizations), available at https://www.ahca.myflorida.com/letkidsbekids/docs/AHCA\_GAPMS\_June\_2022\_Report.pdf; Florida Agency for Health Care Administration, Notice of Proposed Rulemaking 25979915: Rule 59G-1.050 General Medicaid Policy (June 17, 2022) (proposing to amend Florida Medicaid rules to prohibit coverage of treatment for gender dysphoria; providing for 21-day comment period), available at

https://www.flrules.org/gateway/View\_Notice.asp?id=25979915. The June 2022 Medicaid report on gender dysphoria was heavily criticized by medical experts. See, e.g., Meredithe McNamara et al., A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria (July 8, 2022), available at https://medicine.yale.edu/lgbtqi/research/gender-affirming-

care/florida%20report%20final%20july%208%202022%20accessible\_443048\_284\_55174\_v3.pdf.

<sup>143</sup> Final Rulemaking: Rule 59G-1.050 (effective Aug. 21, 2022), available at https://www.flrules.org/gatewav/RuleNo.asp?id=59G-1.050.

<sup>144</sup> See Becky Sullivan, A New Lawsuit Is Challenging Florida Medicaid's Exclusion of Transgender Health Care, NPR (Sept. 7, 2022), available at https://www.npr.org/2022/09/07/1121559771/florida-transgender-health-caremedicaid-lawsuit.

<sup>145</sup> Florida Board of Medicine, Meeting Minutes at 19 (Aug. 5, 2022), available at https://ww10.doh.state.fl.us/pub/medicine/Agenda\_Info/Public\_Information/Public\_Minutes/2022/August/0 8052022\_FB\_Minutes.pdf.

<sup>146</sup> See Part II.A, supra.

<sup>&</sup>lt;sup>147</sup> Sneha Dey, Texas providers are suspending gender affirming care for transgender teens in respone to GOP efforts, TEXAS TRIBUNE (Mar. 22, 2022) https://www.texastribune.org/2022/03/22/texas-transgender-teenagers-medical-care/ (last viewed Sept. 29, 2022).

conjunction the Department of Justice where necessary) to ensure state-level restrictions such as these do not impede transgender and nonbinary people's access to healthcare.

#### b. Prohibited discrimination (§ 92.206(b), (d))

We strongly support the Department's efforts to clarify Section 1557's application to the forms of discrimination identified in proposed § 92.206(b).

The Protect Trans Health coalition collected many personal stories of health care discrimination from public comments on this rulemaking. 148 Further, many transgender and nonbinary people reach out to the Transgender Law Center seeking legal information when experiencing discrimination in healthcare or healthcare insurance companies. We share some of these stories here in order to demonstrate how the proposed rule will impact and benefit the lives of transgender and nonbinary people.

Many commenters described being repeatedly turned away by primary care providers. One told a story of being sent away despite only needing care for a sore throat:

When I was relatively early in transition, I was trying to find a primary care provider. My partner had acute bronchitis and I had a sore throat, so I wanted an appointment soon, but I was nervous about finding a provider who wouldn't mistreat me as a trans person. So I decided to disclose on the phone before setting up an appointment. I called a doctor's office, asked about their hours and the insurance they took, and told them that I was transgender and looking for a primary care provider. The receptionist said, "Oh, um, I'm not sure, one moment," and put me on hold. They then returned to the phone and said, "So you're a post-operative male to female transsexual, right?" I said, "No, I'm female-to-male and haven't had any surgery."

They put me on hold again, then came back and said, "The doctor says that you shouldn't come here because he wouldn't know how to address your special needs." I said, "Oh, but I have a different doctor who prescribes me hormones, I just have a sore throat. He knows how to treat a sore throat, right?" The receptionist said, "Really it's just that he wouldn't feel comfortable having a transgender person as a patient." It hit me harder than I thought it might. It took a lot of calling to eventually find someone who was okay with seeing me at all, and the experience soured me toward doctors.

One person reached out to the Transgender Law Center after their prescribed hormone medication was denied by a pharmacist who stated the medication was "experimental," despite being covered by the person's insurance company:

[Commenter] has a letter from therapist stating that they need hormones. They were issued a denial for hormones stating it was experimental, that hormones would only approved if [Commenter] had fault with ovaries or testicles. The insurance is through Anthem, but CVS is the one denying the prescription. The plan is through [Commenter's] work.

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<sup>&</sup>lt;sup>148</sup> Comments cited herein were delivered to HHS by National Center for Transgender Equality after being shared through a comment portal at <a href="https://protecttranshealth.org">https://protecttranshealth.org</a>. Personal stories have been edited lightly for length, grammar and punctuation only.

Many commenters experienced misgendering, name-calling and abuse. One went so far as to report it to the hospital, but with no recourse:

I was abused by staff at a hospital who refused to call me by my name. I was referred to as "it" and "thing." When I continued to insist that they call me by my name, the nurse threatened chemical restraints and continued to deadname me. The staff didn't protect me. Doctors blamed me for my reactions. The hospital investigated and confirmed it all happened, but said it wasn't against policy or law.

One parent reached out to the Transgender Law Center after her transgender son experienced misgendering and transphobic discrimination from an EMT, leading to ongoing stress for her and her family:

My son was discriminated against by an ems worker and I'm afraid the company isn't going to do anything. I had to beg for help. The EMT did not wear mask (coughed on son) and said transphobic things to my son. My son had white lips and severely low bp (taken by neighbor who is an RN) and the emt (before checking son) said maybe it's just HER period?. After throwing a fit to go to hospital, he also says to my son "you know you're technically a female right??" My son was barely conscious. Can I do anything about this? [Omitted] said they'd handle it but "I had to trust them". I do not trust them after this incident and I've had nightmares ever since. I don't know what else to do.

Some pointed out discrepancies in health access for the same care, based on whether they were trans:

In my own experience, getting insurance's approval for a breast reduction/mastectomy is far easier for a cis woman compared to a trans man like myself – the woman only has to have insurance approve the surgery within 4-6 weeks with no accompanying paperwork, whereas the trans man has to have a letter of approval from a psychologist and wait 8-12 weeks to hear back from insurance (despite knowing they'll say no because they specifically refuse to cover any transition-related medical care).

Many nonbinary commenters reported experiencing multiple forms of gender-based discrimination from primary care, hospital and insurance providers. One reported:

I've experienced significant challenges when being openly trans/nonbinary and seeking healthcare. I was sexually assaulted by a nurse when she was checking me in to a hospital room. The assault was specifically related to her curiosity and disgust about what my primary and secondary sex characteristics looked and felt like—it was a specifically transphobic assault. The hospital did not even respond to my complaint, despite all sexual assault being illegal and transphobic discrimination being explicitly illegal in my state. I continue to avoid that hospital entirely—despite the fact that it has the closest emergency room to my home.

The emotional impact of this trauma impacted my ability to receive care in the future as well, requiring accommodations and sometimes care avoidance due to trauma. Countless times, like most trans people, I have been misgendered, have had the wrong name used for me, and have been asked ignorant questions, including what kinds of genderaffirming surgeries I have had (and asking about my genitals in a context where it is entirely medically unnecessary to do so).

Given a state-level patchwork of health protections, commenters in certain states face disparate threats, leaving some afraid to pursue the care they need to live a "full and happy life" like this Ohioan:

I am a trans person who lives in Ohio, and who wants to medically transition. I am afraid to seek the medical care I need, because of the likelihood that I would encounter discrimination and misunderstanding from health care providers. If more legal protections were in place for trans people seeking care, it would make it much easier for me to transition the way I need to live a full and happy life.

