

October 3, 2022

Via Federal eRulemaking Portal

Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Re: EPPC Scholars Comment Opposing “Nondiscrimination in Health Programs and Activities,” RIN 0945-AA17

Dear Secretary Becerra:

We are scholars at the Ethics and Public Policy Center (EPPC), and we write in strong opposition to the Department of Health and Human Services’ (HHS) proposed rule “Nondiscrimination in Health Programs and Activities” (“Proposed Rule”).¹ Roger Severino is an EPPC Senior Fellow, member of EPPC’s HHS Accountability Project, and the former Director for the Office for Civil Rights at the Department of Health and Human Services (2017–2021). Mr. Severino was instrumental in overseeing the drafting and implementation of the nondiscrimination rule HHS seeks to amend and significantly repeal (the 2020 Rule).² Rachel N. Morrison is an EPPC Fellow, member of the HHS Accountability Project, and former attorney at the Equal Employment Opportunity Commission. Mary Hasson is the Kate O’Beirne Senior Fellow at EPPC, an attorney, and co-founder of EPPC’s Person and Identity Project, an initiative that equips parents and faith-based institutions to counter gender ideology and promote the truth of the human person.

The Proposed Rule would radically remake American healthcare by replacing science-based medicine with ideology-driven mandates. As proposed, the Rule is arbitrary and capricious, exceeds statutory authority, and is unlawful and unconstitutional. The primary proposed changes are unsupported by substantial evidence. The Proposed Rule contradicts long-standing scientific understandings of human biology and thereby endangers public health. The Proposed Rule turns the clock back on girls’ and women’s rights, tramples parental rights, harms children’s interests, dismantles sex-based patient protections, and violates religious freedom and conscience rights of medical professionals, hospitals, and religious institutions. The Proposed Rule inverts our civil rights law and should be withdrawn and abandoned.

The policies HHS is proposing will have destructive impacts in the real world:

The Proposed Rule will drive out faith-based hospitals and medical providers which will especially hurt poor and rural communities.

¹ 87 Fed. Reg. 47824.

² 87 Fed. Reg. 37160, *et seq.*

The Rule would require pregnant women who identify as men to be treated “consistent with the individual’s gender identity”³ which can and has led to disaster. As documented in the preamble to the 2020 Rule, a biological female with abdominal pain had her pregnancy complications misdiagnosed because the hospital treated her consistent with her preferred gender identity of male, resulting in a stillbirth of the child.⁴

Further, the Rule will predictably result in the infliction of devastating permanent physical and psychological harm to children who doctors will reasonably feel bound to place on puberty blockers and cross-sex hormones and to sterilize through the removal of healthy reproductive organs for fear of being sued for “gender identity discrimination” under the Proposed Rule. The risks of inflicting severe physical and psychological trauma to families by not only encouraging, but mandating, medical “transition” and social conversion of children, ostensibly to another sex, cannot be understated and includes an elevated risk of suicide.⁵ It will be the height of arbitrariness and capriciousness to finalize such a dangerous rule in the face of these and the many other grave harms identified in this comment when they are not only not mandated by Congress, but go against the very statute the Proposed Rule purports to enforce.

1. There is no need for regulatory action.

EO 12866, section 1(b) establishes the principles of regulation, including that “Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.” To justify replacing current regulations, including the 2020 Rule, HHS must provide specific evidence as to how those regulations are causing harms or burdens and how the Proposed Rule would remedy the alleged defects *without* causing equal or greater harms and burdens.⁶ HHS has failed to meet that exacting standard in every respect.

HHS claims the Proposed Rule is necessary “to better align the Section 1557 regulation with the statutory text ... to reflect recent developments in civil rights case law, to address unnecessary confusion in compliance and enforcement resulting from the 2020 Rule, and to better address issues of discrimination that contribute to negative health interactions and outcomes.”⁷ It also claims its proposed regulations are “consistent with the statutory text of Section 1557 and Congressional intent.”⁸ As explained in more detail below, the Proposed Rule contradicts 1557’s statutory text (and the text of Title IX, which it incorporates by reference), furthers the polar opposite of Congressional intent, ignores relevant case law, adds unnecessary confusion in compliance and enforcement, and arbitrarily, capriciously, and dangerously meddles in the practice of medicine, and expands the scope of discrimination under 1557 beyond reasonable bounds. Indeed, the Proposed rule fails to cite any

³ Proposed § 92.206(b)(3).

⁴ 85 FR 37189-37190.

⁵ See *Protecting Our Children: How Radical Gender Ideology is Taking Over Public Schools & Harming Kids*, HERITAGE FOUNDATION (Mar. 7, 2022), <https://www.heritage.org/gender/event/protecting-our-children-how-radical-gender-ideology-taking-over-public-schools-harming> (testimony of mother whose daughter took her own life after and because of medical gender “transition”); see also Jay P. Greene, *Puberty Blockers, Cross-Sex Hormones, and Youth Suicide*, HERITAGE FOUNDATION (June 13, 2022), https://www.heritage.org/sites/default/files/2022-06/BG3712_0.pdf, (demonstrating invalidity of leading studies purporting to find that “gender-affirming” interventions prevent suicide *contra* findings using superior research design that show that easing access to puberty blockers and cross-sex hormones by minors without parental consent increases suicide rate.).

⁶ *Michigan v. EPA*, 135 S. Ct. 2699 (2015) (regulation is irrational if it disregards the relationship between its costs and benefits); *Alltelcorp v. FCC*, 838 F.2d 551, 561 (D.C. Cir 1988) (“a regulation perfectly reasonable and appropriate in the face of a given problem is highly capricious if that problem does not exist”).

⁷ 87 Fed. Reg. 47829.

⁸ 87 Fed. Reg. 47828.

legislative history indicating Congress ever contemplated application of sexual orientation, gender identity, or transgender status under Section 1557 in the Affordable Care Act (ACA).

The Section 1557 proposed rule seeks to replace the 2020 Rule on Section 1557. HHS claims that the 2020 Rule “hinder[s] the Department’s mission of pursuing health equity and protecting public health.”⁹ Indeed, on September 30, 2022, Vice President Harris stated in an interview about “disparities” and climate events her belief that “our lowest income communities and our communities of color [] are the most impacted by these extreme conditions . . . so we have to address this in a way that is about *giving resources based on equity*” and “making sure that the bad actors pay a price for what they do that is directly harming [those] communities in terms of their health and well being.”¹⁰ But the mission of HHS is to “enhance the health and well-being of *all* Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.”¹¹ There is nothing in HHS’s mission statement about “health equity,”¹² rather, the law imposes equal protection and nondiscrimination obligations. Thus, it is arbitrary and capricious for HHS to pursue health equity when it contradicts equality, especially when it would result in illegal discrimination. An elementary principle of civil rights law is that disparities in and of themselves do not prove illegal discrimination. It is therefore incumbent on the Agency to prove any disparities are the result of illegal discrimination in every particular instance. Broad, conclusory, and unsubstantiated allegations of “structural racism on health and health care in the United States” made by the Proposed Rule are insufficient to support the equity mandates contained within it, including the idea that “implicit bias must be addressed.”¹³

HHS also claims that the 2020 Rule “caused confusion in compliance by failing to provide clear procedural requirements.”¹⁴ This is mere speculation. HHS fails to cite to any entity, complaint, or enforcement action that demonstrates such confusion exists. Making such a claim without substantial concrete evidence is arbitrary and capricious.

There is no evidence that the 2020 Rule has or will cause *any* harms or burdens necessitating the need for this rulemaking. To justify replacing the 2020 Rule, HHS must provide specific evidence as to how that Rule is causing harms or burdens.¹⁵

⁹ 87 Fed. Reg. 47829.

¹⁰ Priyanka Chopra Jonas interview of Kamala Harris before the Democratic National Committee’s Women’s Leadership Forum in Washington, D.C. (Sept. 30, 2022), <https://youtu.be/o95OaVB79Hk>.

¹¹ U.S. Dep’t Health & Human Servs., Introduction: About HHS, <https://www.hhs.gov/about/strategic-plan/2022-2026/introduction/index.html#mission>. (emphasis added).

¹² For example, several states employed discriminatory racial set asides for their federally funded COVID-19 vaccine distribution to promote “health equity.” EPPC, along with Boyden Gray & Associates, filed a complaint on behalf of a New Hampshire resident whom the state prohibited from receiving a COVID-19 vaccine solely because of his race. *Cf.* EPPC and Boyden Gray & Associates Demand HHS Hold New Hampshire Accountable for Unlawful Racial Set-Asides in COVID-19 Vaccine Distribution, <https://eppc.org/news/eppc-and-boyden-gray-associates-demand-hhs-hold-new-hampshire-accountable-for-unlawful-racial-set-asides-in-covid-19-vaccine-distribution/>. Despite the clear violations of Section 1557 and Title VI of the Civil Rights Act of 1964, HHS inexplicably dismissed the complaint without any conclusions of law. Nevertheless, HHS states in the Proposed Rule that “ensuring nondiscriminatory access to health care, vaccines, and protective equipment during a public health emergency will more effectively and expeditiously end the emergency for everyone.” 87 Fed. Reg. 47831.

¹³ 87 Fed. Reg. 47832.

¹⁴ 87 Fed. Reg. 47830.

¹⁵ See EO 12866 § 1(b) (establishing the principles of regulation, including that “Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem”).

The Proposed Rule explicitly rejects the U.S. Constitution’s Equal Protection Clause standard for sex discrimination claims which allows (and sometimes requires) men and women to be treated differently based on inherent differences in biology when such differences are real, relevant, and not based on stereotypes.¹⁶ By contrast, under the Proposed Rule discrimination “on the basis of sex” includes “deny[ing] or limit[ing] health services, including those that are offered exclusively to individuals of one sex, to an individual based upon the individual’s . . . gender identity, or gender otherwise recorded,”¹⁷ without any room for deviation—no constitutional intermediate scrutiny as under the 2020 Rule, nor even allowance for an “exceedingly persuasive justification” as under the 2016 version of the Rule.¹⁸ Indeed, the Proposed Rule goes beyond denial or limitations on health services and outlaws “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.”¹⁹ The Proposed Rule clarifies that this includes “adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual’s gender identity.”²⁰

Thus, the Proposed Rule would prohibit health care professionals, medical facilities, and insurance companies from using any sex-based distinction, biological or otherwise, unless they can prove it “does not cause more than *de minimis* harm. And even that narrow, practically meaningless, exception does not apply if the sex-based distinction results in a denial or limitation of services.

The Proposed Rule’s claim that it would still allow “the practice of assigning patients to dual-occupancy rooms in hospitals and in-patient treatment facilities on the basis of sex”²¹ is grossly misleading, if not outright subterfuge. While under the Proposed Rule a hospital may perhaps continue to nominally assign “women” to shared rooms, they cannot exclude biological men who merely identify as women, or asexual, or non-binary, or two-spirit, *etc.* While doctors, nurses, and ordinary people will keep using the word women to mean biological women, HHS would respond as Inigo Montoya by saying “I do not think it means what you think it means.”²² In fact, the point of these provisions is not to address real social, cultural, biological, or psychological differences between men and women that are relevant to health care and merit special treatment, but to allow people who identify as transgender, or non-binary, or asexual, or two-spirit, *etc.* to use the facilities of *their* choosing, regardless of how people around them feel about it.

Indeed, the Proposed would contradict and render null an *existing* Voluntary Resolution Agreement OCR entered into with Michigan State University under Section 1557 regarding the Larry Nasser gymnast sex abuse scandal.²³ That resolution requires Michigan State medical facilities to offer patients chaperones of the sex of the patients’ choice when doctors conduct intimate examinations of them. This resolution was negotiated with the input of a parents’ representative of the gymnast victims. It would be a revictimization of those women and girls to say they must allow biological men who identify as women to see them in a vulnerable state, including gynecological exams, when their presence is not necessary for treatment and when they have requested a female chaperone.

¹⁶ *United States v. Virginia*, 518 U.S. 515 (1996).

¹⁷ Proposed § 92.206. *See also* proposed § 92.101(a)(2).

¹⁸ *See* former § 92.101(b)(3)(iv) (2016) (repealed and replaced by 2020 Rule).

¹⁹ Proposed § 92.206(b)(3) (emphasis added); *see also* 87 Fed. Reg. 47866.

²⁰ *Id.*

²¹ *Id.*

²² *The Princess Bride*, 20th Century Fox (1987).

²³ Voluntary Resolution Agreement between HHS OCR and Michigan State University *et al.*, (Aug. 5, 2019) (“the Patient’s wishes and comfort should determine the sex of the chaperone”).

<https://www.hhs.gov/sites/default/files/vra-between-msu-and-ocr.pdf>.

The preamble to the Proposed Rule makes it abundantly clear whose side HHS will take in such conflicts when it declares, without any scientific basis, that some men can get pregnant but “experience significant forms of ‘discrimination, stigma, and erasure’” in pregnancy care thus necessitating the Proposed Rule.²⁴ Under the Proposed Rule biological women who identify as men must always be treated and addressed as “pregnant men” while biological men who identify as women must always be allowed to room with biological women because to do otherwise would be more than *de minimis* harm.

When it comes to saying who is entitled to be treated as a man or a woman, nothing can be more arbitrary and capricious than the Proposed Rule’s Humpty Dumpty abuse of language.²⁵

Functionally, a provider must treat a patient or a customer according to their self-identified sex in all respects and at all times (which includes the counter-scientific “recognition” and “affirmance” that men can get pregnant), without any requirement that a person so identifying has undergone any “transition” treatments or surgeries, dresses or acts in any particular manner, has any diagnosis of gender dysphoria, or has procured a legal name or birth certificate change. The expected changes in the Proposed Rule are not about addressing people being barred from receiving healthcare due to irrelevant immutable characteristics such as race. Those issues were properly addressed by the 2020 Rule. Rather, if the Proposed Rule, as expected, redefines sex discrimination to include discrimination on the basis of sexual orientation and gender identity, then the Proposed Rule would not be about discrimination in any traditional sense because LGBT persons are not being denied healthcare based solely on their self-described identity or self-declared status as “transgender.” Statements and actions from HHS confirm that this Proposed Rule is intended to smuggle in a new, purported standard of care, based on subjective self-identification, into medicine and to impose a requirement for coverage of and participation in gender transition procedures under cover of nondiscrimination.

In 2020 OCR, reviewed all available evidence and found no denials of access based on identity remotely sufficient to justify regulatory intervention. Let’s not be coy about this Rule’s real goals—to require doctors to perform experimental gender transition surgeries and treatments on adults and minors and to require everyone’s insurance plans to pay for them. Because neither law, policy, nor science support such an extreme inversion of medicine, we request the Agency abandon all efforts at amending the Section 1557 Rule.

HHS has not and cannot demonstrate need and a substantial evidentiary basis for such a self-contradictory and unnecessary Proposed Rule. This is nothing more than arbitrary and capricious rulemaking by the Department driven by an unscientific ideology that will permanently disfigure the practice of medicine if finalized.

2. HHS appears to have acted outside the public rulemaking process.

Both the Obama and Trump administrations followed the legally required public comment and rulemaking process in issuing their Section 1557 regulations in 2016 and 2020, respectively. Yet on May 10, 2021, HHS unilaterally issued a “notification of interpretation and enforcement,” stating: “Consistent with the Supreme Court’s decision in *Bostock* and Title IX, beginning today, OCR will interpret and enforce Section 1557’s prohibition on discrimination on the basis of sex to include: (1) discrimination on

²⁴ 87 Fed. Reg. 47865.

²⁵ “‘When I use a word,’ Humpty Dumpty said in rather a scornful tone, ‘it means just what I choose it to mean — neither more nor less.’ ‘The question is,’ said Alice, ‘whether you can make words mean so many different things.’ ‘The question is,’ said Humpty Dumpty, ‘which is to be master — that’s all.’” Lewis Carroll, *Through the Looking-Glass, and What Alice Found There* (1871).

the basis of sexual orientation; and (2) discrimination on the basis of gender identity.”²⁶ First, as discussed below, *Bostock* did not apply to Title IX or Section 1557, and the Supreme Court made clear in its *Bostock* decision that it was not deciding any issue outside the hiring/firing context under Title VII.²⁷ Second, while the Department of Education (ED) has proposed, it has not yet issued, new Title IX regulations interpreting Title IX’s prohibition against sex discrimination to cover gender identity through the public notice and comment process. Third, HHS (as well as ED and the Department of Justice (DOJ)) cannot issue such commands outside the public rulemaking process. Indeed, one judge called HHS’ notification an act of “administrative fiat.”²⁸

Further, HHS issued an additional “guidance” document on March 2, 2022, in which it reiterated that OCR is investigating and enforcing Section 1557 cases involving purported discrimination on the basis of sexual orientation and gender identity.²⁹ The document stated: “Categorically refusing to provide treatment to an individual based on their gender identity is prohibited discrimination. Similarly, federally-funded covered entities restricting an individual’s ability to receive medically necessary care, including gender-affirming care, from their health care provider solely on the basis of their sex assigned at birth or gender identity likely violates Section 1557.”³⁰ By unilaterally issuing these documents outside the public rulemaking process, it appears HHS has already prejudged the outcome; it appears that the Agency will not seriously consider contrary views and is not interested in public input.

Indeed, a federal district court just ruled on October 1, 2022, that the March 2 guidance is “unlawful” and “vacated and set aside.”³¹ The court ruled the guidance is “arbitrary and capricious,” and it violated the APA for failing to follow notice-and-comment rulemaking requirements and to be published in the federal register as required by FOIA.³² As such, the March 2 guidance cannot be the impetus for this rulemaking.

3. The Proposed Rule’s expansive definition of discrimination “on the basis of sex” under Section 1557 is arbitrary and capricious and contrary to law.

Statutory language, logic, and medical history support the view that “sex” means “biological sex” under Title IX, and by extension Section 1557, not “gender identity.”

A. Sex under Section 1557 means biological sex.

Section 1557 guarantees that no individual can be denied benefits in a federally run or federally funded health program or activity based “on the ground prohibited under,” and the enforcement mechanisms from, four existing federal civil rights laws: Title VI of the Civil Rights Act of 1964 (race, color, national origin), Title IX of the Education Amendments of 1972 (sex), the Age Discrimination Act of 1975 (age), and Section 504 of the Rehabilitation Act of 1973 (disability).³³ As now-EPPC President Ryan Anderson and now-EPPC Senior Fellow Roger Severino noted in 2016, “Section 1557 of the ACA

²⁶ U.S. Dep’t Health & Human Servs., Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972 3 (May 10, 2021), <https://www.hhs.gov/sites/default/files/ocr-bostock-notification.pdf>.

²⁷ 140 S. Ct. 1731, 1753 (2020).

²⁸ *Franciscan Alliance, Inc. v. Becerra*, No. 7:16-cv-00108, at 8 (N.D. Tex. Aug. 9, 2021).

²⁹ Office for Civil Rights, U.S. Dep’t Health & Hum. Servs., HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy 1 (Mar. 2, 2022), <https://www.hhs.gov/sites/default/files/hhs-ocr-notice-and-guidance-gender-affirming-care.pdf>.

³⁰ *Id.* at 2.

³¹ *Texas v. Equal Emp’t Opportunity Comm’n*, No. 2:21-cv-194, at *32 (N.D. Tex. Oct. 1, 2022).

³² *Id.* at *17-*18, *24-*25.