Another commenter reported being refused access to essential medical care for their diabetes, post-transition:

After I began transitioning in Montana, an endocrinologist refused to treat me for Type I (juvenile/insulin-dependent) diabetes. He had his receptionist call and cancel my appointment, because he did not and probably still does not treat transgender patients. I have been a diabetic since 1985. I had never been refused care before transitioning. I have experienced small incidents (microaggressions) due to my gender identity, including difficulty having my affirmed gender recognized on hospital paperwork, having the correct pronouns used after receiving affirming care, and being on the receiving end of inappropriate curiosity in medical settings, regarding scarring, sexuality, and genitals. I would like to see these experiences relegated to the past, to a time when providers "didn't know any better."

Hundreds more transgender commenters have shared their harrowing journeys through the healthcare system during this present comment period. One Texan recounted:

I still remember the joy I felt when I first received my referral for care of an endocrinologist. After decades of living within my prison cell of flesh, I was given a path to liberation. I had a referral from my psychiatrist and one from my physician – all that was needed was a specialist to take my referral. What followed was a gauntlet run of abuse by providers. We don't treat people like you was repeated to me in some form or fashion several times. I started to consider alternatives like self-medicating with estrogen purchased over the counter in Mexico or considering how I could make it to a city like Houston, where providers were openly available. Ultimately the last physician I spoke with, who recently located to the area, was willing to take my referral and I could finally receive the necessary care long denied.

Dozens of health care providers echoed support for the 2022 NPRM based on their clinical experience:

Transphobia in healthcare settings drives patients away from receiving necessary care, leading to delays in care and patients arriving sicker. For example, I cared for a trans patient in the hospital with an extremely severe kidney injury, and we were lucky she even came to the hospital in spite of her extensive history of discrimination in healthcare settings. Discrimination on the basis of gender identity also harms patients, preventing access to known, life-saving healthcare. For example, many trans men with cervixes are unable to have their insurance cover pap smears because their gender markers are male. Pap smears are the only screening test that can detect pre-cancer and are crucial for people with cervixes, regardless of gender identity. This affordable, accessible, and life-saving screening should not be withheld based on gender identity.

As demonstrated by these accounts, transgender and nonbinary people experience high rates of discrimination across various healthcare sectors. While the proposed rule goes far to mitigate this discrimination, we believe the rule can be strengthened in several ways.

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.

We also appreciate the examples of such discrimination that the Department provides in the preamble section explaining § 92.206 protections. We ask the Department to go further and include additional sections to § 92.206 that focus on specific forms of discrimination based on sex characteristics, nonbinary status and pregnancy or related conditions prohibited by Section 1557.

#### Accordingly, we propose the following additions and amendments to § 92.206(b):

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, **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, <u>transgender status</u>, 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."

We support the agency's inclusion of "gender otherwise recorded" specifically because it encompasses a broader range of people who may face discrimination based on sex but who do not identify as transgender, such as nonbinary people who do not identify as transgender.

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.

#### For the reasons stated above, section 92.206(b)(3) would be strengthened if modified 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. Prohibited policies include, but are not limited to, policies or practices that:

<u>a.</u> prevents an individual from participating in a health program or activity consistent with the individual's gender identity;

b. subject pregnant people to discriminatory treatment during childbirth, including rough handling, harsh language, or undertreatment of pain;

c. 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, care before, during and after pregnancy, or any other pregnancy-related health services;

d. 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; or

e. deny 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.

While we believe the language in subsection a ("consistent with individual's gender identity") encompasses nonbinary people, we encourage the agency to address this in the preamble of the file rule in order to clarify that the protections under 92.206 extend to all gender identities, including nonbinary people.

This section would also be strengthened by including specific examples of what constitutes discrimination based on sex characteristics, including intersex traits, such as for example subjecting patients to invasive and nonconsensual examinations; intentionally withholding or providing inaccurate information to about their medical records, history, or prognosis; or following policies or procedures to protect informed consent or patient rights with respect to non-intersex patients but not for similarly-situated patients with intersex traits.

Finally, while we strongly support 92.206(d)'s clarification that the enumeration of specific types of discrimination under 92.206(b) does not limit the general prohibition of discrimination under 92.206(a), we encourage HHS to provide preamble language citing additional examples and to provide confirmation that OCR's investigations will not be limited by the enumerated examples in 92.206(b).

2. 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 health insurers as health insurers are frequently key gatekeepers to affirming care for transgender and nonbinary people.

Since March of 2020, Transgender Law Center's Helpdesk has received almost four hundred health care related inquiries from transgender and nonbinary people and their loved ones across the United States.

Over a third of those inquiries pertain to issues accessing gender affirming care due to health insurance barriers, from blanket exclusions of gender affirming care, to repeated denials of medically necessary care that were erroneously deemed cosmetic or elective—particularly for facial feminization surgery, laser hair removal and breast augmentation— as well as denials based on the patient's gender marker, among others. Such denials frequently require onerous and time-consuming advocacy to rectify, which is often overwhelming and results in significant delays to receiving needed care, as paying for care out of pocket is not a realistic option for most patients. Many of the people who have written to us have shared the devastating impacts of these barriers to care including experiencing anxiety, depression and suicidal ideation as a result.

In addition, many people who reach out to TLC's legal helpdesk report forgoing submitting insurance claims in the first place out of fear of future discrimination or denials of other lifesaving healthcare, placing them at increased financial risk:

My daughter is a transgender youth. Before she came out in April of 2018, we had her undergo a private neuropsychology examination. The diagnosis was gender dysphoria with some secondary learning processing focus points. This was a very expensive test that we never processed through our insurance company for fear of forever labeling our child as well as fear of future denial of surgeries or therapies.

One person worked in state government commented on the NPRM through the Protect Trans Health comment portal that they were refused coverage under their employee healthcare plan, forcing them to pay for affirming care out of pocket:

I work for the State Government in Georgia and was denied gender affirming care under the state health benefit plan issued by the Department of Community Health. It literally took me years after being denied coverage to be able to get the care I was seeking, and I am still facing extreme financial hardship after paying out of pocket for my necessary medical care. After my gender affirming surgery though, my life, my joy, my mental health, and my relationships all dramatically improved when I could finally feel at home in my skin. I am sad to think about the years of what could've been a happier life I lost the ability to experience fully because of healthcare discrimination.

Section 92.207 is also critical to end the significant disparities and uncertainties that exist regarding Medicaid coverage of gender-affirming healthcare. At the time of writing, 26 states and the District of Columbia expressly include gender-affirming care in their Medicaid plans, 9 states expressly exclude gender-affirming care, and 15 states have no express policy. These simple numbers, however, fail to reflect the full complexity of the situation. In Maryland, for instance, a state that expressly provides gender-affirming care through Medicaid, a 2016 transmittal to Medicaid managed care organizations expressly excludes 31 procedures from coverage, regardless of medical necessity. 150

At the same time, because Medicaid coverage policies are often determined through the administrative process, rather than through legislation, they can be especially prone to political attack by hostile executive officers. Prior to the August 10 adoption of a rule prohibiting the Florida Medicaid program

<sup>150</sup> See Susan J. Tucker, Maryland Medical Assistance Program Managed Care Organizations Transmittal No. 110 (March 10, 2016), available at <a href="https://health.maryland.gov/mmcp/MCOupdates/Documents/pt\_37\_16.pdf">https://health.maryland.gov/mmcp/MCOupdates/Documents/pt\_37\_16.pdf</a>.

<sup>&</sup>lt;sup>149</sup> See Movement Advancement Project, Healthcare Laws and Policies: Medicaid Coverage for Transgender-Related Care (Aug. 10, 2022), available at <a href="https://www.lgbtmap.org/img/maps/citations-medicaid.pdf">https://www.lgbtmap.org/img/maps/citations-medicaid.pdf</a>.

from providing coverage for gender dysphoria, discussed *supra* at III.C.1.a., Florida had no express policy on coverage (or lack of coverage) for gender-affirming care under the state's Medicaid program.

In order to deter such examples of discrimination in insurance coverage and 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, <u>transgender</u> <u>status</u>, or gender otherwise recorded.

We recommend the 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. As such, we recommend deleting the word "all" from this paragraph, a change that we believe in line with the true intent of the provision. Such an interpretation comports with courts' interpretation of Section 1557. Despite the 2020 Rollback Rule sowing confusion, courts have consistently found that transgender exclusions in health plans violate federal law, including Section 1557.<sup>151</sup>

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Additionally, as with proposed § 92.206, the Department must strengthen the text of proposed § 92.207 to address sex discrimination related to pregnancy or related conditions, including discrimination related to abortion, fertility care, and contraception. **We propose 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 all health services related to gender transition or other gender-affirming care, termination of pregnancy, contraception, fertility care, miscarriage management, pregnancy loss, other reproductive and sexual health services, or any health services,

Section 92.207(b)(5) would be clearer if shortened and likewise should explicitly include examples of pregnancy related care as follows:

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 if such denial, limitation, or restriction results in discrimination on the basis of sex, termination of pregnancy, contraception, fertility care, miscarriage

<sup>&</sup>lt;sup>151</sup> Transgender Legal Defense and Education Fund, *Memorandum to Plan Administrators* (June 6, 2022), *available at* <a href="https://transhealthproject.org/documents/51/2022-06-16\_TLDEF\_memo\_on\_trans\_health\_exclusions.pdf">https://transhealthproject.org/documents/51/2022-06-16\_TLDEF\_memo\_on\_trans\_health\_exclusions.pdf</a>; *Pritchard v. Blue Cross Blue Shield of Illinois*, No. 3:20-CV-06145-RJB, 2021 WL 1758896, at \*4 (W.D. Wash. May 4, 2021) (finding that a transgender exclusion can give rise to a claim because a "claim of discrimination in violation of Section 1557 does not depend on an HHS rule.")

## management, pregnancy loss, other reproductive and sexual health services, or any health services,

We propose the addition of the following subsection to section 92.207(b) to clarify prohibited forms of pregnancy related discrimination:

(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.

#### 3. 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 as well as those of someone with whom they are associated or with whom they have a relationship. As noted in the NPRM preamble, certain protected populations, including transgender people, are particularly susceptible to discrimination based on association. An individual in a relationship with or married to a transgender person could be subjected to discrimination based on their spouse or partner's gender identity or transgender status, whereas that same individual might not be similarly mistreated were their partner not transgender. Similarly, a cisgender parent might be subjected to discrimination based on their child's transgender status, while a cisgender child might be denied services because of a transgender parent or guardian. It is important that the final rule makes clear that this kind of associational discrimination is within the ambit of the rule's protections.

#### D. 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 Rollback Rule 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.

As noted above under our comments to 92.10, we strongly believe that effective notice of claimed religious exemptions is required for third parties to make informed decisions about where to seek healthcare. As such, notice of any claimed religious exemptions should be included in a program participant's 92.10 Notice of Nondiscrimination and the Office for Civil Rights should publish on a periodic basis a list of entities that have been granted exemptions under section 92.302.

#### E. Other Provisions

#### 1. Medicare Part B Meets the Definition of Federal Financial Assistance

We strongly support the revised definition of Federal Financial Assistance ("FFA") that, at long last, include payments made under Medicare Part B. The relationship between Part B providers and HHS is not distinguishable from that of other providers who are already treated as recipients of FFA. The exclusion of Part B has roots in racism, as it came about at least in part to respond to the desires of some physicians to exclude Black patients from their practices. Part B mithin the ambit of FFA and 1557 not only addresses this problematic history but also furthers the core goal of the ACA: to broaden and strengthen civil rights protections in health care. Closing this loophole in 1557's implementing regulations will have a material impact on increasing access to care for transgender and nonbinary patients across the country, as discussed *supra* under III. C. 2. and for older transgender and nonbinary adults living in the United States as discussed *supra* under I.A.1.

#### 2. CMS Amendments

The Rollback Rule inexplicably removed protections against sexual orientation and gender identity discrimination from a number of regulations governing programs run by the Centers for Medicare and Medicaid Services (CMS). We are pleased to see those provisions restored and also included in additional CMS programs. We note, however, that the language around sex discrimination in these CMS "conforming amendments" does not match the proposed sex discrimination language in 1557 itself. We encourage HHS and CMS to adopt identical language to avoid confusion and ensure consistency of implementation.

#### IV. Conclusion

As outlined above, the Protect Trans Health coalition supports the overwhelming majority of HHS' proposals in this Notice of Proposed Rulemaking. Given the extensive discrimination against transgender and nonbinary people – especially those whose identities intersect multiple axes of marginalization – the nondiscrimination provisions in the proposed rules are critical to ensuring that transgender and nonbinary people are able to meaningfully access healthcare. The proposed rule also aligns HHS's interpretation of discrimination on the basis of sex with federal court decisions, including the Supreme Court's decision in *Bostock*.

While opponents of the proposed rulemaking claim that gender-affirming care is experimental and not grounded in science, it is critical to understand that this is inaccurate, but also that it is raised as a badfaith distraction from the very real issue of discrimination against transgender and nonbinary people in access to healthcare. Every major medical organization that has examined the issue has come out in support of gender-affirming care, including age-appropriate gender-affirming care for adolescents. Outlying and cherry-picked studies cited by opponents should not be given weight over the overwhelming consensus of doctors, let alone the lived experiences of transgender people who can speak from personal experience about how critical gender-affirming care is for our survival in an often-hostile world.

<sup>&</sup>lt;sup>153</sup> See Mary Crossley, Infected Judgment: Legal Responses to Physician Bias, 48 VILLANOVA L.R. 195 at 263-68 (2003), available at

https://digitalcommons.law.villanova.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1323&context=vlr

Though we generally support the proposed rule, we have also offered suggestions for ways in which they might be improved, including: working with the Department of Justice to adopt regulations covering other federal agencies; using a consistent, expansive definition of sex discrimination throughout the rules; requiring covered entities claiming religious exemptions to provide notice of those exemptions; ensuring that complaints can be raised on multiple protected identities in a single complaint; adding "transgender status" to the list of prohibited categories of discrimination; clarifying that discrimination on the basis of pregnancy status includes pregnancy termination and adding additional language regarding prohibited forms of pregnancy-related discrimination; and, finally, adding preamble language to clarify that the regulations are intended to and will bar state policies designed to limit or outright prohibit access to gender-affirming healthcare for transgender and nonbinary people.

We strongly encourage the Department to adopt the proposed rules with these amendments, which are supported by the lived experiences of transgender and nonbinary people, ample research, and law, and which we believe will reduce discrimination against transgender and nonbinary people in access to healthcare.

Sincerely,

Kris Hayashi Executive Director Transgender Law Center

Rodrigo Heng-Lehtinen Executive Director National Center for Transgender Equality

Andrea "Andy" Hong Marra Executive Director Transgender Legal Defense and Education Fund

#### No. 21-11174

# IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

FRANCISCAN ALLIANCE, INCORPORATED; CHRISTIAN MEDICAL AND DENTAL SOCIETY; SPECIALTY PHYSICIANS OF ILLINOIS, L.L.C.,

Plaintiffs-Appellees,

v.

XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants-Appellants

AMERICAN CIVIL LIBERTIES UNION OF TEXAS; RIVER CITY GENDER ALLIANCE,

Intervenor Defendants-Appellants.