³³ 42 U.S.C. § 18116.

does not create special privileges for new classes of people or require insurers and physicians to cover or provide specific procedures or treatments.”³⁴

Looking to the statutory text and congressional intent, it is clear that Section 1557 did not extend to sexual orientation or gender identity. Regarding sexual orientation, the ACA makes one reference to the term in a provision related to grant programs.³⁵ If Congress wanted to prohibit LGBTQ discrimination, it would have used the term as it did here. Regarding gender identity, the ACA was passed by Congress in March 2010, and at the time of its passage, there was no such medical concept as gender identity. The DSM-IV, in use in 2010, referred to the term as “gender identity disorder.” Indeed, the Proposed Rule does not (and cannot) cite to any legislative history in support of its expanded definition of sex discrimination, making its claim that the proposal is consistent with Congressional intent arbitrary and capricious.

HHS’s proposed definition of sex discrimination in § 92.101 states: “Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity.”³⁶ Despite defining sex discrimination, HHS does not define “sex.” It is irrational for HHS to define what constitutes discrimination “on the basis of sex,” while failing to define “sex.” Without knowing what “sex” is, one cannot know what sex discrimination is.

As explained below, “sex” in Title IX, and thus 1557 by extension, is clearly and historically meant to refer to “biological sex.” Indeed, HHS’s proposal to expand Section 1557 to include “gender identity” (among other bases) would rewrite the law and create a major question that raises serious constitutional problems concerning the separation of powers under *West Virginia v. EPA*.³⁷

B. Title IX proposed regulations misinterpret “sex discrimination” under Title IX.

Section 1557 incorporates Title IX, which provides, “No person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance.”³⁸ As such, analysis of Section 1557’s redefinition of “sex” starts with an analysis of “sex” under Title IX.

In recently proposed Title IX regulations, ED declines to define the term “sex” because, it argues, “sex can encompass many traits and because it is not necessary for the regulations to define the term for all circumstances.”³⁹ At the same time, however, “to clarify the scope of Title IX’s prohibition on discrimination on the basis of sex,” ED proposes that discrimination on the basis of sex be expanded to include (“at a minimum”) discrimination on the basis of:

- sexual orientation,
- gender identity,

³⁴ Roger Severino & Ryan T. Anderson, Proposed Obamacare Gender Identity Mandate Threatens Freedom of Conscience and the Independence of Physicians, Heritage Found. Background No. 3089 2 (Jan. 8, 2016), <https://www.heritage.org/health-care-reform/report/proposed-obamacare-gender-identity-mandate-threatens-freedom-conscience>.

³⁵ See 42 U.S.C. § 294e-1(b)(2) (“participation in the institutions’ programs of individuals and groups from different racial, ethnic, cultural, geographic, religious, linguistic, and class backgrounds, and different genders and sexual orientations”).

³⁶ 87 Fed. Reg. 41531.

³⁷ No. 20-1530 (U.S. Jun. 30, 2022).

³⁸ 20 U.S.C. § 1681(a).

³⁹ 87 Fed. Reg. 41531.

- sex stereotypes (i.e., “fixed or generalized expectations regarding a person’s aptitudes, behavior, self-presentation, or other attributes based on sex”),
- sex characteristics (including “a person’s physiological sex characteristics and other inherently sex-based traits,” and “intersex traits”), and
- pregnancy or related conditions (defined as “(1) Pregnancy, childbirth, termination of pregnancy, or lactation; (2) Medical conditions related to pregnancy, childbirth, termination of pregnancy, or lactation; or (3) Recovery from pregnancy, childbirth, termination of pregnancy, lactation, or their related medical conditions”).⁴⁰

ED does not define “gender identity” or “termination of pregnancy.”

ED’s Title IX Proposed Rule states that discrimination on the basis of sex includes “discrimination against an individual because, for example, they are or are perceived to be male, female, or nonbinary; transgender or cisgender; intersex; currently or previously pregnant; lesbian, gay, bisexual, queer, heterosexual, or asexual; or gender-conforming or gender-nonconforming. All such classifications depend, at least in part, on consideration of a person’s sex.”⁴¹

ED attempts to justify its expansion of the scope of Title IX to include “sexual orientation” and “gender identity,”⁴² even though it acknowledges that “the Department has at times articulated a narrower scope of Title IX’s prohibition on sex discrimination,” including “previously stated” determinations that “Title IX does not fully encompass discrimination on the basis of sexual orientation and gender identity” (emphasis added).⁴³ To overcome these past determinations, ED relies on the *Bostock* decision (discussed above) and a conclusory determination that ED’s “prior position [i.e., that Title IX’s prohibition on sex discrimination does not encompass discrimination based on sexual orientation and gender identity] is at odds with Title IX’s text and purpose.”⁴⁴ This conclusion—that Title IX’s text and purpose require expansion to include sexual orientation and gender identity—is erroneous.

Title IX prohibits discrimination based on sex in education programs or activities that receive Federal financial assistance.⁴⁵ Title IX and its accompanying regulations clearly recognize the fact of biological sexual difference and presuppose “sex” as a binary classification (male or female). This is shown by the following unambiguous references:

- Title IX provisions are not to be construed as prohibiting an educational institution “from maintaining separate living facilities for the different sexes”⁴⁶;
- “an institution which admits only students of one sex to being an institution which admits students of both sexes”⁴⁷;
- references to “men’s” and “women’s” associations as well as organizations for “boys” and “girls” in the context of organizations “the membership of which has traditionally been limited to persons of one sex”⁴⁸;
- references to “boys” and “girls” conferences⁴⁹;

⁴⁰ 87 Fed. Reg. 41515.

⁴¹ 87 Fed. Reg. 41532.

⁴² 87 Fed. Reg. 41531, sec 106.10.

⁴³ 87 Fed. Reg. 41531, sec. 106.10.

⁴⁴ *Id.*

⁴⁵ Office for Civil Rights, U.S. Dep’t Educ., *Title IX and Sex Discrimination* (last modified Jan. 10, 2020), https://www2.ed.gov/about/offices/list/ocr/docs/tix_dis.html.

⁴⁶ 20 U.S.C. § 1686.

⁴⁷ 20 U.S.C. § 1681(a)(2).

⁴⁸ 20 U.S.C. § 1681(a)(6)(B).

⁴⁹ 20 U.S.C. § 1681(a)(7)(A).

- “separation of students by sex within physical education classes or activities”⁵⁰;
- “classes in elementary and secondary schools that deal primarily with human sexuality may be conducted in separate sessions for boys and girls”⁵¹; and
- “separate teams for members of each sex where selection for such teams is based upon competitive skill or the activity involved is a contact sport.”⁵²

Contrary to the ED’s claims, Title IX’s specific language, based on an understanding of sex as binary (male or female), permits and accommodates separate facilities for males and females (toileting, locker rooms, etc.) and certain kinds of sex-specific activities and athletic competitions *in fulfillment of its* statutory intent to ensure equality between males and females.

While advancing equality between the sexes, Title IX permits separation “on the basis of sex” specifically to take account of biological differences between males and females. At the time Title IX was passed and implemented, no one—not legislators, psychologists, or the average person—would have understood “sex” to mean “gender identity.” Nor would prohibiting discrimination on the basis of sex have been understood to apply to “gender identity”: the term was largely unknown in 1972, beyond the fields of psychiatry and psychology, and connoted a psychological disconnect from the sexed body. (In contrast, the notion of “sex stereotypes,” later included in Title IX analyses, was a familiar concept integral to cultural and political discussions of sex discrimination.)

Efforts to shoehorn “gender identity” into Title IX’s protections against “sex discrimination” undercut the very purpose of Title IX, which was intended to ensure female equality, opportunity, safety, and privacy. Redefining “sex” to mean “gender identity” completely erases those protections and disadvantages *females* who rely on sex-based (not “gender-identity”-based) protections to ensure their safety, privacy, and educational opportunities (including athletic opportunities). Title IX aims to protect reasonable sex-based distinctions, not obliterate them.

Consequently, redefining “sex” (a biological reality) to include “gender identity” (a contradictory self-perception) does violence to the express intent of Title IX, which expressly permits sex-based distinctions in particular circumstances. In practical terms, interpreting discrimination protections “on the basis of sex” to privilege “gender identity” effectively guts Title IX of meaningful protections for females, and threatens to erase 50 years of women’s sex-based rights under the law. Title IX’s sex-based distinctions are grounded in common sense, historical perspective, and biology: they recognize that women’s safety is often threatened by the intrusion of males into private spaces where women are sexually vulnerable (e.g., spaces for toileting, showering, and sleeping) and women’s progress and equality are limited in specific arenas, such as interscholastic athletics, where biological differences between the sexes come into play.

“Gender identity” or “transgender status” is irrelevant when it comes to Title IX’s enumeration of specific exceptions to the rule against “sex” discrimination—only biological sex matters. And the fact remains that males who identify as “transgender girls” or “transwomen” are still biologically male and should be regarded as such for purposes of Title IX.

ED’s Proposed Rule for Title IX not only re-interprets “sex” under Title IX to mean “gender identity” or “transgender status,” but also asserts that the proposed rules prohibit discrimination for additional, unknown and undefined categories: “The Department does not intend that the specific categories of discrimination listed in proposed § 106.10 would be exhaustive, as evidenced by the use of

⁵⁰ 34 CFR § 106.34

⁵¹ 34 CFR § 106.34.

⁵² 34 CFR § 106.41.

the word ‘includes.’”⁵³ ED claims that: “Title IX’s broad prohibition on discrimination “on the basis of sex” under a recipient’s education program or activity encompasses, at a minimum, discrimination against an individual because, for example, they are or are perceived to be male, female, or nonbinary; transgender or cisgender; intersex; currently or previously pregnant; lesbian, gay, bisexual, queer, heterosexual, or asexual; or gender- conforming or gender-nonconforming.”⁵⁴ Elsewhere in the NPRM, ED references “LGBTQI+,” a term it uses “to refer to students who are lesbian, gay, bisexual, transgender, queer, questioning, asexual, intersex, nonbinary, or describe their sex characteristics, sexual orientation, or gender identity in another similar way.”⁵⁵

For your reference, we have attached our public comment submitted in opposition to the proposed Title IX regulations, which elaborate on that rule’s shortcomings.⁵⁶

C. Neither Title IX nor Section 1557 were amended by *Bostock*, and *Bostock* does not support the need for regulatory action.

In support of its proposal, HHS cites to the Supreme Court’s 2020 *Bostock v. Clayton County* decision, several federal court decisions that favor its position, and various “notice[s] of interpretation” and “guidance” documents by HHS (and the Department of Justice).⁵⁷ HHS alleges that *Bostock* held Title VII’s prohibition against sex discrimination in employment prohibits “discrimination on the basis of sexual orientation and gender identity” (even though *Bostock* used the term “transgender status” and did not adopt gender identity as a protected basis).⁵⁸ According to HHS, because Title VII’s and Title IX’s prohibitions against sex discrimination are similar, the *Bostock* Court’s reasoning “applies to Title IX and, by extension, to Section 1557.”⁵⁹ Thus, Section 1557 also prohibits discrimination based on “sexual orientation and gender identity.”⁶⁰

ED relies heavily on the Supreme Court’s decision in *Bostock v. Clayton County*.⁶¹ The Proposed Rule explains that the Department’s “prior position (*i.e.*, that Title IX’s prohibition on sex discrimination does not encompass discrimination based on sexual orientation and gender identity) is at odds with Title IX’s text and purpose and the reasoning of the *Bostock* Court and other courts to have considered the issue in recent years—both before and after *Bostock*.”⁶² ED claims that its proposed definition is “consistent with *Bostock* and other Supreme Court precedent” because *Bostock* “makes clear that it is ‘impossible to discriminate against a person’ on the basis of sexual orientation or gender identity without ‘discriminating against that individual based on sex,’ even assuming that sex refers only to certain ‘biological distinctions.’”⁶³

⁵³ 87 Fed. Reg. 41532.

⁵⁴ *Id.*

⁵⁵ 87 Fed. Reg. 41395.

⁵⁶ Also available here: <https://eppc.org/wp-content/uploads/2022/09/EPPC-Scholars-Comment-Opposing-Title-IX-Proposed-Rule.pdf>.

⁵⁷ 87 Fed. Reg. 47827-47828.

⁵⁸ 87 Fed. Reg. 47827.

⁵⁹ 87 Fed. Reg. 47858.

⁶⁰ 87 Fed. Reg. 47830.

⁶¹ 140 S. Ct. 1731 (2020).

⁶² 87 Fed. Reg. 41530.

⁶³ See 87 Fed. Reg. 47865 (“The Department proposes to not include the word ‘transgender’ in this proposed provision. This approach recognizes that the form of discrimination discussed herein may impact a range of individuals, including transgender people, individuals with intersex conditions, or people who may need these services but do not identify as transgender.”); *id.* (discussing “discrimination experienced by transgender and gender non-conforming individuals”).

But *Bostock* was not a Title IX nor a Section 1557 case. Rather, in *Bostock* the Supreme Court held that under *Title VII of the Civil Rights Act of 1964* “an employer who fires someone simply for being homosexual or transgender has discharged or otherwise discriminated against that individual ‘because of such individual’s sex.’”⁶⁴ Title VII is the federal law that prohibits sex (and race, color, religion, national origin) discrimination in employment, a completely different context from education and Title IX. Notably, *Bostock*’s Title VII analysis does not apply to Title IX (and thus Section 1557) because Title IX has a different sex-specific structure and, unlike Title VII, specifically uses language based on a biological binary, as detailed below.

The Majority in *Bostock* used the term “transgender status,” and did not adopt “gender identity” as a protected class. HHS recognizes in the Proposed Rule that “transgender” is not the same thing as “gender identity.”⁶⁵ Thus, HHS cannot rely on *Bostock* to support the inclusion of the term “gender identity” within the definition of “sex discrimination.” The *Bostock* Court premised its decision on the assumption that “sex” refers only to the “biological distinctions between male and female.”⁶⁶ The Proposed Rule tries to explain this away: “*Bostock* demonstrated with respect to Title VII, even accepting that definition of ‘sex’ would not preclude Title IX’s coverage of these forms of discrimination.”⁶⁷ To be consistent with *Bostock*, HHS must assume “sex” refers to “biological distinctions between male and female” (which it purports to do) and that “sex” is incompatible with a gender spectrum, fluidity, or subjective self-definition (which is promoted in the Proposed Rule).

As a federal district court judge just explained, HHS “misread *Bostock* by melding ‘status’ and ‘conduct’ into one catchall protected class covering all conduct correlating to ‘sexual orientation and gender identity.’ Justice Gorsuch expressly did not do that.”⁶⁸ For example, the court rejects HHS’ conclusion that *Bostock* supports the claim that “‘denial of ... care solely on the basis of [a patient’s] sex assigned at birth or gender identity likely violates Section 1557.’”⁶⁹

Further, *Bostock* was a limited holding. The Supreme Court specifically cabined its decision to the hiring and firing context under Title VII, stating it was not addressing other Title VII issues, such as sex-specific bathrooms, locker rooms, and dress codes, or other laws.⁷⁰ While the Court acknowledged concerns by some that its decision could make sex-segregated bathrooms, locker rooms, and dress codes “unsustainable” and “sweep beyond Title VII to other federal or state laws that prohibit sex discrimination,” the Court did not address those concerns.⁷¹ The Court explained that such questions were for “future cases” and the Court would not prejudge any such questions because “none of th[o]se other laws [we]re before [them].”⁷² Likewise, HHS should not prejudge those questions that the Court left unanswered, especially as it relates to sex-segregated spaces in the health care context. The Supreme Court was clear that *Bostock* did not decide any issue beyond hiring and firing under Title VII, and it is arbitrary and capricious for HHS to ignore *Bostock*’s limitations and claim *Bostock* requires its regulatory action. As the Sixth Circuit recently put it, “*Bostock* extends no further than Title VII.”⁷³

⁶⁴ 140 S. Ct. at 1737.

⁶⁵ 87 Fed. Reg. 41532.

⁶⁶ *Id.* at 1739.

⁶⁷ 87 Fed. Reg. 41530.

⁶⁸ *Texas v. Equal Emp’t Opportunity Comm’n*, No. 2:21-cv-194, at *6 (N.D. Tex. Oct. 1, 2022).

⁶⁹ *Id.* at *18.

⁷⁰ 140 S. Ct. at 1753.

⁷¹ *Id.* at 1753.

⁷² *Id.*

⁷³ *Pelcha v. MW Bancorp, Inc.*, 988 F.3d 318, 324 (6th Cir. 2021).

The Proposed Rule states, “Since *Bostock*, two Federal courts of appeals have held that the plain language of Title IX’s prohibition on sex discrimination must be read similarly.”⁷⁴ In support, HHS cites to a Ninth Circuit and Fourth Circuit case.⁷⁵ This is a far cry from consensus. HHS further mentions DOJ has taken the same position in Title IX litigation.⁷⁶ While citing to a brief DOJ filed in an Eleventh Circuit case, it fails to acknowledge that court rejected DOJ’s position. In *Adams v. School Board of St. Johns County*, the Eleventh Circuit granted rehearing *en banc* and vacated the panel’s 2-1 decision that aligns with the Department’s interpretation.⁷⁷ The vacated panel majority had held that *Bostock*’s reasoning that Title VII with its “starkly broad terms” forbids discrimination against transgender people “applies with the same force to Title IX’s equally broad prohibition on sex discrimination.”⁷⁸ Given that the *en banc* Eleventh Circuit has not issued its opinion,⁷⁹ it would be arbitrary and capricious for HHS to ignore this impending decision and rely on its partisan litigation position over the court’s actions.

To the extent HHS is relying on *Bostock* as the legal impetus for its rulemaking, that basis is deficient. *Bostock* requires no such regulatory action. It is arbitrary and capricious and contrary to law for HHS to claim that *Bostock* requires HHS’s expansion of sex discrimination under Section 1557 and provides grounds to support its rulemaking.

D. The Proposed Rule arbitrarily ignores that a person’s sex is defined by biology.

Even the decision in *Bostock v. Clayton County*, on which the Proposed Rule heavily relies, explicitly assumed that “sex” referred “only to biological distinctions between male and female.”⁸⁰ It is arbitrary and capricious for the proposed rule to avoid specifying precisely what sex in medicine and science means and how it relates to medical necessity with respect to gender dysphoria treatments. The concept of gender dysphoria is meaningless without sex, just as transgender transition as a proposed medical solution is meaningless. What would a person be transitioning to and from exactly? If the agency cannot answer such a basic question with any semblance of scientific and medical rigor, it has no basis to mandate coverage of such “transition” treatments and procedures in any context, and certainly not as an essential health benefit. Moreover, not only *must* the agency answer the question what sex is in medicine, it must answer it correctly and in accordance with logic and science.

A person’s sex is defined as “male or female according to their reproductive organs and functions assigned by the chromosomal complement.”⁸¹ Sex is imprinted in every cell of the person’s body and cannot change.⁸² Even HHS’s National Institutes of Health (NIH) matter-of-factly states that “every cell has a sex”⁸³ and, as of this writing, still requires its 80,000 research grant applicants to account for sex as a biological variable in all animal and human studies.⁸⁴ This is because NIH knows that a person’s

⁷⁴ 87 Fed. Reg. 47829.

⁷⁵ 87 Fed. Reg. 47829.

⁷⁶ 87 Fed. Reg. 47829.

⁷⁷ *Adams v. Sch. Bd. of St. Johns Cnty*, No. 18-13592 (11th Cir. Aug. 23, 2021).

⁷⁸ *Adams v. Sch. Bd. of St. Johns Cnty.*, 968 F.3d 1286, 1305 (11th Cir. 2020), *vacated*, No. 18-13592 (11th Cir. Aug. 23, 2021).

⁷⁹ Oral argument was held February 22, 2022.