On Appeal from the United States District Court for the Northern District of Texas

#### REPLY BRIEF FOR DEFENDANTS-APPELLANTS

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#### **INTRODUCTION**

The district court erred in entering permanent injunctive relief against the government based on positions that the government has not actually adopted and in the absence of an Article III case or controversy. The court's permanent injunction and plaintiffs' arguments are based on the premise that the Department of Health and Human Services (HHS) currently interprets and will enforce Section 1557 to mandate that "Christian [p]laintiffs[] ... perform and provide insurance coverage for gendertransition procedures and abortions." ROA.5065; see also ROA.5062-5063; Pls. Br. 41-42, 46-51. But this premise is fundamentally incorrect. HHS has not taken a position on whether Section 1557 could in any specific circumstance require the provision or coverage of gender-transition procedures or abortions by entities with religious objections to providing or covering those procedures, or how the Religious Freedom Restoration Act (RFRA) interacts with Section 1557's general prohibition on sex discrimination. See Bostock v. Clayton County, 140 S. Ct. 1731, 1754 (2020) (specifically reserving question of how RFRA and other "doctrines protecting religious liberty interact with Title VII" and explaining that these "are questions for future cases"). Whether viewed as a problem of mootness, an Article III standing defect, a lack of ripeness, and/or an absence of irreparable harm to support an injunction, the district court erred and its permanent injunction should be vacated.

First, this case is moot. As presented in the operative complaint and consistently litigated by plaintiffs for the first four years of this long-running litigation,

this lawsuit involves a RFRA challenge to HHS's 2016 Rule implementing Section 1557. Plaintiffs suffer no ongoing harm from the 2016 Rule because the district court vacated its challenged provisions and HHS rescinded and replaced them. The district court cannot grant plaintiffs any additional effective relief against the 2016 Rule.

Second, even if the case were not moot, plaintiffs have not established a concrete case or controversy with respect to their challenge to HHS's hypothetical future enforcement of Section 1557, and their RFRA claims are not ripe. Plaintiffs have not demonstrated any imminent injury, as they have not shown that HHS has ever brought or threatened an enforcement action against plaintiffs or *any* objecting religious entity for declining to provide or cover gender-transition procedures or abortions. Plaintiffs' RFRA claims are not ripe for review, as they cannot properly be evaluated in the abstract and instead require a factual record in which HHS is actually requiring plaintiffs to do something specific. For similar reasons, plaintiffs have not made the necessary showing of imminent irreparable harm sufficient to justify permanent injunctive relief.

#### **ARGUMENT**

- I. This Case Is Moot Because Plaintiffs Only Challenged the 2016 Rule.
- **A.** As explained in our opening brief (at 25-28), plaintiffs brought this case solely as a challenge to HHS's 2016 Rule, and the vacatur, recission, and replacement

of that rule rendered that challenge moot. Plaintiffs' various assertions of a live controversy are unpersuasive.

1. Plaintiffs first assert that the case is not moot because the 2016 Rule's vacated portions have been "revived by other district courts." Pls. Br. 46. Not so. As explained in our opening brief (at 42), the district courts in Whitman-Walker and Walker lacked authority to reverse the district court's vacatur of the 2016 Rule, and they did not purport to do so. The Walker court explicitly stated that it "agrees [with HHS] that it has no power to revive a rule vacated by another district court." Walker v. Azar, 480 F. Supp. 3d 417, 427 (E.D.N.Y. 2020). The Whitman-Walker court explained that the plaintiffs in that case had "identiffied] no authority that would permit either this Court or HHS to disregard the final order of [the Franciscan Alliance] district court vacating part of a regulation," and thus the court was "powerless to revive it." Whitman-Walker Clinic, Inc. v. HHS, 485 F. Supp. 3d 1, 26 (D.D.C. 2020). In any event, to the extent there is any ambiguity in the Walker and Whitman-Walker orders, they should be read to avoid a conflict with the district court's prior order here for reasons of comity. Cf. Feller v. Brock, 802 F.2d 722, 727-28 (4th Cir. 1986) ("Prudence requires that whenever possible, coordinate courts should avoid issuing conflicting orders."); Colby v. J.C. Penney Co., 811 F.2d 1119, 1124 (7th Cir. 1987) (same).

Plaintiffs' attempted "analogy to the contraceptive-mandate cases" (Br. 48) is unavailing. In that context, there was no underlying vacatur rendering it impossible

for a court's subsequent injunction of a replacement rule to restore a previous rule. See Little Sisters of the Poor v. Pennsylvania, 140 S. Ct. 2367, 2373-79 (2020). More generally, the government largely consented to injunctions in the contraceptive-coverage cases, see, e.g., Christian Emps. All. v. Azar, No. 3:16-cv-309, 2019 WL 2130142, at \*1 (D.N.D. May 15, 2019), which further undercuts plaintiffs' attempt to draw parallels here.

- 2. Plaintiffs' reliance (Br. 35-36) on Federal Election Commission v. Cruz, 142 S. Ct. 1638 (2022), is likewise misplaced. Contrary to plaintiffs' argument, Cruz does not suggest that all challenges to implementing regulations must also be understood as challenging the underlying statute. That case did not involve a mootness challenge, and the plaintiffs there specifically sought relief against both the regulation and the underlying statute. Joint Appendix at 26-27, Cruz, 142 S. Ct. 1638 (No. 21-12).
- 3. Plaintiffs' attempt to invoke Federal Rule of Civil Procedure 54(c) and the possibility of broader injunctive relief to circumvent mootness also fails. Plaintiffs contend that "being able to imagine an alternative form of relief is all that's required to keep a case alive," Pls. Br. 54, emphasizing that their complaint "requested all relief that is 'equitable and just," Pls. Br. 37. But plaintiffs fail to grapple with New York State Rifle & Pistol Association v. City of New York, 140 S. Ct. 1525 (2020) (NYSRPA) (per curiam). There, an alternative form of relief was not merely imaginable, it was actually put forward, id. at 1526; and the operative complaint had included a general prayer for all "just and proper" relief. See id. at 1535 (Alito, J., dissenting) (asserting

that case was live based on prayer for relief in conjunction with Rule 54(c)). Rather than find either of these points sufficient to permit merits consideration, the Supreme Court determined that the case was moot. *See id.* at 1526 (per curiam).

Because NYSRPA became moot while on appeal and "mootness [wa]s attributable to a change in the legal framework governing the case," the Supreme Court remanded for the lower courts to consider whether the complaint could be amended to add a claim for the new relief then sought. 140 S. Ct. at 1526-27.

Plaintiffs had the same opportunity in this case following remand from this Court on the previous appeal. But instead of attempting to amend their complaint to add a claim for the new injunctive relief now sought, plaintiffs attempted to recast the nature of their challenge nearly five years later by relying on Rule 54(c). Plaintiffs cannot plausibly claim that they are invoking Rule 54(c) to rectify "omissions' in a 'prayer for relief." Pls. Br. 55. Rather, they seek to use that rule to plug a glaring hole in their core theory of this case, as it had been understood by all parties and the district court and consistently litigated for almost half a decade—that is, that plaintiffs

<sup>&</sup>lt;sup>1</sup> Plaintiffs' failure to seek to amend the complaint distinguishes this case from Religious Sisters of Mercy, in which plaintiffs' counsel—representing other litigants—filed an amended complaint after the issuance of the 2020 Rule, specifically seeking relief from HHS's current interpretation of Section 1557 and not merely the 2016 Rule. See Religious Sisters of Mercy v. Azar, 513 F. Supp. 3d 1113, 1134 (D.N.D. 2021); Amended Complaint at 41-45, 69, Religious Sisters of Mercy, 513 F. Supp. 3d 1113 (No. 3:16-cv-386), ECF 95.

challenged only the 2016 Rule. The Court should reject this attempt to circumvent the limits of Article III.

- **B.** Unable to demonstrate that their challenge to a long-rescinded regulation presents a live controversy, plaintiffs shift gears and insist that this lawsuit never merely challenged the 2016 Rule. But this belated attempt to recharacterize their claims—now almost six years into this litigation—likewise fails.
- 1. Plaintiffs insist that their RFRA challenge was not merely to the 2016 Rule because they sought injunctive relief beyond just that rule in proposed orders accompanying their motions for summary judgment. Pls. Br. 35, 37-38. But that broad characterization of the relief sought is inconsistent with plaintiffs' operative complaint. See, e.g., ROA.311; ROA.352, ¶ 121; ROA.379, ¶ 295; ROA.393-394. It is also unsupported by the actual content of plaintiffs' summary-judgment briefing. See, e.g., ROA.3307; ROA.3354; ROA.4504; ROA.4516. And it is irreconcilable with the understanding the district court evinced in issuing final judgment on plaintiffs' RFRA claims in October 2019. See ROA.4799. Merely inserting a broad request for relief in a proposed injunction order—extending beyond the scope of anything otherwise sought or justified throughout the course of long-running litigation—cannot retroactively transform a focused challenge to discrete agency action into a wideranging assault on any hypothetical future enforcement actions.
- 2. Plaintiffs further suggest that their RFRA claim cannot be construed as challenging only the 2016 Rule because a RFRA claim is never "aimed at a law or

regulation" but rather challenges "government action." Pls. Br. 36 (emphasis omitted). But promulgating a regulation is a government action. Indeed, it is the only government action that plaintiffs identified in the RFRA claims in their operative complaint. See ROA.311-312; ROA.378-381. When HHS rescinded and replaced that regulation—the 2016 Rule—plaintiffs were no longer subject to any burden from the "rule of general applicability" that they had challenged. 42 U.S.C. § 2000bb-1(a). This litigation challenging that agency action under RFRA thus became moot. See Alaska v. U.S. Dep't of Agric., 17 F.4th 1224, 1226 (D.C. Cir. 2021) (describing "well-settled principle of law" regarding mootness of litigation challenging rescinded regulations).<sup>2</sup>

Plaintiffs nonetheless contend that the government action their RFRA claim challenges must now be understood more broadly as HHS's "threat to require them, on pain of penalties under Section 1557, to perform and insure gender transitions and abortions in violation of conscience." Pls. Br. 36. But plaintiffs' preferred reframing of their RFRA claim only underscores that this case is long-dead.

Under Article III's case-or-controversy requirement, "an actual controversy [must] be extant at all stages of review." *Campbell-Ewald Co. v. Gomez*, 577 U.S. 153, 160 (2016) (ellipsis omitted). "[A]ny set of circumstances that eliminates actual controversy after the commencement of a lawsuit renders that action moot." *Environmental Conservation Org. v. City of Dallas*, 529 F.3d 519, 527 (5th Cir. 2008).

<sup>&</sup>lt;sup>2</sup> Plaintiffs do not dispute the basic rule that challenges to a regulation become moot upon the regulation's rescission. *See* Pls. Br. 52-53.

Accordingly, parties must "maintain a 'concrete interest in the outcome" throughout the litigation. *Id.* With respect to plaintiffs' reframed RFRA claim, this means the Court must determine that HHS has consistently imposed this "threat" on plaintiffs from the filing of the operative complaint in October 2016 through the present. However, plaintiffs have not identified *any* agency action after the 2016 Rule was preliminarily enjoined in December 2016 that could plausibly be understood to impose such a "threat."

Any controversy that might have existed when this lawsuit was filed in 2016 was eliminated by the proposal and promulgation of the 2020 Rule, which made clear that objecting religious entities like plaintiffs were under no threat of government enforcement for failing to provide and cover gender-transition procedures or abortions. See 85 Fed. Reg. 37,160, 37,188 (June 19, 2020) ("The Department sees no compelling interest [under RFRA] in forcing the provision, or coverage, of [gender-transition] services by covered entities[] ...."); id. at 37,192-93 ("This final rule ensures that the Department's Section 1557 regulations are implemented consistent with the abortion neutrality and statutory exemptions in Title IX."); see also id. at 37,206; 84 Fed. Reg. 27,846, 27,849, 27,864 (June 14, 2019).

At that point, no agency action could be said to be imposing any "threat" of enforcement burdening plaintiffs' religious exercise. And there can be no credible

<sup>&</sup>lt;sup>3</sup> The absence of any threat of enforcement was clear regardless of the existence or scope of any religious exemption in the 2020 Rule. *Contra* Pls. Br. 53.

assertion that HHS's then-expressed position was a mere act of "litigation posturing." Yarls v. Bunton, 905 F.3d 905, 910-11 (5th Cir. 2018). Accordingly, plaintiffs' RFRA claim for injunctive relief became (and remains) moot, and the district court lost any jurisdiction to grant additional relief. See Empower Texans, Inc. v. Geren, 977 F.3d 367, 369 (5th Cir. 2020) ("[F]ederal courts have no authority to hear moot cases.").

- **C.** Plaintiffs further assert that this case is not moot because HHS currently "impose[s] the same RFRA-violating burden" through the agency's interpretation of "Section 1557 itself." Pls. Br. 46; *see* Pls. Br. 48-51.
- 1. As an initial matter, even if HHS were now imposing the alleged threat of enforcement that plaintiffs purport to challenge in their reframed RFRA claim, that would not reanimate a challenge to the 2016 Rule that has long been moot. See, e.g., Hirschfeld v. ATF, 14 F.4th 322, 325 (4th Cir. 2021) (rejecting attempts to revive case after it became moot); Gayle v. Warden Monmouth County Corr. Inst., 838 F.3d 297, 304 n.8 (3d Cir. 2016) (observing that subsequent event "does not 'unmoot' the case and retroactively confer jurisdiction"); Robertson v. Biby, 719 F. App'x 802, 804 (10th Cir. 2017) (similar).

The various mootness cases that plaintiffs cite (Br. 51-52) are distinguishable on this basis. Those cases involve defendants immediately replacing a challenged action with a new action and arguing that the new action simultaneously mooted the case. See Northeastern Fla. Chapter of Associated Gen. Contractors of Am. v. City of

Jacksonville, 508 U.S. 656, 660-61 (1993) (arguing that challenge to ordinance was mooted by repeal and immediate replacement); Texas v. Biden, 20 F.4th 928, 946 (5th Cir. 2021) (arguing that new memoranda mooted appeal); Opulent Life Church v. City of Holly Springs, 697 F.3d 279, 284-86 (5th Cir. 2012) (arguing that amendment to zoning ordinance mooted challenge to original ordinance). These decisions rejecting mootness thus stand for the limited proposition that a case does not become moot where a defendant "ha[s]n't really ceased anything" and continuously "perpetuat[es] the very same injury that brought the [parties] into court." Texas, 20 F.4th at 959-60 (emphasis omitted).

Here, even under plaintiffs' framing of their RFRA claim, HHS had ceased imposing any threat of enforcement on plaintiffs (assuming one ever existed) as of June 2020 at the latest, when HHS rescinded the 2016 Rule and replaced it with the 2020 Rule. Indeed, plaintiffs assert that HHS's May 2021 "[n]otification by its terms restores the same interpretation of Section 1557 that was embodied in the 2016 Rule." Pls. Br. 52 (emphasis added). Plaintiffs are thus incorrect to characterize this as a case in which challenged conduct consistently continued through other means, keeping the case alive notwithstanding the repeal and replacement of the initially challenged action. Pls. Br. 52-53. That HHS took a new action to allegedly reimpose the

challenged harm almost a full year (at least) after that alleged harm ceased does not retroactively save plaintiffs' claim from mootness.<sup>4</sup>

Plaintiffs appear to take issue with this outcome as a matter of policy. See Pls. Br. 32 (objecting to "play[ing] whack-a-mole every time HHS concocts another method" of imposing a similar burden); see also Pls. Br. 52. But this objection amounts to a request to pursue broad claims for injunctive relief based on free-floating fears of future enforcement, untethered to any actual agency actions or continuous burdens imposed throughout the course of litigation. Article III forecloses this novel request.