⁸⁰ *Bostock*, 140 S. Ct. at 1739 (2020).

⁸¹ Institute of Medicine 2001. *Exploring the Biological Contributions to Human Health: Does Sex Matter?*. Washington, DC: The National Academies Press, at p. 1. <https://doi.org/10.17226/10028>.

⁸² Institute of Medicine 2001. *Exploring the Biological Contributions to Human Health: Does Sex Matter?*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/10028>.

⁸³ National Institutes of Health, Sex as a Biological Variable (March 18, 2021). <https://www.youtube.com/watch?v=oshnZrAKkiY&feature=youtu.be>.

⁸⁴ Consideration of Sex as a Biological Variable in NIH-funded Research, NOT-OD-15-102 (June 9, 2015). <https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html>.

immutable sexual biology explains in significant part why men and women respond differently to medication, vary in their experience and manifestation of pain, and have disparate susceptibility to illnesses, from heart disease and cancer to psychological conditions such as depression and anxiety. Sex in medicine and research cannot be replaced by subjective “gender identity.” Male and female are not part of an ever-multiplying spectrum nor are they merely placeholders assigned at birth. Indeed, in a document just issued by the HHS Office of Population Affairs it defined “gender identity” as “one’s internal sense of self as man, woman, both or neither.”⁸⁵

In contrast, the case for “transitioning” as the medical solution to gender dysphoria rests on the notion that transgender identity is innate—that a person can simply be born as “a man trapped in a woman’s body,” or vice versa. Therefore, adjusting that person’s hormone balance and restructuring the anatomy, to align the body with the inner sense of identity, should make things right. But does HHS have any biological basis to believe that a man could be born in the bodily form of a female, invisible to those who “assign” a sex at birth? Can HHS be confident that hormones and surgery can “reassign” sex? To answer these questions, we must start by examining what science tells us about the biological genesis of sex.

The basics of sex determination are relatively clear. Sex, in terms of male or female, is identified by the organization of the organism for sexually reproductive acts. *Langman’s Medical Embryology* concisely explains how the sex of a new organism is determined at fertilization: “An X-carrying sperm produces a female (XX) embryo, and a Y carrying sperm produces a male (XY) embryo. Hence, the chromosomal sex of the embryo is determined at fertilization.” A new human organism of a particular sex is created at that moment. Scientists now know that “the *presence* of a Y chromosome determines maleness and its *absence* determines femaleness.” This is because the Y chromosome ordinarily carries the SRY (“sex-determining region on Y”) gene. The SRY gene contains a transcription factor known as the testis-determining factor (TDF), which directs the formation of the male gonads.

Sex as a status—male or female—is a recognition of the organization of a body designed for dimorphic sexual reproduction. More than simply being *identified* on the basis of such organization, sex is a *coherent concept* only on the basis of that organization. The fundamental conceptual distinction between a male and a female is the organism’s organization for sexual reproduction. The conceptual distinction between male and female based on reproductive organization provides the only coherent way to classify the two sexes.

Lawrence Mayer and Paul McHugh highlighted the same truth in a recent review of the scientific literature on sexuality and gender identity:

The underlying basis of maleness and femaleness is the distinction between the reproductive roles of the sexes; in mammals such as humans, the female gestates offspring and the male impregnates the female. . . . This conceptual basis for sex roles is binary and stable, and allows us to distinguish males from females on the grounds of their reproductive systems, even when these individuals exhibit behaviors that are not typical of males or females.

Mayer is a scholar-in-residence in the Department of Psychiatry at Johns Hopkins University and a professor of statistics and biostatistics at Arizona State University. McHugh is a professor of psychiatry and behavioral sciences at the Johns Hopkins University School of Medicine, and for twenty-five years was the psychiatrist-in-chief at the Johns Hopkins Hospital. The editor of the *New Atlantis*, in the

⁸⁵ Office of Population Affairs, U.S. Dep’t Health & Hum. Servs., *Gender Affirming Care and Young People* (Mar. 2022), <https://opa.hhs.gov/sites/default/files/2022-03/gender-affirming-care-young-people-march-2022.pdf>.

introductory note to their report, called McHugh “arguably the most important American psychiatrist of the last half-century.”

After explaining the “binary and stable” conceptual basis for maleness and femaleness, Mayer and McHugh note that a structural difference for the purposes of reproduction is the only “widely accepted” way of classifying the two sexes:

In biology, an organism is male or female if it is structured to perform one of the respective roles in reproduction. This definition does not require any arbitrary measurable or quantifiable physical characteristics or behaviors; it requires understanding the reproductive system and the reproduction process. Different animals have different reproductive systems, but sexual reproduction occurs when the sex cells from the male and female of the species come together to form newly fertilized embryos. It is these reproductive roles that provide the conceptual basis for the differentiation of animals into the biological categories of male and female. There is no other widely accepted biological classification for the sexes.

This fundamental difference in organization is what allows scientists to distinguish male from female. When Dr. Deanna Adkins called this “an extremely outdated view of biological sex” in her declaration to a federal court in North Carolina, Dr. Mayer responded in his rebuttal declaration: “This statement is stunning. I have searched dozens of references in biology, medicine and genetics—even Wiki!—and can find no alternative scientific definition. In fact the only references to a more fluid definition of biological sex are in the social policy literature.” Just so, yet the proposed regulation adopts a wholly subjective and amorphous understanding of the person, based on gender identity, divorced from scientific realities.

Here is how one scholar put it in *Best Practice and Research: Clinical Endocrinology and Metabolism*:

Females enter puberty earlier and undergo a more rapid pubertal transition, whereas boys have a substantially longer growth period. After adjusting for dimorphism in size (height), adult males have greater total lean mass and mineral mass, and a lower fat mass than females. These whole-body differences are complemented by major differences in tissue distribution. Adult males have greater arm muscle mass, larger and stronger bones, and reduced limb fat, but a similar degree of central abdominal fat. Females have a more peripheral distribution of fat in early adulthood; however, greater parity and the menopause both induce a more android fat distribution with increasing age. Sex differences in body composition are primarily attributable to the action of sex steroid hormones, which drive the dimorphisms during pubertal development. Oestrogen is important not only in body fat distribution but also in the female pattern of bone development that predisposes to a greater female risk of osteoporosis in old age.

The result is that male and female bodies differ not only in their sex chromosomes (XX and XY) and in their organization for reproduction, but also, on average, in size, shape, bone length and density, fat distribution, musculature, and various organs including the brain. These secondary sex differences are not what define us as male or female; organization for reproduction does that. But this organization leads to other bodily differences. There are organizational differences and organism-wide differences in organs and tissues, as well as differences at the cellular and molecular levels.

E. Innate sex differences affect our health.

There are biological differences between men and women, and they are consequential for our health. Recognizing differences between the sexes is increasingly regarded as vitally important for good medical practice, because scientists have found that male and female bodies tend to be susceptible to certain diseases in different ways, to differing degrees, and they respond to treatments differently. For this reason, the best research protocols now require that both males and females be included in samples, and that the sex of participants be tracked so that any sex-specific results can be recorded.

The Institute of Medicine at the National Academy of Sciences published a report in 2001 titled *Exploring the Biological Contributions to Human Health: Does Sex Matter?* The executive summary answered the question in the affirmative, saying that the explosive growth of biological information “has made it increasingly apparent that many normal physiological functions—and, in many cases, pathological functions—are influenced either directly or indirectly by sex-based differences in biology.” Because genetics and physiology are among the influences on an individual’s health, the “incidence and severity of diseases vary between the sexes.” The difference between male and female is thus “an important basic human variable that should be considered when designing and analyzing studies in all areas and at all levels of biomedical and health-related research.”

The chapter titles of the report sum up basic truths about our bodily nature: “Every Cell Has a Sex.” “Sex Begins in the Womb.” “Sex Affects Behavior and Perception.” “Sex Affects Health.” Some of the biological differences between the sexes that bear on health derive from hormone exposure, but others come more directly from our genetic material. There are “multiple, ubiquitous differences in the basic cellular biochemistries of males and females that can affect an individual’s health. Many of these differences do not necessarily arise as a result of differences in the hormonal regime to which males and females are exposed but are a direct result of the genetic differences between the two sexes.” Written into our genetic code are differences that manifest themselves at the cellular level, in ways that can affect our health. Sexual differentiation begins at conception, progresses in the womb, and continues throughout life, notably at puberty but also, significantly at menopause in females. “Hormonal events occurring in puberty lay a framework for biological differences that persist through life and contribute to the variable onset and progression of disease in males and females.”

“Basic genetic and physiological differences, in combination with environmental factors, result in behavioral and cognitive differences between males and females,” says the Institute of Medicine. These biological differences seem to have consequences for mental health. An article in the *Neuroscience and Biobehavioral Review* points to well-known differences between men and women in susceptibility to mental disorders: “Examples of male-biased conditions include autism, attention deficit/hyperactivity disorder, conduct disorder, specific language impairment, Tourette syndrome, and dyslexia, and examples of female-biased conditions include depression, anxiety disorder, and anorexia nervosa.” This is not to say that these are exclusively male or female conditions, but that one sex or another experiences them with greater frequency.

A literature review in the *Journal of Cellular Physiology* tells us that “men are able to synthesize serotonin, the neurotransmitter commonly associated with pleasant moods, at a greater rate than women,” and therefore, men have a lower incidence of major depression, anxiety, and multiple sclerosis, but a higher incidence of attention deficit hyperactive disorder and coronary artery disease. There are also differences in susceptibility to Alzheimer’s disease and dementia. While scientists don’t know how much of these differences are due to environment and how much to biology, they do know that “innate physiological differences between males and females may play a large role in sex differences in disease onset, susceptibility, prevalence, and treatment responses.”

Men and women also tend to respond differently to pain, which has important implications for the use of painkillers and other medicines. Men and women have “variable responses to pharmacological agents and the initiation and manifestation of diseases such as obesity, autoimmune disorders, and coronary heart disease, to name a few.” Differences in the chemistry and structure of the brain influence our response to stressful events and how we remember them. The differences between men and women in memory formation surrounding “emotionally arousing incidents” have implications for the treatment for post-traumatic stress disorder.

Acknowledging sex-based differences is vital for women’s health, as Jill Goldstein and colleagues emphasize in a paper for *Frontiers in Neuroscience*. “We now know there are significant sex differences in many chronic diseases, including brain disorders,” they write, so understanding the causes of these differences “is critical to understanding women’s mental health and healthcare needs.” They cite studies demonstrating, for example, that “the vulnerability for sex-dependent risk for MDD [major depressive disorder] begins in fetal development.” Neuroscience must therefore “adopt a ‘sex-dependent’ and/or ‘sex-specific’ lens on investigations of the brain.”

Of course, male and female bodies are alike in many ways, but there are notable differences in average male and average female bodies beyond our different organizations for reproduction. In other words, there is a fundamental, essential difference, and there are subsidiary, average differences. There is also wide variation among males and among females, and considerable overlap between them, even in the areas just discussed. While environmental factors are likely to influence many of these differences, there’s no denying the role of biology.⁸⁶

As cited in HHS’s 2020 Rule on Section 1557 and referenced above, in an actual case from 2019, a person who was admitted to an emergency room with severe abdominal pain was tracked according to a preferred male gender identity. Unbeknownst to the triage staff, the patient was actually a woman in late-stage labor. The result was the stillbirth of a very real human child who possibly could have been saved but for gender identity politics distorting the truth of the situation. According to HHS, “this case is not based on speculation. Rather, it involved the actual death of an unborn child and attendant trauma and anguish for those involved, all potentially because of a misdiagnosis resulting from a reliance on stated gender identity as opposed to sex. Given that life-and-death decisions are frequently made in healthcare settings and often in urgent circumstances, this story serves as an example of the consequences that could result from the confusion caused by the ... mandate to treat individuals ‘consistent with’ stated gender identity.”⁸⁷ HHS also found that using non-discrimination rationales to impose a gender identity rule “risked masking clinically relevant, and sometimes vitally important, information by requiring providers and insurers to switch from a scientifically valid and biologically based system of tracking sex to one based on subjective self-identification according to gender identity.”⁸⁸

When science is supplanted by ideological concerns, real people suffer, yet the proposed rule ignores the science and attempts to impose a national standard of care and coverage without answering any of the necessary predicate medical and scientific questions.

⁸⁶ RYAN T. ANDERSON, WHEN HARRY BECAME SALLY: RESPONDING TO THE TRANSGENDER MOMENT 77-88 (2018) (internal citations omitted).

⁸⁷ 85 FR 37190.

⁸⁸ *Id.*

F. Incorporating “gender identity” into Section 1557 anti-discrimination laws governing healthcare is harmful, unsustainable, and unconstitutional.

Logic, language, and medical history show that “gender identity” is not “sex.” HHS’s National Institutes of Health (NIH) matter-of-factly states that “every cell has a sex.” NIH requires its 80,000 research grant applicants to account for sex as a biological variable in all animal and human studies. That’s because it knows that a person’s immutable sexual biology explains in significant part why men and women respond differently to medication, vary in their experience and manifestation of pain, and have disparate susceptibility to illnesses, from heart disease and cancer to psychological conditions such as depression and anxiety. But sex in medicine and research is to be replaced by subjective “gender identity,” male and female by a never-ending spectrum, biology by placeholders assigned at birth and mothers by “birthing persons.” Indeed, in a document just issued by the HHS Office of Population Affairs it defined “gender identity” as “one’s internal sense of self as man, woman, both or neither.”⁸⁹

The term “gender identity” was coined by psychoanalyst Robert J. Stoller, writing in *Sex and Gender* (1968), to express a person’s psychological self-categorization, distinct from one’s sex (male or female).⁹⁰ The term was instrumental in describing the psychological experience of a person who felt alienated from the sexed body (male or female). “Gender identity disorder,” a mental health diagnosis describing the mismatch between a person’s perceived identity and biological sex, did not even appear in the APA Diagnostic and Statistical Manual of Mental Health Disorders (DSM) until 1980.⁹¹ Subsequent versions of the DSM retained the conceptual distinction between a person’s natal sex and psychological self-perception. DSM-IV described “gender dysphoria” as distress arising out of perceived conflict between “biological sex” and “gender identity.”⁹² In 2013, the DSM was revised to replace the diagnosis of “gender identity disorder” with “gender dysphoria,” based on clinical distress arising from the experience of gender incongruence (a perceived discordance or lack of harmony between the fact of a person’s biological sex and the individual’s self-perceived identity).⁹³

The American Psychological Association’s current guidance on “Gender and sexual orientation diversity in children and adolescents in schools” (which promotes a gender-affirming approach to transgender identification) delineates the difference between “sex” and “gender identity. It defines “sex” as “a person's biological status... typically categorized as male, female or intersex. There are a number of indicators of biological sex, including sex chromosomes, gonads, internal reproductive organs and external genitalia.” Gender identity, in contrast, “refers to one's sense of oneself as male, female or something else (APA, 2011).” “Sex” is an objective fact; “gender identity” is a subjective perception.

The APA describes a person who identifies as “transgender” as one who has a “gender identity and biological sex [that] are not congruent.”⁹⁴ According to the American Psychological Association, “transgender” is “an umbrella term ... wherein one’s assigned biological sex doesn’t match their felt identity.”⁹⁵

⁸⁹ Office of Population Affairs, U.S. Dep’t Health & Hum. Servs., *Gender Affirming Care and Young People* (Mar. 2022), <https://opa.hhs.gov/sites/default/files/2022-03/gender-affirming-care-young-people-march-2022.pdf>.

⁹⁰ R. Green, *Robert Stoller’s Sex and Gender: 40 Years On*, 39 *Arch Sex Behav*, 1457 (2010), <https://doi.org/10.1007/s10508-010-9665-5>. (Dr. John Money previously used the term “gender roles.”)

⁹¹ Am. Psychiatric Ass’n, *Diagnostic And Statistical Manual Of Mental Disorders* 261 (3d Ed. 1980).

⁹² Am. Psychiatric Ass’n, *Diagnostic And Statistical Manual Of Mental Disorders* 532–33 (4th Ed. 1994).

⁹³ Am. Psychiatric Ass’n, *Diagnostic And Statistical Manual Of Mental Disorders* 452 (5th Ed. 2013).

⁹⁴ *Gender And Sexual Orientation Diversity in Children And Adolescents in Schools*, Am. Psychological Ass’n (last updated Sept. 2021), <https://www.apa.org/Pi/Lgbt/Resources/Diversity-Schools>.

⁹⁵ American Psychological Association & National Association of School Psychologists, *Resolution on Gender and Sexual Orientation Diversity in Children and Adolescents in Schools* (2015), <https://www.apa.org/pi/lgbt/resources/diversity-schools?item=3>.

The Human Rights Campaign Foundation publication entitled *Coming Out: Living Authentically as Transgender or Non-binary* defines “gender identity” as a person’s subjective self-perception, and a “transgender” gender identity as one that is “different from their sex assigned at birth.”⁹⁶ Expressing a transgender “gender identity” *contradicts* but cannot *change* a person’s immutable biological sex. Simply put, “gender identity” is not the same as “biological sex.” In fact, a declaration that one’s “gender identity” is “transgender” signals a *rejection* of one’s biological sex or sex-based identity.

In educational materials designed to explain the concept of “gender identity” in classroom settings, Welcoming Schools, the Human Rights Campaign Foundation’s educational arm, recently described “gender identity” as simply “how you feel.”⁹⁷ If “gender identity” can be reduced to “feelings,” then what does “discrimination on the basis of “gender identity” actually mean? *Hurt* feelings? *Unwelcome* feelings? *Unpleasant* feelings?

Medicine is a science, dependent on observable biological facts and scientific investigation. The determination of “sex,” as explained above, is based on objective, empirically demonstrable facts. Classification of “sex” is necessary to the ethical, safe, and effective practice of medicine. The benefit of a particular treatment is determined primarily by evaluating measurable, physiological results (that is, evidence), not on the basis of the patient’s subjective positive or negative feelings about the treatment.⁹⁸

The subjective, psychological, and arbitrary nature of “gender identity” renders it an unstable basis for medical determinations or treatment decisions that, by nature, must consider objective facts about the person’s whole body (including sex). Given the fluid, feeling-based premise of “gender identity,” it is especially unsuitable for determining whether a person has experienced “sex” discrimination in any aspect of healthcare.

By re-defining “sex” to include “gender identity” in the healthcare arena, and consequently privileging “gender identity” over sex-based determinations, HHS undermines the coherent and ethical practice of medicine in ways that cannot be overstated. HHS embeds “gender identity” in its regulations as a tool for social engineering, not the better care of patients. “Gender identity” is based on feelings which are indeterminable by others unless declared. And yet, HHS uses “gender identity” as a vehicle to alter the science-based, sex-based language and practice of medicine, even though medicine necessitates recognizing sexual difference and the immutable reality of the sexed body for the provision of medically appropriate care.

HHS’s redefinition of sex to include “gender identity” will wreak havoc in the healthcare field. Under the proposed rule, nearly all aspects of medical practice will become subject to scrutiny and necessary medical protocols will suddenly become suspect, liable to be labeled a “pretext” for unlawful discrimination. How do we know? Because the Proposed Rule tells us.⁹⁹

The arbitrary decision by HHS to reframe “discrimination” through the prism of “gender identity” jeopardizes essential aspects of care that depend on recognizing the reality of biological sex. Instead,

⁹⁶ “Gender identity - One’s innermost concept of self as man, woman, a blend of both or neither – how individuals perceive themselves and what they call themselves. One’s gender identity can be the same or different from their sex assigned at birth.” *Coming Out: Living Authentically as Transgender or Non-binary*, Human Rights Campaign Foundation, <https://www.hrc.org/resources/coming-out-living-authentically-as-transgender-or-non-binary>.

⁹⁷ Defining LGBTQ+ Words for Elementary School Students, Welcoming Schools, Human Rights Campaign Foundation. <https://welcomingschools.org/resources/definitions-lgbtq-elementary-school>

⁹⁸ Michael Egnor, Operating on Healthy Bodies Defies Surgical Ethics, and Trans People are no exception, *The Federalist*, September 23, 2022. <https://thefederalist.com/2022/09/23/operating-on-healthy-bodies-defies-surgical-ethics-and-trans-people-are-no-exception/>.

⁹⁹ 87 Fed. Reg. 47867, 47868, 47870, 47874.

under the Proposed Rule, each of these elements is suddenly a vulnerability, a potential fact pattern for a claim of discrimination on the basis of gender identity. The Rule is an astonishing display of bureaucratic, arrogance, in furtherance of an ideological goal, which attempts to supplant and dictate medical judgments of skilled healthcare providers and institutions:

- **Scientific assumptions (facts of nature):** HHS has arbitrarily decided that a medical provider who acknowledges undeniable facts of nature—e.g., only females get pregnant and give birth—is making discriminatory assumptions. For example, it states that “transgender men who are pregnant experience significant forms of ‘discrimination, stigma, and erasure’ when navigating pregnancy and prenatal care, particularly because pregnancy and childbirth are often treated as something exclusively experienced by cisgender women.”¹⁰⁰ Further on, HHS spells out the discriminatory nature of “incorrect [factual] assumptions,” noting that “[p]roviders and issuers frequently formulate *incorrect assumptions* about transgender and gender non-conforming individual’s bodies when assessing medical necessity for sex-specific preventive care.”¹⁰¹
- **Ethical basis for determining care:** HHS has arbitrarily decided that because (1) it claims that “sex” means “gender identity” and (2) people who experience a mismatch of “gender identity” and sexed body often desire medical or surgical interventions to facilitate a change in appearance or to impair the body’s natural function, that consequently there is no ethical basis for refusing to accede to the “gender-identity”-based treatment demands of an individual. No covered entity or provider is permitted to refuse, on ethical, moral, or medical judgment grounds, to facilitate an individual’s gender-identity-based request for medical or surgical interventions. This amounts to giving the person experiencing “gender dysphoria” or identifying as transgender a “super-right” to a “gender transition,” entitling them to insist that *any and every* physician, facility, or provider capable of complying with their demands must comply or risk an anti-discrimination complaint.

For example, HHS states that “the proposed rule [would not] require a pediatrician to prescribe hormone blockers for a prepubescent gender- nonconforming minor if that health care provider concluded, pursuant to a nondiscriminatory bona fide treatment decision, that social transition was the clinically indicated next step for that child.” This example communicates HHS’s expectation that every provider is expected to endorse “gender affirming care.” The only non-discriminatory basis for refusing hormone blockers is the decision to pursue a different “gender-affirming” pathway (social transition). HHS explicitly states that a provider’s categorical refusal to prescribe or offer “gender-affirming care” constitutes discrimination: “[A] provider’s view that no gender transition or other gender-affirming care can ever be beneficial for such individuals (or its compliance with a state or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not clinically appropriate.” An ethical judgment that “gender-affirming” care for minors, including recommending a psychosocial transition, is never ethically justifiable is not considered to be “a legitimate, nondiscriminatory basis for their challenged action or practice.”¹⁰²

- **Relevance of sex-based distinctions (and sex-based language):** The proposed rule’s arbitrary excision from coverage determinations or service provision of sex-based language and sex-based clinical treatments puts patients in a precarious position. It also distorts the medical fact that certain kinds of care are appropriate only for individuals of a particular sex. Providers should not be forced to ignore the relevance of sex-based distinctions, but this is clearly what is intended under the proposed rule’s “gender identity” regime. The Rule provides the example of a “health

¹⁰⁰ 87 Fed. Reg. 47867.

¹⁰¹ 87 Fed. Reg. 47871 n.451 (emphasis added).

¹⁰² 87 Fed. Reg. 47867.

plan that excludes ‘coverage for surgery, such as a vaginoplasty and mammoplasty’ for any enrollee whose sex assigned at birth is male ‘while providing coverage for such medically necessary surgery’ for enrollees whose sex assigned at birth is female ‘is discriminatory on its face.’”¹⁰³ Similarly, the Rule includes a “general prohibition on the denial or limitation of health services, including those that are offered exclusively to individuals of one sex, to an individual based on the individual’s sex assigned at birth, gender identity, or gender otherwise recorded.”¹⁰⁴

- **Medical inquiries:** HHS states that while it recognizes that medical providers “need to make inquiries about a patient’s sex-related medical history, health status, or physical traits related to sex in the course of providing care,” it considers it discriminatory when such inquiries result in more than “de minimis harm.”¹⁰⁵ In response to an allegation of discrimination, HHS (OCR) “may consider whether a provider’s inquiries may be evidence of discrimination” by assessing whether the inquiries “have a relationship to the care provided, or [whether] they are made in a manner that is harassing, hostile, or evinces disregard for a patient’s privacy.”¹⁰⁶ Put differently, if a healthcare provider asks the wrong question or asks an appropriate question in the wrong “manner,” then the provider is likely to face a claim of discrimination on the basis of “gender identity.” The Proposed Rule states that “[w]here relevant, OCR will consider the totality of the circumstances in determining whether overbroad, irrelevant, or hostile inquiries may constitute evidence of discrimination.”¹⁰⁷ This amounts to an arbitrary and capricious extension of the grounds for sex discrimination claims.
- **Provider beliefs and medical judgment (which conflict with ideology-based “standards of care”):** The entire rule is premised on gender ideology, a “gender identity-based” belief system that is unproven, lacks empirical support, and is highly controversial. And yet the rule makes clear that medical providers and healthcare institutions are expected to endorse the “gender identity” belief system, to use ideological terminology (such as “cisgender” and “sex assigned at birth”) instead of fact-based, scientific terms (such as male or female), and to provide “gender-affirming care” or “transition” care on demand. Otherwise, they risk becoming the subject of a discrimination claim. As discussed elsewhere in these comments, HHS leaves little room for the exercise of conscience-based or medical judgment-based refusals to provide “gender affirming care” to anyone who seeks it. The Proposed Rule relies on WPATH’s purported “standards” and the Endocrine Society’s Clinical practice guidelines for “gender-affirming care,” even though the cited guidelines are controversial and the evidentiary basis for those guidelines is of “low” quality. Although the Rule states that “[g]ender-affirming care, like all medical care, should follow clinical practice guidelines and professional standards of care,” it is clear that HHS has made an arbitrary determination, far outside its competence as a government regulatory agency, that only ideologically-favored “guidelines” or “standards” will be count.¹⁰⁸ (The HHS attempt to impose an arbitrary standard of care through the regulatory process is addressed more at length below.)

¹⁰³ “For example, a health plan that excludes “coverage for surgery, such as a vaginoplasty and mammoplasty” for any enrollee whose sex assigned at birth is male “while providing coverage for such medically necessary surgery” for enrollees whose sex assigned at birth is female “is discriminatory on its face.”

¹⁰⁴ 87 Fed. Reg 47865.

¹⁰⁵ 87 Fed. Reg 47867.

¹⁰⁶ 87 Fed. Reg 47868.

¹⁰⁷ 87 Fed. Reg 47868.

¹⁰⁸ 87 Fed. Reg 47868.

- Benefits determinations:** The Proposed rule prohibits “benefit designs that impermissibly limit coverage based on a person’s sex at birth, gender identity, or gender otherwise recorded.”¹⁰⁹ HHS asserts that discrimination “against transgender people in health insurance and other health-related coverage remains pervasive, especially for individuals who experience intersectional discrimination, such as individuals who experience both transphobia and racism.”¹¹⁰ HHS produces scant evidence to show that “transgender” and “gender diverse” individuals (or the many other descriptive labels covered by the proposed rule) have suffered “pervasive” discrimination. Instead, it appears to rely on self-reported “discrimination” that equates denial of demanded services with presumptive discrimination. “As reported in a 2020 study of self-identified LGBTQ adults, 38 percent of transgender respondents—and 52 percent of transgender respondents of color—said that they had been denied hormone therapy coverage by their health insurer, and 43 percent reported being denied coverage for surgery for their transition.”¹¹¹
- Healthcare entities’ limits on provider care:** Healthcare institutions might limit, for a variety of reasons (such as risk management or ethics), a provider’s ability to perform certain procedures or to use particular medical treatments in their facilities. One example of this is a set of ethical constraints on Catholic hospitals, called the Ethical and Religious Directives (ERD) for Catholic Health Care Services. The ERDs prohibit, for ethical reasons, Catholic Health Care entities from performing, providing, or referring for certain treatments, notably abortions, sterilizations, and medical or surgical interventions for purposes of gender transition. The Proposed Rule takes direct aim at Catholic and other faith-based hospitals that impose ethical limits on their providers, stating: “restrictions by covered entities on the ability of providers to prescribe or provide care based on their patient’s gender identity or sex assigned at birth would likely constitute prohibited discrimination in violation of this rule.”¹¹² In fact, Catholic healthcare entities do not discriminate on the basis of a person’s identity but, because they view “gender-affirming” treatments as unethical and immoral, they prohibit their affiliated providers from conducting those treatments. The Rule thus attempts to force healthcare entities to be in the business of providing “gender-affirming care,” regardless of their concerns over benefit to patients, ethics, or even malpractice risks.
- Sex-based clinical trials:** Even though the NIH mandates that all clinical trials specify the biological sex of clinical subjects in every clinical trial, HHS indicates that it is willing, for ideological purposes (producing no evidence that sex-based distinctions in clinical trials cause discriminatory harm), to pressure clinical researchers and organizations to disregard sex-based distinctions for fear of inviting a gender identity discrimination claim. The rule states: “Similarly, sex-specific clinical trials may be permissible based upon the scientific purposes of the study, *i.e.*, trials based on a particular sex-characteristic(s), such as those that test treatments for specific conditions or that evaluate differences in responses to treatment regimens among individuals with different sex characteristics. In evaluating a complaint of discrimination challenging a covered entity’s sex-specific health program or activity, OCR may consider a variety of factors relevant to the particular health program or activity. In particular, this provision would prohibit the adoption of a policy, or engaging in a practice, that prevents any individual from participating in a covered entity’s health program or activity consistent with their gender identity.” In other words, even though the NIH says that every clinical trial must include sex-specific recruitment and labeling of subjects, because sex is a biological variable, HHS is laying down an unscientific marker that sex-specific clinical trials can only be justified in limited circumstances (*e.g.*, trial of a prostate

¹⁰⁹ 87 Fed. Reg 47870.

¹¹⁰ 87 Fed. Reg. 47870.

¹¹¹ 87 Fed. Reg 47870.

¹¹² 87 Fed. Reg 47866.

cancer drug is limited to males who have prostates), but not generally. Instead, a person must be granted access to clinical trials on the basis of gender identity, absent a showing of particular relevance.¹¹³ This is a step backwards, and of particular harm to females who were long excluded from clinical trials on the presumption that sex-based differences did not matter to the evaluation of diseases and treatments—until science recognized the impact of “sex as a biological variable” that must be taken into account if medicine is to benefit all, females in particular.

G. The HHS interpretation of “sex” to include “gender identity” arbitrarily expands the scope of protection afforded under Section 1557 to a set of undefined, poorly defined, or open-ended categories.

Similar to ED’s expansion of “sex” to include “gender identity” protections under Title IX, HHS proposes to expand Section 1557’s sex discrimination protections to “gender identity.” In addition, it injects additional undefined or poorly defined terms into the Rule, signaling its intent to afford anti-discrimination protections to these new categories. As described below, HHS’s expansive actions gives these new categories protected status. However, given the undefined or poorly defined definition of these new categories, it is nearly impossible to determine the exact scope of the Proposed Rule, rendering it arbitrary and capricious to extend anti-discrimination protections to undefined and novel categories. Healthcare entities, insurers, and providers have a right to be given notice and clarification of the extent of their legal obligations—and the HHS actions deprives them of this right.

For example, in describing the applicable history of Section 1557 interpretations and the intended scope of the Proposed Rule’s “gender identity” protections, the Rule describes Section 1557 anti-discrimination protections as extending, variously, to:

- “LGBTQI+ individuals”¹¹⁴
- “people who identify as nonbinary, genderqueer, or gender nonconforming, regardless of whether those individuals explicitly use the term transgender”¹¹⁵
- “transgender and gender- nonconforming individuals”¹¹⁶
- “transgender people”¹¹⁷
- “lesbian, gay, bisexual, transgender, queer, and intersex (LGBTQI+) individuals”¹¹⁸
- “some individuals [who] may identify as nonbinary or gender diverse, meaning they do not identify with traditional binary gender or a single gender.”¹¹⁹
- “gender otherwise recorded”¹²⁰
- people seeking gender-affirming care may refer to their gender identity using terms other than “transgender,” such as “nonbinary,” “gender nonconforming,” “genderqueer,” or “genderfluid.”¹²¹

Few of these additional terms are defined. The Proposed Rule also incorporates the language of gender ideology throughout the Rule, using terms such as “sex assigned at birth,” which suggests sex is an arbitrary classification made by a third party, rather than an immutable fact of the person’s identity.

¹¹³ 87 Fed. Reg. 47866.

¹¹⁴ 87 Fed. Reg. 47831

¹¹⁵ 87 Fed. Reg. 47831 n.75.

¹¹⁶ 87 Fed. Reg. 47830.

¹¹⁷ *Id.*

¹¹⁸ 87 Fed. Reg. 47831.

¹¹⁹ 87 Fed. Reg. 47870.

¹²⁰ 87 Fed. Reg. 47865.

¹²¹ 87 Fed. Reg. 47867.

The Rule also arbitrarily classifies all persons who do not identify as “transgender” as “cisgender,” another unscientific term premised on the ideological belief that identity is self-determined, and on the ideological assumption that it is neither better nor worse when an individual’s self-perception fails to align with the reality of the person’s body (“transgender”). The term “cisgender” is not universally accepted; in fact, it is rejected outright by biologists and others who view it as an “ideological stance” akin to asserting a religious belief.¹²² Faith-based advocates also contest the use of the term “cisgender,” as an offensive repudiation of both science and faith. “There is no need to call women ‘cisgender women,’” says Bill Donahue of the Catholic League, “Nature, and nature’s God, have made it crystal clear that there are only two sexes: man and woman.”¹²³

The Rule defines “transgender” as referring to “people who identify as a gender other than their sex assigned at birth. This may include people who identify as nonbinary, genderqueer, or gender nonconforming, regardless of whether those individuals explicitly use the term transgender to describe themselves.”¹²⁴ The final phrase of that definition (“regardless of whether those individuals explicitly use the term transgender to describe themselves”) highlights the Rule’s arbitrary and unfair constructions, which appear to privilege anyone who asserts a claim of discrimination on the basis of “gender identity.”

“Gender-non-conforming,” undefined by the Proposed Rule, is an especially problematic expansion of the scope of Section 1557 anti-discrimination protections under the “gender identity” classification. “Gender-nonconforming” is used in some places to describe an “identity,”¹²⁵ while elsewhere it suggests non-conformity regarding stereotypical behavior or dress.¹²⁶ Further, although a person’s self-perception as “gender non-conforming” would not ordinarily imply either a transgender identity or an asserted “need” for “gender-affirming” medical or surgical interventions, the Proposed Rule lists a “gender non-conforming” identity as one which might require receipt of “gender affirming . . . hormone therapy, [or] surgery.”¹²⁷ This development is without precedent, and suggests that the categories of “gender identity” and “transgender” are elastic enough to cover anyone who “simply does not conform to traditional stereotypes of masculinity or femininity associated with being male or female.”¹²⁸

HHS justifies its broad inclusion of a range of self-described identities by claiming its “review of the literature” showed “continued discrimination experienced by transgender and gender non-conforming individuals.”¹²⁹ However, HHS fails to provide any clarifying citation to explain who is included in the category of “gender non-conforming” or to provide any evidence supporting the need to extend to these individuals (whomever they might be) specific non-discrimination protections under Section 1557.¹³⁰ In fact, the Proposed Rule uses the “+” designation to indicate that its language describing covered individuals is expansive and nearly infinite. It states that: “We use ‘+’ in this acronym to indicate

¹²² Colin Wright, @SwipeWright, Twitter, March 31, 2021. “The notion that we all have a gender identity is a religious framework. It’s not an empirical fact, but rather an ideological stance. I don’t have a gender identity. I simply acknowledge that I’m male and express myself according to my own individual personality. I am not ‘cis.’” <https://twitter.com/SwipeWright/status/1377272252895387656>.

¹²³ Ian M. Giatti, *Catholic League calls out Air Force gender ideology ‘fiction’ for fellowship excluding ‘cisgender’ men*, The Christian Post (Sept. 29, 2022), <https://www.christianpost.com/news/catholic-league-slams-air-force-for-gender-ideology-fiction.html>.

¹²⁴ *Id.*

¹²⁵ 87 Fed. Reg. 47831.

¹²⁶ 87 Fed. Reg. 47830, 47858 n.333.

¹²⁷ 87 Fed. Reg. 47834.

¹²⁸ Colin Wright, *The Transgender Umbrella Casts Its Shadow over Gender Non-Conformity*, Reality’s Last Stand Substack (Aug. 31, 2022), <https://www.realitylaststand.com/p/the-transgender-umbrella-casts-its>.

¹²⁹ 87 Fed. Reg. 47833.

¹³⁰ 87 Fed. Reg. 47865.

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.”¹³¹

This is especially troubling because the HHS analysis [“Equal Program Access on the Basis of Sex (§ 92.206)] appears to anticipate including access to gender-affirming care and other undefined “services”¹³² for a broad range of undefined identities, as well as to require healthcare providers to grant “access” to sex-specific medical care regardless of the person’s identity.

4. The Proposed Rule uses nondiscrimination regulations to impose a medical standard of care when there is not medical consensus.

The Proposed Rule attempts to force medical providers and institutions to accept “gender affirming care” as the presumptive and authoritative “standard of care” covering treatments for an ever-expanding group of people, including those not previously considered appropriate candidates for “gender-affirming care.” Although “gender dysphoria” is the DSM-V diagnosis that the American Psychological Association links to “gender-affirming care,” the Proposed Rule defines “gender-affirming care” as an appropriate treatment beyond the diagnosis of “gender dysphoria,” without citing any evidence to support its arbitrary decision, to include persons who are not diagnosed with “gender dysphoria” but merely seek “support” for a “gender transition,” as well as individuals with “intersex” conditions seeking “treatment for gender dysphoria.”¹³³

The Rule states: “For purposes of this preamble, the term ‘gender-affirming care’ refers to care for transgender individuals (including those who identify using other terms, for example, nonbinary or gender nonconforming) that may include, but is not necessarily limited to, counseling, hormone therapy, surgery, and other services designed to treat gender dysphoria or support gender affirmation or transition. Gender-affirming care may also be, but is not necessarily, referred to as ‘gender-affirming health services’ or ‘transition-related care.’ The terms ‘gender-affirming care’ or ‘transition-related care’ also include care sought by individuals with intersex conditions who seek treatment for gender dysphoria.”¹³⁴

HHS grounds its claims about “gender-affirming care” in publications by the World Association for Transgender Health (WPATH) and the Endocrine Society, in spite of the weak evidentiary basis of those documents (a point addressed in subsequent paragraphs).¹³⁵

However, HHS’s arbitrary decision to use the Proposed Rule as a mechanism to establish the “gender-affirming” protocol as a medically appropriate treatment—or even the *only* medically appropriate treatment—for gender dysphoria exceeds statutory authority and the intent of Section 1557. In addition, the Rule’s framing of “gender-affirming care” as appropriate and “medically necessary” to treat anything other than a diagnosis of “gender dysphoria” has no basis in science and is a patently arbitrary and capricious exercise of regulatory power.