2. In any event, plaintiffs mischaracterize HHS's current position regarding Section 1557's interpretation and enforcement. In its May 2021 notification, HHS explained that, "[c]onsistent with ... Bostock and Title IX," it would "interpret and enforce Section 1557's prohibition on discrimination on the basis of sex to include ... discrimination on the basis of gender identity." 86 Fed. Reg. 27,984, 27,985 (May 25, 2021). The agency made clear, however, that this interpretation "does not itself determine the outcome in any particular case or set of facts." *Id.* And HHS further emphasized that in enforcing Section 1557, it would "comply with the Religious Freedom Restoration Act ... and all other legal requirements." *Id.* 

<sup>&</sup>lt;sup>4</sup> Similarly, HHS's forthcoming Notice of Proposed Rulemaking regarding Section 1557 could not revive an otherwise moot case, regardless of its contents.

More recently, in its March 2022 notice, HHS addressed how the prohibition on gender-identity discrimination relates to gender-affirming care. *See* HHS, Office for Civil Rights, *HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy* (Mar. 2, 2022), https://go.usa.gov/xzGbp. However, that document did not specifically address the provision of such care by objecting religious entities, or otherwise undermine HHS's commitment to respect such entities' religious exercise through a faithful application of RFRA.

HHS's recent statements thus do not establish that the agency currently interprets and will enforce Section 1557 to require entities raising religious objections to nonetheless perform and cover gender-transition services or abortions. Nor do the various district-court decisions that plaintiffs point to in litigation between *private* parties under Section 1557 support plaintiffs' characterization regarding how the government currently interprets and will enforce Section 1557. See Pls. Br. 49-50. In short, the district court could not properly continue to exercise jurisdiction in this case based on positions that HHS has not actually adopted.

## II. In the Alternative, Plaintiffs Failed to Demonstrate Standing, Ripeness, and Imminent Irreparable Harm Sufficient to Support a Permanent Injunction.

## A. Plaintiffs Lack Standing.

1. Plaintiffs argue that they have demonstrated an injury-in-fact because their conduct is "arguably proscribed" by the 2016 Rule and Section 1557. Pls. Br. 23. However, "plaintiffs must demonstrate standing for each claim that they press and for

each form of relief that they seek." TransUnion LLC v. Ramirez, 141 S. Ct. 2190, 2208 (2021). Under their reframed RFRA claim, plaintiffs purport to seek an injunction against enforcement of Section 1557, not the 2016 Rule. Accordingly, whatever indication the 2016 Rule might have given with respect to the permissibility of plaintiffs' conduct based on their religious objections is now irrelevant.<sup>5</sup>

Plaintiffs also miss the point in arguing that Section 1557 itself arguably proscribes their conduct. Pls. Br. 23-24. Plaintiffs ignore Article III's requirements that an injury must be "concrete and particularized" and "actual or imminent, not 'conjectural' or 'hypothetical." Susan B. Anthony List v. Driehaus, 573 U.S. 149, 158 (2014) (SBA List) (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992)). Plaintiffs' allegations of harm rest entirely on their speculation that HHS will one day interpret Section 1557 to require them to provide or cover gender-transition services or abortions over their religious objections, despite RFRA's protections. But this speculative "allegation of future injury" cannot establish standing where plaintiffs have not demonstrated that the threatened injury is "certainly impending" or that there is a "substantial risk" that it will occur. Id. (quoting Clapper v. Amnesty Int'l USA, 568 U.S. 398, 414 & n.5 (2013)).

<sup>&</sup>lt;sup>5</sup> Regardless, HHS recognized that the 2016 Rule did not displace "the protections afforded by provider conscience laws" and RFRA, and explained that "application of RFRA" on a case-by-case basis "is the proper means to evaluate any religious concerns about the application of Section 1557 requirements." 81 Fed. Reg. 31,375, 31,379-80 (May 18, 2016).

As explained in our opening brief (at 41-42), in assessing this prong of the preenforcement standing analysis, the relevant question is whether plaintiffs' conduct is
proscribed under Section 1557 and RFRA, as viewed together. Plaintiffs suggest (Br.
28-29) that the Court should consider only Section 1557 at this step of its inquiry.
But plaintiffs provide no justification for ignoring a critical part of the statutory
interpretation analysis that pre-enforcement standing requires. The Court can no
more disregard RFRA in addressing whether plaintiffs' conduct is proscribed than it
could ignore a subsection of Section 1557. *See Bostock*, 140 S. Ct. at 1754 ("RFRA
operates as a kind of super statute, displacing the normal operation of other federal
laws ....").

At best, plaintiffs can only demonstrate uncertainty about how Section 1557 and RFRA interact, and how HHS might act with respect to potential enforcement, in each situation involving an objecting religious entity. Such uncertainty does not confer standing. See, e.g., City of Los Angeles v. Lyons, 461 U.S. 95, 107 n.8 (1983).

2. Plaintiffs further argue that they face a credible threat of prosecution and thus have demonstrated an injury-in-fact. Pls. Br. 24-26. But plaintiffs have pointed to no instances of HHS revoking federal funding from, or bringing enforcement actions in court against, religious providers for declining to provide or cover gender-transition procedures or abortions in the twelve years since Section 1557 was enacted. Cf. SBA List, 573 U.S. at 164 (substantial threat of future enforcement demonstrated

where enforcement agency had already found probable cause that plaintiffs had violated challenged statute in the past).

Plaintiffs attempt to rely on HHS's general statements that it will enforce

Section 1557's prohibition of sex discrimination, including the fact that HHS did not

"disavow[] enforcement" against plaintiffs. Pls. Br. 24-25. But the prospect that

HHS might bring an enforcement action against a provider who refuses to treat a

transgender patient's broken bone based on the patient's gender identity provides no

basis for concluding that HHS will bring an enforcement action against providers who

decline to provide gender-transition services due to their religious beliefs. The type of

religious objections that could be asserted in those two scenarios would be quite

different, and the likelihood of government enforcement activity would likewise vary.

Plaintiffs declare that there is a "history of past enforcement" (Br. 25), but the examples they cite do not support this assertion. That HHS (1) received a complaint against a Catholic hospital for denying birth control to a cis gender woman, see ROA.1722 & n.3; (2) indicated that it would initiate an investigation against a provider for denying gender-transition services, see Complaint, Conforti v. St. Joseph's Healthcare Sys., Inc., No. 2:17-cv-50, 2017 WL 67114 (D.N.J. Jan. 5, 2017)<sup>6</sup>; and (3) investigated a

<sup>&</sup>lt;sup>6</sup> Indeed, this example underscores the lack of any credible threat of enforcement. HHS halted its investigation when the provider in *Conforti* invoked religious protections; once a private lawsuit was filed, HHS did not proceed with the investigation; and the administrative complaint was ultimately withdrawn after the private lawsuit was settled.

state, which cannot assert a RFRA defense, for declining to cover gender-transition procedures in its Medicaid program, *see* ROA.1773 & n.15, does not show that HHS has brought enforcement actions in court or initiated funding-termination proceedings against religious providers who decline to provide gender-transition services or abortions. Nor does it show a "substantial" likelihood of future enforcement sufficient to support standing. *See California v. Texas*, 141 S. Ct. 2104, 2114 (2021).

Plaintiffs further assert that they need not actually demonstrate a credible threat of enforcement, because such a threat is "assumed" whenever a "recently enacted" law proscribes plaintiffs' conduct. Pls. Br. 24 (alteration omitted). As the case plaintiffs cite demonstrates when quoted in full, however, any such assumption only applies when dealing with "statutes that facially restrict expressive activity by the class to which the plaintiff belongs." Speech First, Inc. v. Fenves, 979 F.3d 319, 335 (5th Cir. 2020) (emphasis added). In other contexts, such as here, the ordinary requirement applies whereby challengers "must show that the likelihood of future enforcement is 'substantial." California, 141 S. Ct. at 2114. Plaintiffs have failed to do so.