¹³¹ 87 Fed. Reg. 47831 n.77.

¹³² 87 Fed. Reg. 47865.

¹³³ 87 Fed. Reg. 47834 n.139.

¹³⁴ 87 Fed. Reg. 47834 n.139.

¹³⁵ 87 Fed. Reg. 47834 n.139 (citing World Prof. Ass’n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, pp. 68–71 (7th Version 2012) [hereinafter WPATH Standards],

https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English2012.pdf?_t=1613669341 (last visited Feb. 7, 2022)).

In fact, there is no consensus within the medical profession regarding an authoritative standard of care for gender dysphoria or transitioning treatments. This lack of medical consensus is reflected historically, internationally, and in actions by the federal government and various states, and the continuing public controversy surrounding the use of transitioning treatments on minors.

A. There is no consensus within the medical profession historically or internationally.

Since the first transitioning surgeries were performed in the U.S. on adults in the mid-20th century to the present day, there has been no medical consensus regarding the authoritative standard of care to treat gender dysphoria (previously, “gender identity disorder”) in minors or to evaluate the risks and benefits of medically assisted “transitions.”

Historically, there have been uneven and, at times, competing trajectories in the development of therapeutic responses to gender dysphoria; diagnostic labels, criteria, and interventions have evolved significantly over a relatively short time.¹³⁶ The American Psychiatric Association (APA) defines gender dysphoria as “clinically significant distress or impairment related to a strong desire to be of another gender, which may include desire to change primary and/or secondary sex characteristics.”¹³⁷ An “inherently subjective phenomenon,” gender dysphoria is variously classified as “a mental disorder” or “a condition related to sexual health.”¹³⁸

Until recently, responding to a child’s gender dysphoria with “watchful waiting” or family therapy was not controversial because, in most cases, the child’s gender incongruence resolved by puberty.¹³⁹ In contrast, the use of medical transitioning treatments for minors has been controversial since its inception—and remains so.

The Dutch researchers who pioneered the use of puberty suppression as a transitioning treatment for minors acknowledge persistent skepticism towards their work, including from providers concerned that gender dysphoria “can only be diagnosed with certainty in adulthood,” and fearful of “disapproval of the peer group, reactions of the correctional medical boards, or litigation.”¹⁴⁰

Dr. Norman Spack opened the first U.S. pediatric gender clinic at Boston Children’s Hospital in 2007 and used puberty suppression as a transitioning treatment for minors. With scant research available, he viewed “stopping puberty” as “a diagnostic test.”¹⁴¹ If it brought relief, the diagnosis was right.

¹³⁶ The APA’s Diagnostic and Statistical Manual (DSM) changed terminology and diagnostic criteria as follows: “transsexualism” (DSM-III), “gender identity disorder” (DSM-IV), and “gender dysphoria.” *Gender Dysphoria Diagnosis*, Am. Psychiatric Ass’n (2022), <https://www.psychiatry.org/psychiatrists/diversity/education/transgender-and-gender-nonconforming-patients/gender-dysphoria-diagnosis>.

¹³⁷ *What Is Gender Dysphoria?*, Am. Psychiatric Ass’n (Nov. 2020), <https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria>.

¹³⁸ The APA classifies “gender dysphoria” under mental health disorders, while the World Health Organization classifies “gender incongruence” under “sexual health.” Karl Gerritse et al., *Decision-Making Approaches in Transgender Healthcare: Conceptual Analysis and Ethical Implications*, 24 Med. Health Care & Phil. 687, 688 (2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8557156/>.

¹³⁹ Devita Singh et al., *A Follow-Up Study of Boys with Gender Identity Disorder*, Front. Psychiatry 632784 (2021), <https://pubmed.ncbi.nlm.nih.gov/33854450/>.

¹⁴⁰ Peggy Cohen-Kettenis et al., *The Treatment of Adolescent Transsexuals: Changing Insight*, J. Sexual Med. 1892, 1893 (2008), <https://doi.org/10.1111/j.1743-6109.2008.00870.x>.

¹⁴¹ Pagan Kennedy, *Q & A with Norman Spack*, Boston.com (archives Boston Globe), (Mar. 30, 2008), http://archive.boston.com/bostonglobe/ideas/articles/2008/03/30/qa_with_norman_spack/?page=full.

No professional medical society recommended medically treating gender dysphoria in minors until 2009,¹⁴² when the Endocrine Society’s then-newly-released Clinical Practice Guidelines supported puberty suppression and cross-sex hormones for minors—despite lacking “rigorous evaluation of the effectiveness and safety of endocrine protocols.”¹⁴³

In 2012, the World Professional Association for Transgender Health (WPATH), an advocacy group and early promoter of medical transitioning for minors, noted that adoption of medical transitioning for minors “differs among countries and centers. Not all clinics offer puberty suppression.... The percentages of treated adolescents are likely influenced by the organization of health care, insurance aspects, cultural differences, opinions of health professionals, and diagnostic procedures offered in different settings.”¹⁴⁴ In short, no consensus.

Although a 2014 Dutch study reported positive psychological functioning for fifty-five patients who received medical transitioning treatments as adolescents and surgery as adults,¹⁴⁵ subsequent studies failed to replicate those positive outcomes,¹⁴⁶ and many have criticized the study’s methodology.¹⁴⁷ The Endocrine Society’s 2017 guidelines rely on the Dutch study but acknowledge the overall “low” and “very low” quality of supporting evidence generally¹⁴⁸ and note new concerns emerging since 2009, including “effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain.”¹⁴⁹

In 2019, Boston Children’s opened the first pediatric center for gender surgery, solely dedicated to removing minors’ breasts, ovaries, testicles, and genitals as part of medicalized transition.¹⁵⁰ The surgery center reflects gender medicine’s bold extension of transitioning treatments to younger and younger adolescents—controversial decisions unsupported by consensus.¹⁵¹

¹⁴² Edwards-Leeper & Norman P. Spack, *Psychological Evaluation and Medical Treatment of Transgender Youth in an Interdisciplinary “Gender Management Service” (GeMS) in a Major Pediatric Center*, 59 *J. Homosexuality* 321, 323 (2012), <https://pubmed.ncbi.nlm.nih.gov/22455323/>.

¹⁴³ Wylie C. Hembree et al., *Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline*, 94 *J. Clinical Endocrinology & Metabolism* 3132, 3134 (2009), <https://pubmed.ncbi.nlm.nih.gov/19509099/>.

¹⁴⁴ World Prof’l Ass’n for Transgender Health, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People Version 7* 13 (2012) [hereinafter “WPATH SOC7”], <https://www.wpath.org/publications/soc>.

¹⁴⁵ Annelou L.C. de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 *Pediatrics* 696, 702 (2014), <https://pubmed.ncbi.nlm.nih.gov/25201798/>.

¹⁴⁶ Polly Carmichael et al., *Short-Term Outcomes of Pubertal Suppression in a Selected Cohort of 12 to 15 Year Old Young People with Persistent Gender Dysphoria in the UK*, 16 *PLoS ONE* (2021), <https://doi.org/10.1371/journal.pone.0243894> (failing to replicate Dutch study).

¹⁴⁷ Stephen B. Levine et al., *Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults*, *J. Sex & Marital Therapy* 9 (2022), <https://www.tandfonline.com/doi/full/10.1080/0092623X.2022.2046221>.

¹⁴⁸ Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 *J. Clinical Endocrinology & Metabolism* 3869, 3880 (2017), <https://doi.org/10.1210/je.2017-01658>.

¹⁴⁹ *Id.* at 3874.

¹⁵⁰ *Center for Gender Surgery: Conditions & Procedures*, Boston Children’s Hospital, <https://www.childrenshospital.org/programs/center-gender-surgery-program/conditions-and-treatments>.

¹⁵¹ See Hembree et al., *supra* note 148, at 3872; Christine & Dan Karasic, *Age Is Just a Number: WPATH-Affiliated Surgeons’ Experiences and Attitudes Toward Vaginoplasty in Transgender Females Under 18 Years of Age in the United States*, 14 *J. Sex Med.* 624, 625 (2017), <https://pubmed.ncbi.nlm.nih.gov/28325535/> (urging lowering of recommended age for surgeries); Elizabeth R. Boskey & Judith A. Johnson, *Ethical Issues Considered when Establishing a Pediatric Gender Surgery Center*, 143 *Pediatrics* 1, 2 (2019), <https://pediatrics.aappublications.org/content/143/6/e20183053.figures-only>.

In the fifteen years since U.S. gender clinicians began the controversial practice of offering transitioning treatments for minors, the number of minors seeking and receiving them has skyrocketed. So too has the number of gender clinics for minors, growing from one in 2007 to over 60 today.¹⁵² But market expansion should not be mistaken for a medical consensus. The next chapter in treatment for gender dysphoria is still being written.

Many countries that initially embraced transitioning treatments, including for minors, are now reconsidering. For example, Sweden's National Board of Health and Welfare commissioned an extensive evidence review and concluded in 2022 "that the risks of anti-puberty and sex-confirming hormone treatment for those under 18 currently outweigh the possible benefits."¹⁵³ Finland likewise has reversed course. Following an extensive literature review, the Finnish Health Authority issued new guidelines that prioritize psychotherapy as the first-line treatment for gender dysphoric minors.¹⁵⁴

In the United Kingdom, whistleblower complaints exposed the inadequate psychological care for gender dysphoric minors at the National Health Service's (NHS) gender clinic.¹⁵⁵ A landmark case against the NHS in 2020 by "de-transitioner" Keira Bell found that minors lacked capacity to consent to transitioning treatments that cause sterility and impair sexual function. The NHS initially suspended the use of puberty blockers and instituted new procedures to ensure better psychological care.¹⁵⁶ (The decision was later reversed on procedural grounds.) Two separate evidence reviews assessing the impact of puberty suppressing drugs and cross-sex hormones to treat gender dysphoria were published in 2021 by the UK's National Institute for Health and Care Excellence (NICE). The NICE evidence review found little evidence of benefit and substantial risk of harm from "gender affirming" treatment in minors.¹⁵⁷ A 2022 independent review commissioned by NHS England (the "Cass report"), found that "[a]t present the professional community does not have a shared understanding about the meaning of gender dysphoria in young people," its cause, or best treatment approaches.¹⁵⁸ The report notes that "[m]uch of the research base is observational," with little "longer term follow up data," resulting in a "weak evidence base."¹⁵⁹ The lack of evidence and the "unsafe" care delivered to gender dysphoric adolescents resulted in a decision by the UK National Health Service to close the Tavistock gender clinic (GIDS) by spring 2023. The UK medical authorities intend to disperse care to local and regional authorities, reducing waiting lists

¹⁵² *Comprehensive Care Clinics*, Human Rights Campaign Foundation, <https://www.thehrcfoundation.org/professional-resources/comprehensive-care-clinics>.

¹⁵³ Support, Investigation and Hormone Treatment for Gender Incongruence in Children and Adolescents - Partial Update of Knowledge Support (2022), <https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-2-7774.pdf>; see also Lisa Nainggolan, *Hormonal Tx of Youth with Gender Dysphoria Stops in Sweden*, Medscape (2021), <https://www.medscape.com/viewarticle/950964>.

¹⁵⁴ Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland): Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors (2020), available at https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf. COHERE Finland works in conjunction with the Ministry of Social Affairs and Health.

¹⁵⁵ Lauren Lewis, *NHS's Only Gender Service for Children Believes All Girls Who Don't Like 'Pink Ribbons and Dollies' Must Be Transgender*, *Whistleblower Claims*, Daily Mail (Nov. 22, 2021), <https://www.dailymail.co.uk/news/article-10231507/NHSs-gender-service-children-believes-girls-dont-like-pink-transgender.html>.

¹⁵⁶ Becky McCall, *NHS Makes Child Gender Identity Service Changes After High Court Ruling*, Medscape (Dec. 4, 2020), <https://www.medscape.com/viewarticle/941781>.

¹⁵⁷ Nat'l Inst. for Health & Care Excellence, Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria (2021); Nat'l Inst. for Health & Care Excellence, Evidence Review: Gender-Affirming Hormones for Children and Adolescents with Gender Dysphoria (2021) [hereinafter "NICE Evidence Review" collectively].

¹⁵⁸ Hilary Cass, *Review of Gender Identity Services for Children and Young People*, BMJ 376 (2022), <https://www.bmj.com/content/376/bmj.o629>.

¹⁵⁹ *Id.*

and ensuring the adolescents receive comprehensive mental health care, while the Cass evidence review continues.¹⁶⁰

Psychotherapists in Australia and New Zealand recently issued a new policy statement emphasizing mental health treatment for gender dysphoric minors, rather than “gender affirmation.” They stressed the importance of assessing the “psychological state and context in which gender dysphoria has arisen,” before any treatment decisions are made.¹⁶¹ In February 2022, France’s National Academy of Medicine warned medical professionals that the increase in young people seeking transitioning treatments may be due to social contagion and urged “great medical caution.”¹⁶²

In short, within the international medical community, “gender-affirming care,” for minors in particular, is not backed by a supportive consensus.

This lack of consensus is also reflected among U.S. medical professionals. In the months leading up to its 2022 national conference, the American Academy of Pediatrics (AAP) was accused by some of its own members of “censoring” concerns over the use of gender-affirming medical and surgical interventions for minors, amid a rising outcry from clinicians and parents.¹⁶³ Parent-organized protests at gender clinics across the U.S., including at Boston Children’s Hospital’s flagship program, underscore the rising numbers of Americans who believe minors should never undergo irreversible medical or surgical “gender-affirming” treatments.¹⁶⁴

B. The federal government has recognized the lack of medical consensus.

Despite the efforts under the current administration to push transitioning treatments for minors, and notwithstanding the Proposed Rule, the federal government has never formally determined that such treatments are the appropriate standard of care.

As recently as June 2020, HHS regulations acknowledged that “there is no medical consensus to support one or another form of treatment for gender dysphoria.”¹⁶⁵ The Department explained that prior HHS regulations regarding gender-transition surgeries “relied excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding,” such as the CMS factfinding for its most recent National Coverage Determination.¹⁶⁶ After its factfinding, CMS declined to issue a National Coverage Determination on gender-transition surgeries for Medicare beneficiaries with

¹⁶⁰ Hurd, D., ‘Not Safe’: Britain’s Tavistock Sex-change Clinic Closed After Damning Report, CBN News, July 29, 2022. <https://www1.cbn.com/cbnnews/world/2022/july/not-safe-britains-tavistock-sex-change-clinic-for-children-closed-after-damning-report>.

¹⁶¹ Position Statement, The Royal Australian and New Zealand College of Psychiatrists, *Recognising and Addressing the Mental Health Needs of People Experiencing Gender Dysphoria/Gender Incongruence* (Aug. 2021), <https://www.ranzcp.org/news-policy/policy-and-advocacy/position-statements/gender-dysphoria>.

¹⁶² Press Release, French National Academy of Medicine, *Medicine and Gender Transidentity in Children and Adolescents* (Feb. 25, 2022), <https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en>.

¹⁶³ Abigail Anthony, *American Academy of Pediatrics Accused of Censoring Concerns about ‘Gender-Affirming’ Care*, National Review, July 29, 2022. <https://www.nationalreview.com/2022/07/american-academy-of-pediatrics-accused-of-censoring-concerns-about-gender-affirmative-care/>.

¹⁶⁴ Mary Harrington, *Boston Children’s Hospital’s transgender insanity reveals how unhinged elites make money off our kids*, NY Post, August 24, 2022. <https://nypost.com/2022/08/24/boston-childrens-hospitals-transgender-insanity-elites-profit-from-kids/>.

¹⁶⁵ 85 Fed. Reg. 37160, 37198.

¹⁶⁶ *Id.*

gender dysphoria “because the clinical evidence is inconclusive.”¹⁶⁷ “Based on an extensive assessment of the clinical evidence,” CMS determined that “there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries [which include non-seniors] with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.”¹⁶⁸

Similarly, a 2018 Department of Defense (DOD) report on gender dysphoria found that there is “considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments, such as cross-sex hormone therapy and sex reassignment surgery—interventions which are unique in psychiatry and medicine—remedy the multifaceted mental health problems associated with gender dysphoria.”¹⁶⁹ Indeed, none of the drugs used to block puberty and induce cross-sex masculine or feminine features are approved as safe or effective for such uses by the U.S. Food and Drug Administration, and the National Institutes of Health only began investigating the long-term outcomes of transitioning treatments for youth in 2015.¹⁷⁰

C. State action reflects the lack of medical consensus.

State actions reflect the lack of medical consensus for the appropriate standard of care for gender dysphoria and transitioning interventions, especially for minors. For instance, several states have passed laws that prohibit providing minor children with transitioning treatments.¹⁷¹ Other states have and are considering similar bills.

State executives also have weighed in on the issue. For example, in February 2022, the Texas Attorney General issued an opinion letter stating that sterilizing treatments and other permanent “sex-change procedures,” including puberty suppression, cross-sex hormones, and various surgeries, “can constitute child abuse when performed on minor children.”¹⁷² Texas’s governor subsequently directed the Texas Department of Family and Protective Services to “conduct a prompt and thorough investigation of any reported instances of these abusive procedures in the State of Texas.”¹⁷³

More recently, Florida’s Department of Health (DOH) issued guidelines in response to an HHS document promoting “gender-affirming care” for young people. Florida’s DOH clarified that the treatment of gender dysphoria for children and adolescents should *not* include social gender transition, puberty blockers, cross-sex hormones, or transitioning surgeries because of “the lack of conclusive evidence, and the potential for long-term, irreversible effects.”¹⁷⁴ The state Secretary of the Agency for

¹⁶⁷ CMS Decision Memo for Gender Dysphoria and Gender Reassignment Surgery, CAG–00446N (Aug. 30, 2016) [hereinafter “CMS Decision Memo”], <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282>.

¹⁶⁸ *Id.*

¹⁶⁹ Dep’t of Defense, Report and Recommendations on Military Service by Transgender Persons 5 (Feb. 22, 2018).

¹⁷⁰ See Juliana Bunim, First U.S. Study of Transgender Youth Funded by NIH, U.C. San Francisco (Aug. 17, 2015), <https://perma.cc/URA6-CERX>.

¹⁷¹ See, e.g., Ariz. S.B. 1138 (2022); Ark. H.B. 1570 (2021); Tenn. H.B. 0578 (2021); AL S.B. 184 (2022).

¹⁷² Tex. Att’y Gen. Op. Letter No. KP-0401, from Ken Paxton, Attorney General, to Matt Krause, Chair, House Committee on General Investigating, Texas House of Representatives 1-2 (Feb. 18, 2022), <https://www.texasattorneygeneral.gov/sites/default/files/opinion-files/opinion/2022/kp-0401.pdf>.

¹⁷³ Letter from Greg Abbott, Governor, State of Texas, to Jaime Masters, Commissioner, Texas Department of Family and Protective Services (Feb. 22, 2022), <https://gov.texas.gov/uploads/files/press/O-MastersJaime202202221358.pdf>.

¹⁷⁴ Office of the State Surgeon Gen., Fla. Dep’t of Health, Treatment of Gender Dysphoria for Children and Adolescents (Apr. 20, 2022), <https://www.floridahealth.gov/documents/newsroom/press->

Health Care Administration subsequently requested that the Florida Medicaid program review whether such treatments are “consistent with generally accepted professional medical standards.”¹⁷⁵ The report, published on June 2, 2022, found that transitioning interventions for the treatment of gender dysphoria “are not consistent with widely accepted professional medical standards and are experimental and investigational with the potential for harmful long term affects [sic].”¹⁷⁶ The Florida Board of Medicine conducted hearings throughout the summer of 2022 on the risks and benefits of gender affirming transition procedures and is reportedly considering imposing restrictions on their use in both minors and adults.¹⁷⁷

5. Transitioning treatments inflict irreversible harm on children.

The Proposed Rule makes no distinction regarding the provision of gender-affirming care to minors versus adults. In fact, the Rule applies its expansive definition of “sex” to include “gender identity” to regulations governing the Children’s Health Insurance Program (CHIP),¹⁷⁸ as the Obama administration had done previously in its 2016 regulations,¹⁷⁹ and specifically mentions “children” as negatively affected by discrimination in healthcare.¹⁸⁰ The Rule states: “The proposed amendments to 42 CFR 438.3(d)(4), 438.206(c)(2), 440.262, and 457.495(e) would explicitly prohibit discrimination on the basis of sexual orientation and gender identity in addition to the existing prohibitions imposed on Medicaid and CHIP under Section 1557.”¹⁸¹ In addition, the Proposed Rule claims the authority to define Essential Health Benefits that pertain to, among others, children: “Section 1302(b) of the ACA also gives CMS the statutory authority to prohibit discrimination in the small group and individual markets pursuant to the authority to define EHB at section 1302(b) of the ACA. The statute specifies that in defining EHB the Secretary must take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups.”¹⁸²

Although the Rule’s “gender identity” language is clearly intended to apply to children in the context of health care, and the Rule also purports to establish “gender affirming care” as the standard of care for non-discriminatory treatment of gender dysphoria, the Rule’s failure to address the growing controversy over the provision of “gender affirming care” to minors, including medical and surgical interventions that carry permanent consequences, is shocking. HHS instead glosses over the growing international backlash against the use of permanent or life-altering medical and surgical interventions—styled as “gender-affirming care”—with minors. HHS’s reliance on the discredited WPATH standards is

[releases/2022/04/20220420-gender-dysphoria-guidance.pdf](https://www.fda.gov/oc/2022/04/20220420-gender-dysphoria-guidance.pdf); cf. *Setting the Record Straight*, Florida Agency for Health Care Administration (2022), <https://ahca.myflorida.com/LetKidsBeKids/page3.shtml> (“detailing the lack of conclusive evidence in recent directives and ‘fact sheets’ issued by the US Department of Health and Human Services for the coverage of ‘gender affirming’ care, for children and adolescents”).

¹⁷⁵ Florida Agency for Health Care Administration, Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria 14 (June 2022) [hereinafter Florida Medicaid Report], https://ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf (from report, description of comments from U.S. Senate Committee on Appropriations, 2022) at 2.

¹⁷⁶ *Report Overview*, Florida Agency for Health Care Administration (2022), <https://ahca.myflorida.com/letkidsbekids/>.

¹⁷⁷ Brooke Migdon, *Florida’s Board of Medicine considers restricting gender-affirming health care for transgender youth, adults*, The Hill, Aug. 5, 2022. <https://thehill.com/changing-america/respect/equality/3589754-floridas-board-of-medicine-considers-restricting-gender-affirming-health-care-for-transgender-youth-adults/>

¹⁷⁸ 87 Fed. Reg. 47824, 47828-29. 47831.

¹⁷⁹ 87 Fed. Reg. 47892

¹⁸⁰ 87 Fed. Reg. 47831.

¹⁸¹ 87 Fed. Reg. 47892.

¹⁸² 87 Fed. Reg. 47898.

another indication of the arbitrary and capricious nature of the Proposed Rule,¹⁸³ especially in light of the recent WPATH action eliminating all minimum age recommendations for medical and surgical “gender-affirming” treatments in minors.¹⁸⁴

The Proposed Rule is deeply troubling, and should be withdrawn, in light of the evidence that “gender-affirming care” causes irreversible harm to children and adolescents. The number of children and adolescents diagnosed with gender dysphoria or identifying as “transgender” has risen dramatically over the past decade and become “an international phenomenon, observed across North America, Europe, Scandinavia, and elsewhere.”¹⁸⁵ The typical patient profile has changed markedly—in the past, patients seeking treatment for gender dysphoria were usually either adult males or pre-pubescent males. Today, the typical patient is an adolescent, usually female.¹⁸⁶

For years, gender dysphoria in children was addressed through “watchful waiting” or family therapy. About eighty-eight percent of the time, the child’s gender dysphoria resolved naturally by puberty without transitioning interventions.¹⁸⁷ The recent, “gender-affirming” approach has changed that pattern dramatically, causing most children who are “affirmed” in their transgender beliefs to persist in those beliefs and pursue transitioning treatments that irreversibly modify their bodies.¹⁸⁸ This approach has led to widespread regret and lifelong harm.¹⁸⁹

Clinical concerns over the outcomes of transitioning treatments have escalated.¹⁹⁰ Puberty blockers, originally described as safe and fully reversible, are known to have negative effects on bone density, social and emotional maturation, and other aspects of neuro-development.¹⁹¹ They generally fail

¹⁸³ Coleman, E., Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *International Journal of Transgender Health*, Vol. 23, Issue 1 (2022). CORRECTION, Statement of Removal. *International Journal of Transgender Health*, 23(sup1), p. S259.

¹⁸⁴ Lane, B., *Not Up to Standard*, Gender Clinic News, September 28, 2022. <https://genderclinicnews.substack.com/p/not-up-to-standard>.

¹⁸⁵ Kenneth J. Zucker, *Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues*, 48 ARCHIVES SEXUAL BEHAV. 1983 (2019), <https://pubmed.ncbi.nlm.nih.gov/31321594/>.

¹⁸⁶ *Id.*

¹⁸⁷ Devita Singh et al., *A Follow-Up Study of Boys with Gender Identity Disorder*, *Front. Psychiatry* 632784 (2021), <https://pubmed.ncbi.nlm.nih.gov/33854450/>.

¹⁸⁸ Carmichael et al., *supra* note 146 (study by Tavistock and Portman NHS Gender Identity Development Service (UK) finding ninety-eight percent of adolescents who underwent puberty suppression continued on to cross-sex hormones); *see also* Lisa Littman, *Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners*, 50 *Archives Sexual Behav.* 3353 (2021), <https://pubmed.ncbi.nlm.nih.gov/34665380/>.

¹⁸⁹ Carmichael et al., *supra* note 146 (study by Tavistock and Portman NHS Gender Identity Development Service (UK) finding ninety-eight percent of adolescents who underwent puberty suppression continued on to cross-sex hormones); *see also* Lisa Littman, *Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners*, 50 *Archives Sexual Behav.* 3353 (2021), <https://pubmed.ncbi.nlm.nih.gov/34665380/>.

¹⁹⁰ William Malone, *Puberty Blockers for Gender Dysphoria: The Science is Far from Settled*, 5 *Lancet Child & Adolescent Health* 33 (2021), <https://pubmed.ncbi.nlm.nih.gov/34418372/>.

¹⁹¹ NICE Evidence Review.

to lessen the child’s gender dysphoria, and deliver mixed results for mental health.¹⁹² Long term effects remain unknown.¹⁹³

Nearly all children who begin puberty blockers go on to receive cross-sex hormones, the next step in transitioning, with life-altering consequences.¹⁹⁴ Blocking a child’s natural puberty prevents maturation of genitals and reproductive organs; subsequently introducing cross-sex hormones renders the child permanently sterile.¹⁹⁵ Gender clinicians also admit that puberty suppression may impair the child’s later sexual functioning as an adult.¹⁹⁶ These losses cannot be fully comprehended by a child, precluding the possibility of informed consent.

Cross-sex hormones carry numerous health risks and cause significant irreversible changes in adolescents’ bodies, including genital or vaginal atrophy, hair loss (or gain), voice changes, and impaired fertility.¹⁹⁷ They increase cardiovascular risks and cause liver and metabolic changes.¹⁹⁸ The flood of opposite sex hormones has variable emotional and psychological effects as well. Females taking testosterone experience an increase in gender dysphoria, particularly regarding their breasts, which heightens the likelihood they will undergo double mastectomies—as young as thirteen.¹⁹⁹ Far from an evidence-based standard of care, transitioning treatments for gender dysphoria amount to unethical human experimentation—on *children*. One Swedish teen who underwent medical transition, suffered serious bodily harm, and then de-transitioned describes gender-transitioning treatments for gender dysphoria in stark terms: “They’re experimenting on young people ... we’re guinea pigs.”²⁰⁰ Or, as psychotherapist Alison Clayton warns, this is nothing less than “dangerous medicine.”²⁰¹

Detransitioners are the tragic victims of the “dangerous medicine” that masquerades as “gender-affirming care.” They are predominantly young people who, after being hurried down the “gender-affirming” path of permanent bodily alterations, eventually realized the harm wrought by their pursuit of the “gender identity” mirage. Their testimonies are compelling and deserve to be heard. In refusing to hear the testimony of detransitioners, HHS betrays its bias and demonstrates once again the arbitrary and capricious nature of the Proposed Rule. Chloe Cole is an 18-year-old detransitioner who courageously

¹⁹² Polly Carmichael et al., *Short-Term Outcomes of Pubertal Suppression in a Selected Cohort of 12 to 15 Year Old Young People with Persistent Gender Dysphoria in the UK*, 16 PLoS ONE (2021), <https://doi.org/10.1371/journal.pone.0243894> (failing to replicate Dutch study).

¹⁹³ Diane Chen et al., *Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth*, 5 *Transgender Health* 246 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7759272/>.

¹⁹⁴ *Id.*

¹⁹⁵ Stephen B. Levine, *Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria*, 44 *J. Sex & Marital Therapy* 29 (2018), <https://pubmed.ncbi.nlm.nih.gov/28332936/>.

¹⁹⁶ Abigail Shrier, *Top Trans Doctors Blow the Whistle on “Sloppy” Care*, *Real Clear Politics*, (Oct. 5, 2021), https://www.realclearpolitics.com/2021/10/05/top_trans_doctors_blow_the_whistle_on_sloppy_care_553290.html.

¹⁹⁷ Stephen B. Levine et al., *Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults*, *J. Sex & Marital Therapy* 9 (2022), <https://www.tandfonline.com/doi/full/10.1080/0092623X.2022.2046221>.

¹⁹⁸ *Gender-Affirming Hormone in Children and Adolescents*, *BJM EBM Spotlight* (Feb. 25, 2019), <https://blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirming-hormone-in-children-and-adolescents-evidence-review/>.

¹⁹⁹ Johanna Olson-Kennedy et al., *Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts*, 172 *JAMA Pediatrics* 431 (2018), <https://pubmed.ncbi.nlm.nih.gov/29507933/> (Figure: Age at Chest Surgery in the Post-surgical Cohort).

²⁰⁰ Video, *Mission: Investigate: Trans Children (“Trans Train 4”)* (Nov. 26, 2021), <https://www.svtplay.se/video/33358590/uppdrag-granskning/mission-investigate-trans-children-avsnitt-1>.

²⁰¹ Alison Clayton, *The Gender Affirmative Treatment Model for Youth with Gender Dysphoria: A Medical Advance or Dangerous Medicine?*, 51 *Archives Sexual Behav.* 691 (2022), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8888500/>.

shared her experience with numerous state legislatures and policymakers. Her testimony to Louisiana policy officials speaks to the irreversible harm inflicted by “gender-affirming” interventions.

My name is Chloe Cole, and I am from the Central Valley of California and a former transgender child patient. I am currently 17 years old and was medically transitioning from ages 13-16.

After I came out to my parents as a transgender boy at 12, I consulted a pediatric therapist in July of 2017 and was diagnosed with dysphoria by a ‘gender specialist’ the following month. The healthcare workers are trained to strictly follow the affirmative care system, even for child patients, in part because of California’s ‘conversion therapy’ ban. There was very little gatekeeping or other treatments suggested for my dysphoria.

When my parents asked about the efficacy of hormonal, surgical, and otherwise ‘affirming’ treatments in dysphoric children, their concerns were very quickly brushed aside by medical professionals. I didn’t even know detransitioners existed until I was one.

The only person who didn’t affirm me was the first endocrinologist I met. He refused to put me on blockers and expressed concerns for my cognitive development. However, it was easy to see another endocrinologist to get a prescription for blockers and testosterone, just like getting a second opinion for any other medical concern. After only two or three appointments with the second endocrinologist, I was given paperwork and consent forms for puberty blockers (Lupron) and androgens (Depo-Testosterone), respectively. I began blockers in February of 2018, and one month later, I received my first testosterone shot. I received Lupron shots for about a year.

After two years on testosterone, I expressed to my therapist that I was seeking top surgery, or the removal of my breasts. I was recommended to another gender specialist, who then sent me to a gender-affirming surgeon. After my first consultation with the surgeon, my parents and I were encouraged to attend a ‘top surgery’ class, which had about 12 Female-to-Male (FTM) kids. I was immediately struck by how early some of them seemed in their transition and how some were much younger than I was; I was 15 at the time and had been transitioning for 3 years.

In retrospect, the class inadvertently helped to affirm my decision because of the sense of community provided by seeing girls like me going through the same thing. Despite all these consultations and classes, I don’t feel like I understood all the ramifications that came with any of the medical decisions I was making. I didn’t realize how traumatic the recovery would be, and it wasn’t until I was almost a year post-op, that I realized I may want to breastfeed my future children; I will never be able to do that as a mother.

The worst part about my transition would be the long-term health effects that I didn’t knowingly consent to at the time. I developed urinary tract issues during my transition that seem to have gotten worse since stopping testosterone. I have been getting blood clots in my urine and have an inability to fully empty my bladder. Because my reproductive system was still developing while I was on testosterone, the overall function of it is completely unknown. I have irreversible changes, and I may face complications for the rest of my life.

I was failed by modern medicine.²⁰²

²⁰² Chloe Cole, Testimony to Louisiana Attorney General and Other State Officials, May 4, 2022, <https://www.facebook.com/InternationalPartnersforethicalcare/videos/chloe-cole-testimony-in-louisiana/412402700331012/>.

6. The Proposed Rule would harm religious liberty.

A. Section 1557 incorporates Title IX's religious exemption.

Title IX contains a religious exemption, which states that Title IX's prohibition against sex discrimination "shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization."²⁰³

Section 1557 prohibits discrimination on "the ground prohibited under" Title IX, specifically "20 U.S.C. § 1681 *et seq.*"²⁰⁴ Section 1557 citation of Title IX's entire statutory scheme demonstrates that the "more natural understanding" is that all of Title IX's provisions, including its exemptions are incorporated. Congress didn't need to expressly incorporate Title IX's exemptions, because it did so by reference to the statutory provisions (20 U.S.C. § 1681 *et seq.*). If Congress just wanted to prohibit discrimination based on sex generally, it could have said so explicitly. Rather, Congress incorporated the four civil rights statutes because those discrimination prohibitions reflected careful balance of various concerns and competing interests by Congress. Contrary to HHS's assertion, the proposed regulations do not reflect Section 1557's statutory language or Congressional intent.

As a textual manner, applying sex discrimination prohibitions to a religious institution to the extent it "would not be consistent with the religious tenets of such organization" is not a ground prohibited under Title IX. Further, Title IX's prohibition against sex discrimination is in 20 U.S.C. § 1681(a) as is the religious exemption (§ 1681(a)(3)). Title IX's sex discrimination prohibition cannot be read separate and apart from the exemptions—especially those in the same section! To say otherwise, would be arbitrary and capricious and contrary to law.

The Proposed Rule state that "the application of the Title IX exception for entities controlled by religious organizations, in particular, could raise distinctive concerns in the health care context that are not typically present in education programs and activities."²⁰⁵ The Department gives several examples, such as "the ability of affected parties to choose or avoid a certain religiously affiliated health care institution and the urgency of the need for services provided by the covered entities."²⁰⁶ It alleges that "patients seeking health care are much more likely to be driven by considerations of availability, convenience, urgency, geography, cost, insurance network restrictions, and other factors unrelated to the question of whether the health care provider is controlled by or affiliated with a religious organization." HHS fails to provide support for this statement, making its reasoning arbitrary and capricious. Countless patients, including the undersigned, seek health care specifically from a provider that shares their religious beliefs, even if such a provider is less convenient, further away, or costs more. HHS states that in many communities, patients may have no other option than to seek health care from religious affiliated providers, indicating that patients do have preferences regarding the religious nature of their health care provider and do make care decisions based on such affiliation. HHS cannot disregard the statutory contours of the Section 1557 of the ACA and its obligations under the First Amendment, RFRA, and federal conscience and religious freedom protection laws, to promote the ACA's general principal objection of "increasing access to health care."²⁰⁷

²⁰³ 20 U.S.C. § 1681(a)(3).

²⁰⁴ 42 U.S.C. § 18116 (emphasis added).

²⁰⁵ 87 Fed. Reg. 47841.

²⁰⁶ *Id.*

²⁰⁷ 87 Fed. Reg. 47840.

HHS also claims that a case-by-case analysis of burden and interests is required under RFRA, “something the Title IX exemption does not allow.”²⁰⁸ But this is inapposite. Different laws can have different and overlapping religious protections with differing standards. It is not inconsistent or contradictory for Title IX to give a blanket exemption where a requirement would violate a religious tenet while RFRA requires a substantial burden (and no compelling interest achieved by the least restrictive means).

B. The proposed conscience and religious objection process is an empty gesture.

The Proposed Rules states that HHS is “fully committed to respecting conscience and religious freedom laws when applying this rule, including an organization’s assertion that the provisions of this rule conflict with their rights under Federal conscience and religious freedom laws.”²⁰⁹ As such, the Proposed Rule proposes in § 92.302 “to adopt a process by which recipients may inform the Department of their views that the application of a specific provision or provisions of this part to them would violate Federal conscience or religious freedom laws, so that the Department may, as appropriate, make a determination that recipients are exempt from, or entitled to a modification of the application of, a provision or provisions of this part.”²¹⁰ Proposed regulations would provide a specific means for recipients to notify HHS of their views regarding the application of federal conscience or religious freedom laws.²¹¹ HHS would be required to “promptly consider those views,” pause any agency investigation or enforcement activity during consideration, and make a “case-by-case” determination about any applicable legal protections.²¹² HHS notes that a “case-by-case approach to such determinations ... will allow it to account for any harm an exemption could have on third parties.”²¹³

We applaud the Department’s explicit recognition of federal conscience and religious freedom rights and the need for a formal process for people’s rights to be vindicated, but the proposed process is meaningless because all that matters is who makes the final determinations and on what basis. While we agree that any investigation should be paused until a final determination has been made, we have every reason to believe that the process will exclude the Conscience and Religious Freedom Division and lead to religious and conscience objectors losing and “harmed third parties” winning every time.

It is clear that HHS has excluded the Conscience and Religious Freedom Division from the rulemaking process because it is nowhere mentioned as part of the process or rulemaking even though the Division was created and staffed with career professionals *precisely* to address the religious freedom and conscience questions raised by the rule and the proposed process. If an entity or individual believes the Department is violating its federal conscience protection rights (be it with respect to sexual orientation, gender identity, or abortion) they must, in most cases, submit an objection or complaint to OCR—the very entity tasked with evaluating sexual orientation, gender identity, and “termination of pregnancy” discrimination claims. Without the explicit, formal, required participation of the Conscience and Religious Freedom Division, the proposed process has no accountability for HHS and perverse incentives for the Agency to disregard conscience and religious freedom rights.