**3.** Plaintiffs' reliance on private lawsuits is similarly misplaced. Pls. Br. 4, 23-24. Private lawsuits under Section 1557 have no bearing on whether *defendant HHS* will bring enforcement actions against plaintiffs for declining to provide or cover gender-transition services, and an injunction against HHS has no effect on private litigants. *See Balogh v. Lombardi*, 816 F.3d 536, 544 (8th Cir. 2016) (plaintiff did not

have standing despite threat of private lawsuits because the "injury is "fairly traceable" only to the private civil litigants").

Nor do the private lawsuits plaintiffs cited (Br. 24 n.1) demonstrate that plaintiffs' conduct—declining to perform and cover gender-transition services and abortions based on religious objections—is arguably proscribed. Plaintiffs identify only three district-court decisions in Section 1557 lawsuits that purportedly involve religious entities with objections to gender-transition procedures. Two of those decisions do not discuss RFRA at all. See Scott v. St. Louis Univ. Hosp., No. 4:21-cv-1270, 2022 WL 1211092 (E.D. Mo. Apr. 25, 2022); Hammons v. University of Md. Med. Sys. Corp., 551 F. Supp. 3d 567 (D. Md. 2021). The third does not address the merits of the RFRA claim or otherwise discuss whether an entity with a religious objection and a valid RFRA claim would nonetheless be required to perform or cover gender-transition services under Section 1557. See C.P. ex rel. Pritchard v. Blue Cross Blue Shield of Ill., 536 F. Supp. 3d 791, 797 (W.D. Wash. 2021).

4. As explained in our opening brief (at 44-45), plaintiffs have failed to demonstrate any likelihood that they will be subject to an enforcement action. Plaintiffs contend (Br. 30) that a declaration from Dr. Robert Hoffman, a CMDA member who does not prescribe hormones for gender transitions, demonstrates that he is "one patient away from a complaint" being filed against him. But the cited declaration undermines any claim to standing based on this individual: Dr. Hoffman specifically explains that his hospital "has always accommodated [his] beliefs" and

"[t]hat accommodation is quite easy[]" because he "work[s] with other pediatric endocrinologists who are able to perform gender transition procedures for children, and so there is no need for [him] to do so." ROA.976-977.

Plaintiffs also assert (Br. 30) that a complaint is unnecessary, because HHS could learn about potential Section 1557 violations from the failure to certify compliance with Section 1557. Although HHS can initiate an investigation through means other than the receipt of a complaint, see 45 C.F.R. § 80.7(c), that is beside the point. The fact that HHS could receive complaints alleging violations of Section 1557, or could assess compliance otherwise, does not demonstrate a likelihood that HHS will bring enforcement actions against objecting religious entities. See AT&T Co. v. EEOC, 270 F.3d 973, 976 (D.C. Cir. 2001) (explaining that even "law enforcement agencies rarely have the ability, or for that matter the need, to bring a case against each violator").

Nor does the motion to modify the injunction in this case support plaintiffs' claim that they face a credible threat of prosecution. Pls. Br. 26. HHS sought to clarify that it would not violate the injunction "by taking any action under Section 1557 as to any entities that Defendants are unaware are covered by the scope of the Order, given that Plaintiffs' members are not known to Defendants." ROA.5072.

That HHS may enforce Section 1557 against non-religious entities and cannot identify

all of plaintiffs' members<sup>7</sup> without further information does not demonstrate that HHS intends to bring enforcement actions against plaintiffs or any other religious entities, or that plaintiffs suffer imminent injury sufficient to support standing. The motion to modify simply reflects an understandable desire by HHS to avoid risking contempt by taking enforcement action against a seemingly non-religious entity.

5. The various standing cases plaintiffs cited only confirm that this suit is not justiciable.

First, plaintiffs cite *Barilla v. City of Houston*, 13 F.4th 427 (5th Cir. 2021), for the proposition that "all Plaintiffs need to show is that it's 'plausible' their conduct is proscribed." Pls. Br. 18-19. In *Barilla*, this Court held at the motion-to-dismiss stage that plaintiffs had standing because under a "plausible reading" of the challenged statute their conduct was arguably proscribed. *See* 13 F.4th at 433. Because this case was resolved on summary judgment, however, plaintiffs have a higher burden to demonstrate standing, and plaintiffs have not met it. *See Clapper*, 568 U.S. at 411-12 ("The party invoking federal jurisdiction bears the burden of establishing standing—and, at the summary judgment stage, such a party ... must set forth by affidavit or other evidence specific facts." (quotation marks omitted)).

Second, plaintiffs cite Contender Farms, LLP v. U.S. Department of Agriculture, 779 F.3d 258 (5th Cir. 2015), for the principle that objects of a regulation generally have

<sup>&</sup>lt;sup>7</sup> CMDA alone has "around 19,000" members. Christian Med. & Dental Ass'ns, *About Us* (2022), https://perma.cc/5QU3-96GJ.

standing to challenge that regulation because "[a]n 'increased regulatory burden' itself 'satisfies the injury in fact requirement." Pls. Br. 29. This is correct as a general principle of administrative law, and perhaps would have applied in the context of plaintiffs' Administrative Procedure Act challenge to the 2016 Rule. But under their reframed RFRA claim, plaintiffs no longer challenge the 2016 Rule; instead, they challenge hypothetical future enforcement actions by HHS of which plaintiffs may never be the object and upon which they thus cannot establish standing under this principle.

Third, plaintiffs' invocation (Br. 26-27) of Federal Election Commission v. Cruz is irrelevant. The issue in Cruz was whether an injury caused by a live regulation was traceable to, and could be redressed by the invalidation of, the underlying statute. 142 S. Ct. at 1649. Here, by contrast, the relevant question is whether plaintiffs have demonstrated a credible threat of enforcement of Section 1557 alone (and thus an injury-in-fact) at the time of filing this lawsuit, given that they now seek to enjoin the enforcement of the statute and not the rescinded 2016 Rule.

Finally, in two cases on which plaintiffs rely (Br. 28), the injury sufficient to support standing was chilled speech under the First Amendment. *See Speech First*, 979 F.3d at 330-31 (highlighting evidence in record that speech was deterred by challenged university policies concerning speech); *Pool v. City of Houston*, 978 F.3d 307, 312-13 (5th Cir. 2020) (holding that plaintiff had "standing to seek an injunction that would guard against continued chilling of his speech" based on history of attempted

enforcement of challenged requirement). Plaintiffs do not attempt to argue on appeal that HHS's interpretation of Section 1557 has chilled their speech or religious exercise, much less point to any support in the record for such a finding. To the contrary, their brief makes clear that plaintiffs have not provided or covered gender-transition procedures or abortions against their religious beliefs despite their alleged fear of enforcement actions. See Pls. Br. 8 ("In accordance with its ... religious beliefs, [Franciscan Alliance] does not perform gender-transition procedures .... Also according to its Catholic beliefs, Franciscan does not perform abortions."); Pls. Br. 29 ("Plaintiffs are already engaged in the relevant conduct."); see also Pls. Br. 3, 30, 32.

#### B. Plaintiffs' Claim Is Not Ripe.

Plaintiffs' argument that their RFRA claim is ripe also fails. Plaintiffs assert that this case presents a "purely legal question" of "whether the challenged interpretation of Section 1557 violates RFRA." Pls. Br. 55 (cleaned up). But as we have explained, *supra* pp. 11-12; Gov't Br. 36-38, HHS has not actually adopted the interpretations that plaintiffs challenge, rendering any analysis purely hypothetical. Plaintiffs are thus asking the Court to broadly declare that a wide range of hypothetical future HHS enforcement actions all violate RFRA such that plaintiffs are entitled to an anticipatory permanent injunction divorced from the specific context necessary to evaluate a RFRA claim.