Current leadership at HHS have never disavowed statements from OCR’s former chief of staff and political appointee Laura Durso under the Biden Administration who said “The new HHS religious liberty police sends shivers down my spine. I trained as a psychologist to help those who were struggling,

²⁰⁸ 87 Fed. Reg. 47840.

²⁰⁹ 87 Fed. Reg. 47841.

²¹⁰ 87 Fed. Reg. 47828.

²¹¹ 87 Fed. Reg. 47885.

²¹² 87 Fed. Reg. 47885.

²¹³ 87 Fed. Reg. 47886.

no matter who they were. This new office – and any policies that come from it – will only enable discrimination and pain.”²¹⁴

In the Proposed Rule, HHS refuses to incorporate Title IX’s religious exemption, contrary to law, demonstrating that it does not value religious rights. Indeed, HHS under Secretary Becerra has systematically targeted or ignored conscience and religious freedom protections, such as by sidelining HHS’s Conscience and Religious Freedom Division, abandoning the case of a nurse illegally forced to participate in abortion, rescinding protections for faith-based adopted and foster care agencies in three states, and proposing to rescind conscience protection regulations.²¹⁵ HHS even refused in federal court to “disavow enforcement” of Section 1557 to require medical professionals to perform gender transition surgeries or abortions in violation of their sincerely held religious beliefs.²¹⁶

Further, HHS is now appealing a decision in *Christian Employers Alliance v. EEOC* (8th Cir. Sept. 23, 2022), which held that HHS could not force both non-profit and for-profit religious employers and healthcare providers to pay for and perform surgeries, procedures, counseling, and treatments that seek to alter one’s biological sex even if such actions violate the employers’ or providers’ religious beliefs.²¹⁷ Specifically, the federal district court enjoined HHS from “interpreting or enforcing Section 1557 of the ACA and any regulations against the Alliance’s present or future members in a manner that would require them to provide, offer, perform, facilitate, or refer for gender transition services” and “in a manner that prevents, restricts or compels the Alliance’s members’ speech on gender identity issues.”²¹⁸ On good evidence, it is clear HHS never consulted the career professionals in the Conscience and Religious Freedom Division to solicit their views on these matters that are squarely in their expertise.

HHS’s litigation positions are even more evidence that the agency does not respect or recognize conscience and religious rights in the Section 1557 context. It is apparent that HHS does not believe there should be conscience and religious exemptions to Section 1557 regulations, and it is doubtful that OCR would seriously give effect to those legal protections through the proposed notification process when its litigation positions say otherwise.

To the extent that health care entities and professionals notify HHS of their conscience or religious objections to requirements under Section 1557 regulations, HHS should not make publicly accessible a list of religious objectors. This would open the door for those who do not agree to single out, target, or harass those institutions and professionals of conscience and faith. HHS should also issue a guarantee that if an entity or professional notifies the Agency of a possible or actual objection, that HHS will not abuse its authority by then investigating or targeting that entity or professional for possible violations of law. To do so would chill the benefits of seeking guidance or technical assistance in good faith.

C. HHS should consult with and follow the recommendations of the Conscience and Religious Freedom Division and protect conscience and religious freedom rights.

Religious health care professionals and faith-based health care organizations live out their faith-based vocation to love and care for the sick and suffering through health care based on the biological

²¹⁴ Laura E. Durso (@TheDursoIsIn) January 18, 2018, <https://t.co/v62IALBrNa>.

²¹⁵ Rachel N. Morrison, *In Its First Year, Biden’s HHS Relentlessly Attacked Christians and Unborn Babies*, THE FEDERALIST (Mar. 18, 2022), <https://thefederalist.com/2022/03/18/in-its-first-year-bidens-hhs-relentlessly-attacked-christians-and-unborn-babies/> (listing the anti-religion and pro-abortion acts of the Biden-Becerra HHS).

²¹⁶ *Franciscan All. v. Becerra*, No. 21-11174, at *10 (5th Cir. Aug. 26, 2022).

²¹⁷ *Christian Emp’rs All. v. EEOC*, Case No. 1:21-cv-195 (D.N.D. May. 16, 2022).

²¹⁸ *Id.* at *18.

scientific reality of the human person and the human body. These professionals and organizations are vital to health care access for the poor and vulnerable, especially where Catholic health care alone provides over 15 percent of all health care delivery in America.

Regulations that fail to uphold federal protections for medical conscience and religious liberty in health care will lead to decreasing access to care for poor communities and racial minority communities throughout much of the country—this should never occur generally and especially not during the “public health emergency” declared by HHS Secretary Becerra to still exist.²¹⁹

At a minimum, federal regulations should uphold existing medical conscience and religious freedom protections under federal law. HHS acknowledges that its Section 1557 regulations will implicate conscience and religious freedom concerns as it proposes a process in §92.302 to handle such conflicts.²²⁰

Since the proposed rule would implicate conscience and religious freedom concerns, HHS should request input from the career professionals at the Conscience and Religious Freedom Division and follow their expert recommendations. There has been a concerning trend by HHS to cut the Division out of review of proposed rules that implicate conscience and religious freedom rights. Indeed, HHS has only made it more difficult across the board for the Agency to enforce vital conscience and religious protections in healthcare. It should not do so here. While HHS has paid lip service to conscience and religious freedom rights in its proposed rules, it has blatantly disregarded and ignored those rights, including by effectively dismantling its Conscience and Religious Freedom Division and crippling the ability of the Office for Civil Rights (OCR) to receive complaints and enforce religious protections under the Religious Freedom Restoration Act and the First Amendment.²²¹ And most recently, by proposing to rescind the 2019 Conscience Rule.²²²

The removal of the delegation of authority from OCR to enforce RFRA and the First Amendment said that “Department components, in consultation with OGC, have the responsibility, and are best positioned, to evaluate RFRA-based requests for exemptions, waivers, and modifications of program requirements in the programs they operate or oversee. Department components, further, are best situated to craft exemptions or other modifications when required under RFRA and to monitor the impact of such exemptions or modifications on programs and those they serve. Moreover, they are best positioned to evaluate how their programs must be run to comply with the Free Exercise Clause and the Establishment Clause of the First Amendment.”²²³

²¹⁹ Cf. EPPC Scholars Call on HHS Secretary Becerra to End Covid-19 Public Health “Emergency” (Mar. 15, 2022), <https://epcc.org/news/epcc-scholars-call-on-hhs-secretary-becerra-to-end-covid-19-public-health-emergency/>.

²²⁰ Further, in its 2021 notification, HHS stated: “In enforcing Section 1557, as stated above, OCR will comply with the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq.*, and all other legal requirements.” U.S. Dep’t Health & Human Servs., Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972 3 (May 10, 2021), <https://www.hhs.gov/sites/default/files/ocr-bostock-notification.pdf>.

²²¹ Rachel N. Morrison, *In Its First Year, Biden’s HHS Relentlessly Attacked Christians and Unborn Babies*, THE FEDERALIST (Mar. 18, 2022), <https://thefederalist.com/2022/03/18/in-its-first-year-bidens-hhs-relentlessly-attacked-christians-and-unborn-babies/> (listing the anti-religion and pro-abortion acts of the Biden-Becerra HHS).

²²² Rescission of the Regulation entitled “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority,” RIN 0945-AA18.

²²³ 86 Fed. Reg. 67,067 (Nov. 24, 2021) (Delegation of Authority); *see also* Letter from Lisa J. Pino, Director, Office for Civil Rights, to Xavier Becerra, Secretary, on Decision—Sign Delegation of Authority on the Religious Freedom Restoration Act and the Religion Clause of the First Amendment to the U.S. Constitution (Nov. XX, 2021), <https://www.lankford.senate.gov/imo/media/doc/HHS%20RFRA%20Memo.pdf>.

But OCR is the “department component” for this rule. Despite its withdrawn authority, HHS must explain whether OCR has RFRA and First Amendment authority to evaluate any violations and receive complaints under this OCR rule. In the proposed rule, the Agency must explain how it will fulfill its statutory duty to protect and enforce conscience protection laws within its 1557 regulations, while at the same time proposing to rescind the Conscience Rule giving effect to those protections.

D. Requiring third party health insurance issuers to cover medical interventions that violate conscience and religious rights of employers violates the First Amendment Free Exercise Clause and RFRA.

HHS is proposing to regulate third party insurers to include coverage of gender transition interventions and possibly elective abortions. To the extent that those third-party insurers are regulated, HHS should recognize the conscience and religious rights of those who are required to purchase insurance plans. HHS cannot use a third party to do what it could not do directly. In an ongoing case out of Washington State, the Ninth Circuit held that a church’s Free Exercise Clause claim to state law requiring health insurance providers provide plans with abortion coverage created a redressable injury in fact.²²⁴ Apart from violating the First Amendment, such a regulation of health insurance providers to coopt employers (in an attempted end-run of *Hobby Lobby*) would also violate RFRA as there is no compelling government interest in requiring employers with conscience and religious objections to pay for gender transition interventions and abortions, and there are many lesser restrictive means for the government to provide and pay for such services without using objecting employers’ insurance plans.

E. The Proposed Rule must recognize federal laws protecting conscience and religious freedom.

As explained above, HHS and OCR has gone out of its way to ignore and minimize any conscience and religious protections and instead attacks those who hold contrary views based on conscience or religious beliefs.

The Proposed Rule recognizes by name some federal conscience or religious freedom protection laws: RFRA, the Coats-Snowe Amendment, the Church Amendments, Section 1303 of the ACA, Section 1553 of the ACA, and the Weldon Amendment²²⁵ and explains that “OCR will apply such provisions consistent with law.”²²⁶ But in the regulations, proposed § 92.206(c) states: “Nothing in this section requires the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where the covered entity typically declines to provide the health service to any individual or where the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual. *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.*”²²⁷ This is religious hostility plain and simple and contradicts HHS’s obligations under various federal conscience and religious protection laws.

While recognizing certain federal conscience and religious protection laws exist, HHS fails to explain how those laws would interact with its clearly conflicting requirements under the proposed regulations. This approach does not ensure that all constitutional and statutory rights are protected, as the Department promises. The current regulations should be retained.

²²⁴ *Cedar Park Assembly of God of Kirkland, Washington v. Kreidler*, No. 20-35507 (9th Cir. Jul. 22, 2021).

²²⁵ 87 Fed. Reg. 47842.

²²⁶ 87 Fed. Reg. 47879.

²²⁷ 87 Fed. Reg. 47918 (emphasis added).

The Department also states that recognition of statutory rights must take into consideration “potential harms to third parties that may result from granting a religious exemption in the health care context,” which is particularly relevant under a RFRA analysis.²²⁸ But apart from RFRA, the other conscience and religious freedom protection laws create affirmative protections, separate and apart from any third-party harms.

F. The Church Amendments provide robust protection for sterilization procedures, including for gender transitions.

The Church Amendments, enacted in the 1970s, protect the conscience rights of individuals and entities that object to performing or assisting in the performance of abortion or sterilization procedures if doing so would be contrary to the provider’s religious beliefs or moral convictions.²²⁹ Since many of the gender transition treatments are sterilizing, such as genital surgeries, cross-sex hormones, and puberty blockers (especially when followed by cross-sex hormones), HHS must make clear that no provider will be required to provide such sterilizing treatments contrary to their religious beliefs or moral convictions.

G. HHS must apply RFRA to its regulations at the outset.

In proposing this Rule, HHS must analyze its regulatory action under the Religious Freedom Restoration Act (RFRA) and refrain from imposing a substantial burden on religious exercise absent a compelling interest imposed by the least restrictive means. The government does not have a compelling interest in forcing health care providers to end the life of another human being through abortion or assisted suicide, or to sterilize adults or minors, including through gender transition surgeries and hormones. As the Supreme Court made clear in *Fulton v. City of Philadelphia*, 141 S. Ct. 585 (2021), the government does not have a compelling interest in enforcing its nondiscrimination policies generally. Rather, any interest must reference the specific application of the requirements to those specifically affected. Indeed, the Court in *Fulton* stated: “so long as the government can achieve its interests in a manner that does not burden religion, it must do so.”

HHS states that “OCR would also consider the application of Federal conscience and religious freedom laws, where relevant.”²³⁰ But since HHS recently withdrew the delegation of authority from OCR to enforce RFRA,²³¹ any perfunctory statement that HHS will comply with and follow RFRA and other conscience protection laws is suspect. HHS must explain *specifically* how it intends to uphold its duty to enforce conscience and religious freedom protection laws in relation to its proposed regulations.

7. HHS cannot use Section 1557 to promote abortion and preempt state abortion laws.

A. Section 1557 does not prohibit discrimination based on pregnancy-related conditions.

HHS proposes that § 92.208 include a provision “to specifically address discrimination on the basis of pregnancy-related conditions.”²³² Under the Title IX proposed regulations, “Discrimination on the basis of sex” would include discrimination on the basis of “pregnancy or related conditions” which is defined in regulations as: “(1) Pregnancy, childbirth, termination of pregnancy, or lactation; (2) Medical conditions related to pregnancy, childbirth, termination of pregnancy, or lactation; or (3) Recovery from

²²⁸ 87 Fed. Reg. 47842.

²²⁹ 42 U.S.C. § 300a-7 *et seq.*

²³⁰ 87 Fed. Reg. 47867.

²³¹ 86 Fed. Reg. 67067.

²³² 87 Fed. Reg. 47878.

pregnancy, childbirth, termination of pregnancy, lactation, or their related medical conditions.”²³³ “Termination of pregnancy” is not defined in the proposed Title IX regulations. This definition of “pregnancy-related conditions” should not be adopted.

In *General Electric Co. v. Gilbert*, the Supreme Court held that Title VII’s sex discrimination prohibition did not extend to classifications based on pregnancy.²³⁴ In response, Congress passed the Pregnancy Discrimination Act in 1978 to explicitly state that discrimination because of sex includes discrimination “because of or on the basis of pregnancy, childbirth, or related medical conditions.”²³⁵ Congress also included an explicit exemption for health insurance benefits for abortion,²³⁶ once again demonstrating Congress chooses neutrality when it comes to abortion. Unless or until *Gilbert* is overruled, it is contrary to law for HHS to interpret discrimination based on sex to cover pregnancy and related conditions, when the Supreme Court has already ruled that it does not.

The Proposed Rule arbitrarily and capriciously fails to recognize the biological reality that only females can get pregnant and give birth—a reality that is recognized in the ACA itself.²³⁷ The Proposed Rule states that “transgender man or nonbinary person assigned female at birth” can give birth.²³⁸ No one is “assigned female at birth”; a person *is* (or is not) a female and that biological reality is recognized at birth. Second, men cannot get pregnant or give birth and to imply otherwise is insulting and degrading to women. HHS, as a federal health organization, should not continue perpetuating unscientific lies and misinformation when it comes to human reproduction. Proposed § 92.206(b) should not use the nonsense and unclear phrase “sex assigned at birth.” There is a more precise word that should be used: sex.

B. Section 1557 incorporates Title IX’s abortion neutrality provision.

The Proposed Rule states that it is “[t]he Department’s view is that Section 1557 does not require the Department to incorporate the language of Title IX’s abortion neutrality provision into its Section 1557 regulation.”²³⁹ This is incorrect.

Title IX contains an explicit abortion neutrality provision: Nothing in Title IX “shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion.”²⁴⁰ Thus, “the ground prohibited under” Title IX does not include “provid[ing] or pay[ing] for any benefit or service, including the use of facilities, related to an abortion.” Moreover, Section 1557 cites Title IX’s statutes as “20 U.S.C. 1681 *et seq.*,”²⁴¹ demonstrating that the entire Title IX scheme is supposed to be incorporated. To say otherwise, would be arbitrary and capricious and contrary to law.

It is arbitrary and capricious for HHS to rely on Title IX regulations to prohibit discrimination based on pregnancy-related conditions (and marital, parental, and family status), while ignoring and

²³³ 87 Fed. Reg. 41568.

²³⁴ 429 U.S. 125 (1976).

²³⁵ 42 U.S.C. § 2000e(k).

²³⁶ *Id.*

²³⁷ *See, e.g.*, ACA Section 2301 (“pregnant woman’s); Section 2951 (“a woman who is pregnant”); Section 1943 (“pregnant women”); Section 2303 (“pregnant women”); Section 2801 (“pregnant women”); Section 511 (“pregnant women”); Section 2952 (relative mental health consequences for women of resolving a pregnancy); Section 10213 (“pregnant and parenting women”); *see also* Section 3021 (“women’s unique health care needs”).

²³⁸ 87 Fed. Reg. 47865.

²³⁹ 87 Fed. Reg. 47879.

²⁴⁰ 20 U.S.C. § 1688.

²⁴¹ 42 U.S.C. § 18116 (emphasis added).

refusing to rely on Title IX’s statutory abortion neutrality provision and religious exemption. 45 CFR 92.6(b) should not be repealed.

C. HHS should clarify that Section 1557 does not prohibit discrimination based on termination of pregnancy or abortion.

The Department should consider the alternative of not including “termination of pregnancy” as a pregnancy-related condition or clarifying that “termination of pregnancy” does not cover abortion under 1557. Abortion is not the moral equivalent to pregnancy and childbirth and should not be treated as such. Further, if HHS finalizes a rule that promotes abortion, it must consider the irreparable loss of life to unborn who are killed via abortion as a result of abortion required or promoted by Proposed Rule.

D. After *Dobbs*, HHS has no compelling interest in promoting abortion.

HHS also seeks comment on “what impact, if any, the Supreme Court decision in *Dobbs v. Jackson Women’s Health Organization* has on the implementation of Section 1557 and these regulations.”²⁴² *Dobbs v. Jackson Women’s Health Organization* overruled *Roe v. Wade*, holding that there is no constitutional right to abortion.²⁴³ Post-*Dobbs* the Biden administration is seeking ways for the federal government to pay for and promote abortion,²⁴⁴ but *Dobbs* made clear that there is no federal constitutional right to abortion and no compelling government interest in promoting abortion. Considering the Proposed Rule does not mention abortion would be considered a pregnancy-related condition, it would be arbitrary and capricious and not a logical outgrowth for HHS to use 1557 regulations to promote abortion.

And as the *Dobbs* Court stated, “the ‘goal of preventing abortion’ does not constitute ‘invidiously discriminatory animus’ against women.”²⁴⁵ Thus, as *Dobbs* explained, “laws regulating or prohibiting abortion are not subject to heightened scrutiny. Rather, they are governed by the same standard of review as other health and safety measures.”²⁴⁶

E. Section 1557 cannot preempt state abortion laws.

We ask that HHS clarify whether it is the Department’s view that the proposed regulations could preempt a state abortion law. To the extent HHS would say its Section 1557 regulations would preempt certain state abortion laws, it must explain as such in a proposed rule and give states and the American public proper notice so that they can comment on the far-reaching implications of HHS’s regulations. The lack of discussion in the Proposed Rule about the application to abortion would make any final rule requiring preemption of state abortion laws arbitrary and capricious and not a logical outgrowth of the Proposed Rule. Preempting state abortion laws would raise a major question under *West Virginia v. EPA*. It is ludicrous to think that Section 1557, which promotes health care, all of a sudden preempts state laws protecting life. Abortion is not health care, and it is not discriminatory to not perform or provide an elective abortion.

²⁴² 87 Fed. Reg. 47879.

²⁴³ No. 19-1392 (U.S. Jun. 24, 2022).