In any event, courts have long recognized that even a "purely legal" question is unfit for adjudication where a concrete factual context would facilitate a court's

"ability to deal with the legal issues presented." National Park Hosp. Ass'n v.

Department of Interior, 538 U.S. 803, 812 (2003); see, e.g., Texas v. United States, 523 U.S.

296, 301 (1998); California Bankers Ass'n v. Shultz, 416 U.S. 21, 56 (1974); Toilet Goods

Ass'n v. Gardner, 387 U.S. 158, 163-64 (1967); Zemel v. Rusk, 381 U.S. 1, 18-20 (1965);

United Pub. Workers of Am. v. Mitchell, 330 U.S. 75, 89-90 (1947); Pennzoil Co. v. FERC,

645 F.2d 394, 398 (5th Cir. 1981). Judicial review is thus properly deferred if "[t]he operation of [a] statute" would be "better grasped when viewed in light of a particular application." Texas, 523 U.S. at 301.

The issues that plaintiffs raise would much better be resolved in the context of a fully-developed factual record where HHS actually requires plaintiffs to do something specific. Gov't Br. 46-47; see also American Fed'n of Gov't Emps. v. O'Connor, 747 F.2d 748, 755-56 (D.C. Cir. 1984) ("Courts customarily deal in specific facts or circumstances drawn with some precision and legal questions trimmed to fit those facts or circumstances; they are not in the business of deciding the general without reference to the specific."). One example of a concrete dispute would be if HHS brought an enforcement action against an objecting religious hospital for denying use of an operating room to perform a hysterectomy for a transgender man, where the treating physician has indicated that the procedure was intended to treat severe endometriosis but the hospital denied the surgery, arguing that it constituted a gender-transition procedure. Among other things, a court would have to determine, based on the evidence in the record, whether the procedure was deemed medically necessary to

treat severe endometriosis, how the hospital treats other patients with similar conditions, whether performing the procedure would substantially burden the hospital's religious exercise, whether there is a compelling government interest, and whether the government satisfied RFRA's least-restrictive-means requirement. This highly fact-specific inquiry underscores why plaintiffs' RFRA claims cannot be evaluated in the abstract.

Plaintiffs do not dispute that RFRA requires consideration of "the specific factual context of the religious exemption requested by a particular plaintiff." Pls. Br. 57. For good reason: The Supreme Court and this Court have repeatedly made clear that "RFRA, and the strict scrutiny [standard] it adopted [from First Amendment jurisprudence]," requires "a case-by-case, fact-specific inquiry." Brown v. Collier, 929 F.3d 218, 230 (5th Cir. 2019); Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418, 430-31 (2006); see also Ramirez v. Collier, 142 S. Ct. 1264, 1283 (2022). That is true at every stage of the RFRA analysis. See Brown, 929 F.3d at 230 (substantial-burden analysis is fact-specific); U.S. Navy Seals 1-26 v. Biden, 27 F.4th 336, 350 (5th Cir. 2022) (per curiam) (compelling interest must be focused on "particular claimant").

Instead, plaintiffs contend (Br. 57) that HHS was required to raise this issue below as a partial defense to the RFRA claim on the merits. That response misses the point: HHS is not contesting merely the scope of relief awarded, but rather that *any* relief could be awarded in the absence of sufficiently-concrete factual circumstances

required to properly assess every element in the RFRA analysis. This is appropriately framed as an issue of ripeness because it demonstrates that plaintiffs' reframed RFRA claim is not currently fit for judicial resolution.

Moreover, plaintiffs face little, if any, cognizable harm from deferring judicial review. Although plaintiffs may prefer to press broad RFRA claims divorced from any government enforcement activity compelling any specific action, and to obtain broad injunctive relief as soon as possible, that preference does not constitute hardship justifying premature judicial review. Plaintiffs do not contest (Br. 56) that "mere uncertainty" does not "constitute[] a hardship for purposes of the ripeness analysis." National Park Hosp. Ass'n, 538 U.S. at 811. Their only response is that HHS's actions also cause "practical harm" by forcing plaintiffs to either change their behavior or risk financial consequences, including losing federal funding. Pls. Br. 56 (cleaned up); see Pls. Br. 1, 37.8 But as explained in our opening brief (at 51), HHS has not evaluated whether Section 1557 could in any specific circumstance require the provision or coverage of gender-transition procedures or abortions by objecting religious entities, and thus plaintiffs are not being forced to do anything.

<sup>&</sup>lt;sup>8</sup> Plaintiffs claim that HHS requires them to "immediately revise their policies," Pls. Br. 56 (cleaned up)—but this alleged directive comes from the regulatory impact analysis section of the 2016 Rule. Ripeness is assessed as of the time of this Court's decision. See Walmart Inc. v. U.S. Dep't of Justice, 21 F.4th 300, 313 (5th Cir. 2021). Plaintiffs' assertion of current hardship cannot depend on a statement in the discussion of costs imposed by a rule that was rescinded over two years ago. In any event, it does not appear that plaintiffs revised their policies. See supra p. 21.

Even if HHS were to determine at some point that Section 1557 requires plaintiffs to provide or cover gender-transition procedures or abortions, plaintiffs would still be many steps removed from losing federal funding. *See Colwell v. HHS*, 558 F.3d 1112, 1128 (9th Cir. 2009). First, HHS would be required to attempt to achieve informal or voluntary compliance. 45 C.F.R. § 80.8(c); *see id.* § 92.5(a). Second, there must be a formal adjudication and an administrative hearing. *Id.* § 80.8(c). Third, HHS must wait thirty days after providing a full written report to Congressional committees. *Id.* Moreover, "[j]udicial review of any funding termination is available in an Article III court." *Colwell*, 558 F.3d at 1128. Plaintiffs make no effort to explain why they would be harmed by waiting to bring their RFRA claims in the context of a factual record, at the outset of an investigation by HHS, if HHS were to ever initiate an investigation of them.

C. The District Court Erred in Concluding that Plaintiffs
Demonstrated Imminent Irreparable Harm Sufficient to
Justify Permanent Injunctive Relief.

For many of the same reasons discussed above and in our opening brief (at 52-53), plaintiffs have not demonstrated imminent irreparable harm sufficient to justify permanent injunctive relief against HHS. Plaintiffs argue that the "loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." Pls. Br. 31. Similarly, plaintiffs assert that they have been irreparably harmed by being made to "choose between violating their consciences and harming their patients, or suffering crippling penalties destroying their ministries."

Pls. Br. 32. But as explained above, *supra* pp. 21, 24, plaintiffs do not actually argue that their religious exercise has been chilled; nor have they faced any such choice.

Plaintiffs attempt to invoke other cases in which injunctive relief was rewarded for successful RFRA claims. Pls. Br. 31, 34-35. But just because such relief is often appropriate does not mean that it is automatic. *See, e.g.*, ROA.4798-4799 (declining to grant injunctive relief in issuing final judgment on RFRA claim). Plaintiffs must still satisfy the ordinary requirements to establish entitlement to such relief. They have not done so here. Plaintiffs' speculation about enforcement positions that HHS might take at some unspecified future time does not demonstrate irreparable harm.

#### **CONCLUSION**

For the foregoing reasons, this Court should vacate the district court's permanent injunction and remand with instructions to dismiss for lack of jurisdiction.

Respectfully submitted,

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# **CERTIFICATE OF SERVICE**

I hereby certify that on July 1, 2022, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system.

/s/ McKaye L. Neumeister

McKaye L. Neumeister

### **CERTIFICATE OF COMPLIANCE**

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6,458 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Garamond 14-point font, a proportionally spaced typeface.

/s/ McKaye L. Neumeister
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