²⁴⁴ Rachel N. Morrison, *The Biden Administration’s Post-Dobbs, Post-Roe Response*, FedSoc Blog (July 13, 2022), <https://fedsoc.org/commentary/fedsoc-blog/the-biden-administration-s-post-dobbs-post-roe-response>.

²⁴⁵ *Dobbs v. Jackson Women’s Health Organization*, NO. 597 U.S. (2022) at 11 (quoting *Bray v. Alexandria Women’s Health Clinic*, 506 U. S. 263, 273–274 (1993) (internal quotation marks omitted)).

²⁴⁶ *Id.*

F. HHS must recognize application of Section 1303 of the ACA.

The Proposed Rule cites Section 1303 of the ACA which contains special rules related to abortion but fails to elaborate on its implications. Under Section 1303, nothing in the ACA “shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor.”²⁴⁷ Thus, any suggestion that the Proposed Rule preempts state abortion laws is contrary to law.

Further, Section 1303 states:

Nothing in this Act shall be construed to have any effect on Federal laws regarding—

- (i) conscience protection;
- (ii) willingness or refusal to provide abortion; and
- (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.²⁴⁸

Thus, it would be contrary to law for HHS’s regulations to undercut federal conscience protections related to abortion. Regarding insurance coverage for abortion, states are allowed to opt-out of abortion coverage: “A State may elect to prohibit abortion coverage in qualified health plans offered through an Exchange in such State if such State enacts a law to provide for such prohibition.”²⁴⁹ Further, nothing in the ACA requires any qualified health plan to provide coverage of abortion services as part of its essential health benefits for any plan year.²⁵⁰

G. EMTALA does not require provision of elective abortions or preempt state abortion laws.

The Proposed Rule cites EMTALA obligations and a July 11, 2022, letter from CMS.²⁵¹ EMTALA requires hospitals to medically screen, stabilize, and appropriately transfer an individual with an “emergency medical condition,” defined as “a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman *or her unborn child*) in serious jeopardy, (ii) serious impairment to bodily functions, or (iii) serious dysfunction of any bodily organ or part.”²⁵² The EMTALA statute explicitly and repeatedly recognizes the unborn child. Indeed, “appropriate transfer” is defined as a transfer “in which the transferring hospital provides the medical treatment within its capacity which minimizes the risks to the individual’s health and, in the case of a woman in labor, *the health of the unborn child.*”²⁵³ By its own terms, EMTALA imposes a duty to save both mother and child.

CMS’s July 11 letter, which purportedly “does not contain new policy,” states (with emphasis): “*If a physician believes that a pregnant patient* presenting at an emergency department is experiencing an emergency medical condition as defined by EMTALA, and that abortion is the stabilizing treatment necessary to resolve that condition, the physician must provide that treatment. When a state law prohibits abortion and does not include an exception for the life and health of the pregnant person—or draws the

²⁴⁷ 42 U.S.C. § 18023(c)(1).

²⁴⁸ 42 U.S.C. § 18023(c)(2)(A).

²⁴⁹ 42 U.S.C. § 18023(a)(1).

²⁵⁰ 42 U.S.C. § 18023(b)(1)(A).

²⁵¹ 87 Fed. Reg. 47879.

²⁵² 42 U.S.C. § 1395dd(e)(1)(A) (emphasis added).

²⁵³ 42 U.S.C. § 1395dd(c)(2)(A) (emphasis added).

exception more narrowly than EMTALA’s emergency medical condition definition—that state law is preempted.”²⁵⁴

But no state abortion law prohibits a hospital from taking necessary steps to save a mother’s life or properly treat ectopic pregnancy or miscarriage. An abortion with the intended outcome of the death of the child is never necessary to save the life of the mother. Indeed, if a hospital performs an emergency abortion that results in the mother and child surviving, it is considered a failed abortion.

H. HHS should clarify telehealth nondiscrimination provisions do not apply to abortion.

HHS should clarify that proposed § 92.211 on nondiscrimination through telehealth services does not apply to prescribing abortion pills or referring for abortion.

8. The Proposed Rule would harm free speech.

A. The Proposed Rule raises First Amendment concerns.

Proposed § 92.8 requires training on the proposed nondiscrimination regulations, while proposed § 92.10 requires notices of nondiscrimination. Both requirements could raise concerns under the First amendment.

The Sixth Circuit recently found that a teacher who was disciplined for not using a student’s preferred title and pronouns was able to claim protection under the First Amendment.²⁵⁵ HHS should clarify that, under its proposed regulations, medical professionals retain free speech protections and it will not be considered discriminatory based on the sex to acknowledge a patient’s biological sex or to choose not to use a person’s preferred pronouns based on gender identity.

Further, HHS should clarify whether it would be discriminatory to use the word “woman” or say that “there are only males and females.” It is unclear whether such statements would be deemed discriminatory and whether signs or statements about, for example, “pregnant women” would be permitted under the Proposed Rule.

HHS should also clarify that its regulations do not prohibit talk therapy (sometimes mischaracterized as “conversion therapy”) as it relates to discussing issues of gender or sexuality with a patient.

B. No regulatory action should be taken on the issue of pronouns before the Supreme Court decision in *303 Creative*.

²⁵⁴ Reinforcement of EMTALA Obligations specific to Patients who are Pregnant or are Experiencing Pregnancy Loss (UPDATED JULY 2022). <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey/certificationgeninfo/policy-and-memos-states-and/reinforcement-emtala-obligations-specific-patients-who-are-pregnant-or-are-experiencing-pregnancy-0>.

²⁵⁵ *Meriwether v. Hartop*, 992 F.3d 492 (6th Cir. 2021) (reversing dismissal of First Amendment free speech and free exercise claims by professor disciplined by university for not following university’s gender identity nondiscrimination policy when he refused to address transgender identifying student by student’s preferred title and pronouns and instead used only student’s last name), *settled & voluntarily dismissed sub nom. Meriwether v. Trustees of Shawnee State Univ.*, No. 1:18-cv-00753 (S.D. Ohio Apr. 14, 2022), *press release available at* <https://adfmmedia.org/case/meriwether-v-trustees-shawnee-state-university> (university agreed to pay teacher \$400,000 plus attorneys’ fees, and agreed teacher has a right to choose when to use, or avoid using, titles or pronouns when referring to or addressing students, including when student requests preferred pronouns).

To the extent the Department believes 1557 applies to use of pronouns, HHS should hold this proposed rule until after the Supreme Court issues its decision in *303 Creative LLC v. Elenis* (U.S. No. 21-476). That case, which will be argued during the October 2022 term, involves the issue of government-compelled speech related to marriage and sexuality under the First Amendment. For HHS to act on the issue of pronouns prior to *303 Creative* is resolved by the Court would be arbitrary and capricious as that opinion could greatly impact analysis, application, and enforcement of Section 1557 as it relates to pronouns. As we saw with the 2020 1557 Rule and the Court's *Bostock* decision, publishing agency positions on an issue a short time period before the Supreme Court rules on an issue identified as being relevant can lead to legal vulnerability and potential invalidation. At a minimum, the public should have sufficient time to provide meaningful public comment on the issue of pronouns after the Supreme Court issues its decision in *303 Creative*.

9. HHS cannot use Section 1557 to protect marital, parental, or family status.

HHS proposes that § 92.208 will “provide that covered entities are prohibited from discriminating on the basis of sex in their health programs and activities with respect to an individual’s marital, parental, or family status.”²⁵⁶ The Department notes that the 2016 and 2020 Final Rules did not include a similar provision, which was for good reason. First, nowhere does Section 1557, or Title IX on which it is based, protect marital, parental, or familial status. When Congress wants to add those protected classes it knows how to do so, as it did with the Equal Credit Opportunity Act (ECOA)²⁵⁷ and the Fair Housing Act (FHA)²⁵⁸ which protect marital status and familial status respectively. Importantly, both ECOA and the FHA prohibit sex discrimination which would make the addition of marital and familial status mere surplusage. Additionally, HHS’s cavalier addition of these protected classes here would imply that suddenly, because they cover sex discrimination, ECOA now covers familial status and the FHA now covers marital status even though neither does so explicitly and have never been interpreted in that manner. Further, any such change would have to fully account for the additional costs, including the impact on religious liberty with respect to family and marital counseling by institutions and people of faith that may be covered by the expansive Proposed Rule.

10. The Proposed Rule conflicts with an injunction in *Franciscan Alliance v. Burwell*.

The Proposed Rule states: “We acknowledge that the *Franciscan Alliance* court vacated the challenged provisions of the 2016 rule and reasoned that the Department was required to incorporate the language of Title IX’s abortion neutrality provision; however, we disagree with that decision, which does not bind this new rulemaking.”²⁵⁹ HHS blatantly ignores the fact that on December 31, 2016, a federal district court in *Franciscan Alliance v. Burwell* entered a nationwide preliminary injunction against enforcement of the Section 1557 regulations in so far as they were purporting to prohibit discrimination based on “gender identity.”²⁶⁰ The court held that it would violate the Administrative Procedure Act to expand the scope of sex discrimination under Title IX to encompass gender identity.²⁶¹ Section 1557, of course, granted HHS explicit authority to prohibit “sex” discrimination in certain HHS funded programs. Yet an existing nationwide injunction *to this day* prevents HHS from reinterpreting sex discrimination to cover gender identity in the health care context.

²⁵⁶ 87 Fed. Reg. 47878.

²⁵⁷ 15 U.S.C. 1691 *et seq.*

²⁵⁸ 42 U.S.C. 3601 *et seq.*

²⁵⁹ 47 Fed. Reg. 47879.

²⁶⁰ 227 F. Supp. 3d 660, 695 (N.D. Tex. 2016).

²⁶¹ *Id.* at 689.

The Proposed Rule “disagrees” with *Franciscan Alliance*, citing *Bostock*.²⁶² As explained above, *Bostock* says nothing about Title IX or Section 1557 and was a narrow decision limited to the employment context (not the health care context where biological sex matters). Thus, HHS cannot rely on *Bostock* to ignore the injunction in *Franciscan Alliance*.

11. HHS must consider its Proposed Rule in conjunction with other laws.

Section 1554. The Proposed Rule violates Section 1554 of the Affordable Care Act, which provides: “the Secretary of Health and Human Services shall not promulgate any regulation that—

- (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
- (2) impedes timely access to health care services;
- (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
- (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
- (5) violates the principles of informed consent and the ethical standards of health care professionals;
- or
- (6) limits the availability of health care treatment for the full duration of a patient’s medical needs.”²⁶³

Specifically, the Rule would violate:

- (1), (2), and (6) by pressuring health care providers out of federally funded health programs and the practice of health care;
- (3) and (4) by requiring health care providers to speak contrary to their medical, ethical, and religious beliefs, such as by requiring affirmance of gender identity or abortion and prohibiting speech that is negative: towards gender transition or in accord with patient’s biological sex; and
- (5) by requiring health care providers to deprive patients of informed consent by preventing them from warning patients of the risks associated with abortion or gender transition surgeries, cross-sex hormones, and puberty blockers, and by forcing providers to violate moral and medical standards as health care professionals.

Civil Rights Restoration Act. The Civil Rights Restoration Act of 1987 (CRRRA) delineates the scope of coverage of several of the civil rights statutes that are incorporated into Section 1557.²⁶⁴ As discussed in the preamble to the 2020 Rule, with respect to scope of “program or activity,” the CRRRA made certain the above-mentioned statutes apply to the “all the operations” of certain federally funded entities but only if they are (as relevant here) “principally engaged in the business of providing ... health care.”²⁶⁵ That limitation should be fully respected and preserved as set forth in the 2020 Rule.

Family Policymaking Assessment. The Treasury and General Government Appropriations Act of 1999 requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect

²⁶² 47 Fed. Reg. 47858.

²⁶³ 42 U.S.C. § 18114.

²⁶⁴ Pub. Law 100–259, 102 Stat. 28 (Mar. 22, 1988).

²⁶⁵ 85 Fed. Reg. 37,160, 37,171.

family well-being.²⁶⁶ As explained above, this rule would negatively affect family well-being, requiring HHS to provide an assessment of the Proposed Rule.

RFRA and First Amendment. As, the Supreme Court in *Bostock* explained, it is “deeply concerned with preserving the promise of the free exercise of religion enshrined in our Constitution”—a “guarantee” that “lies at the heart of our pluralistic society.”²⁶⁷ It flagged three doctrines protecting religious liberty it thought relevant to claims of sex discrimination:

1. Title VII’s religious organization exemption, which allows religious organizations to employ individuals “of a particular religion”²⁶⁸;
2. 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’”²⁶⁹; and
3. The Religious Freedom Restoration Act (RFRA), which the Court described as a “super statute” that “might supersede Title VII’s commands in appropriate cases.”²⁷⁰

Because it is constitutionally and statutorily required and since HHS is relying on *Bostock* in the Proposed Rule, HHS should recognize the important protections for religious exercise under the First Amendment and RFRA.

Title VII. HHS must also consider its rule in connection with Title VII’s religious nondiscrimination and accommodation requirements. Employers cannot create a hostile work environment based on religion and are generally required to reasonably accommodate an employee’s sincerely held religious belief, observance, and practice. These protections are in addition to protections under the federal conscience protection laws discussed above.

12. Section 1557 generally excludes gender dysphoria from disability discrimination protections.

Section 1557 also prohibits discrimination of the “ground prohibited under” Section 794 of Title 2, which prohibits disability discrimination in federally funded programs or activities.²⁷¹ Not every disability qualifies for protection under Section 794. The DOJ and HHS have been pushing a theory in “guidance” and federal court that gender dysphoria qualifies as a protected disability. But section 794 (which mirrors Section 504 of the Rehabilitation Act) explicitly excludes gender dysphoria in most circumstances: “For purposes of [section 794], ... the term ‘individual with a disability’ does not include an individual on the basis of homosexuality or bisexuality[,] ... transvestism, transsexualism, pedophilia,

²⁶⁶ Pub. L. 105-277 (“(c) FAMILY POLICYMAKING ASSESSMENT.—Before implementing policies and regulations that may affect family well-being, each agency shall assess such actions with respect to whether—(1) the action strengthens or erodes the stability or safety of the family and, particularly, the marital commitment; (2) the action strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children; (3) the action helps the family perform its functions, or substitutes governmental activity for the function; (4) the action increases or decreases disposable income or poverty of families and children; (5) the proposed benefits of the action justify the financial impact on the family; (6) the action may be carried out by State or local government or by the family; and (7) the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society.”).

²⁶⁷ 140 S. Ct. at 1754.

²⁶⁸ 42 U.S.C. § 2000e-1(a). Title VII defines “religion” as “all aspects of religious observance and practice, as well as belief.” *Id.* § 2000e(j).

²⁶⁹ *Bostock*, 140 S. Ct. at 1754 (quoting *Hosanna-Tabor Evangelical Lutheran Church & Sch. v. EEOC*, 565 U.S. 171, 188 (2012)).

²⁷⁰ *Id.* (citing 42 U.S.C. § 2000bb-3).

²⁷¹ 29 U.S.C. § 794(a).

exhibitionism, voyeurism, *gender identity disorders not resulting from physical impairments*, or other sexual behavior disorders.”²⁷² Thus, gender dysphoria is not a protected disability unless it is the result of a physical impairment, which is generally not the case. Indeed, a federal district court judge recently called out and enjoined HHS’s March 2 guidance on the issue because “[b]y its terms, . . . 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.”²⁷³

Moreover, to the extent HHS is concerned about disability discrimination,²⁷⁴ OCR has in its possession a completed draft rule on disability discrimination left by the previous administration that it can propose at any time.

13. The Proposed Rule would disallow legitimate prohibitions on coverage for cosmetic surgery.

In the 2020 Section 1557 Rule, HHS clarified that it was not discriminatory for insurers to decline to cover surgeries that removed non-diseased tissue in people with gender dysphoria. This is because removal of healthy tissue to address psychological discomfort related to one’s appearance is the quintessential definition of cosmetic surgery, which is traditionally not covered by insurance, and certainly not as an *essential* health benefit. A significant number of women have persistent emotional and psychological distress because of their breast size, which helps explain why breast augmentation is the leading cosmetic surgery procedure in America.²⁷⁵ Regardless of the level of psychological relief felt, such surgeries are not generally covered by insurance. But breast reconstruction surgery after breast cancer is covered, even if a patient desires it primarily for psychological reasons. Why so? Because surgery is a *physical* intervention, and in the first case, there is no physical trauma or disease to treat, while in the second there clearly is. The same distinction applies to hair transplant surgeries in men. Male pattern baldness is not a disease that inhibits a bodily function. Hair loss causes intense and persistent psychological distress in some men such as to qualify as body dysmorphic disorder under the DSM V,²⁷⁶ yet hair transplant surgeries are generally not covered by insurance even under those circumstances.

It is thus incumbent on the agency to identify every other instance where it has required insurance coverage of surgical interventions to treat purely psychological distress related to the presence of healthy, non-diseased tissue. If the answer is that there are none other than those related to gender dysphoria, the agency must explain why that is. Why must insurers cover breast augmentation in a boy who identifies as a girl as opposed to a woman who is clinically obsessed with her smaller than average breast size and has suffered anxiety and avoided social situations for years as a result? The agency must explain why it considers the first an essential health benefit but the latter can only receive cognitive behavioral therapy and psychological treatment. It would be stunningly arbitrary and capricious for the agency to deem one, and only one, clinical body dysmorphia not only worthy of surgical coverage, but essential. And not only one surgery, but a variety of augmentations, tucks, reshaping, and inserts must be provided. Under the proposed regulation, a gender dysphoric man is not only entitled to be reshaped to look somewhat like a woman, he is entitled to be transformed into a facsimile of a lingerie supermodel if he desires. All he would need is a doctor to say his dysphoria symptoms persist to qualify for yet another surgery.²⁷⁷

²⁷² 29 U.S.C. § 705(20)(E)-(F) (emphasis added); *see also* 42 U.S.C. § 12211.

²⁷³ *Texas v. Equal Emp’t Opportunity Comm’n*, No. 2:21-cv-194, at *18 (N.D. Tex. Oct. 1, 2022).

²⁷⁴ 87 Fed. Reg. 47836.

²⁷⁵ American Society of Plastic Surgeons, *Plastic Surgery Statistics Report* (2018), <https://www.plasticsurgery.org/documents/News/Statistics/2018/plastic-surgery-statistics-full-report-2018.pdf>.

²⁷⁶ Diagnostic and Statistical Manual of Mental Disorders 5 at DSM-5 300.7 (F45.22), [https://www.theravive.com/therapedia/body-dysmorphic-disorder-dsm--5-300.7-\(f45.22\)](https://www.theravive.com/therapedia/body-dysmorphic-disorder-dsm--5-300.7-(f45.22)).

²⁷⁷ Relatedly, the regulation must make clear that prior authorizations for those insurers that voluntarily choose to cover gender dysphoria treatments are not discriminatory and are part of reasonable medical management practices.

14. The Proposed Rule would open up Pandora’s box for discriminatory insurance coverage claims based on sex and disability.

Under the Proposed Rule, not providing insurance coverage for medical interventions for gender transitions would be discrimination based on gender identity either because those same interventions are covered for other reasons or excluding coverage of certain interventions for transitioning is targeting individuals based on gender dysphoria, transgender status, or gender identity.²⁷⁸ But if this is the new discrimination standard for what medical interventions must be covered by insurance, it would open up Pandora’s box for a host of other claims on other protected bases. For example, if a biological male who identifies as a woman receives insurance coverage for breast augmentation, why can’t a biological female who identifies as a woman receive insurance coverage for breast augmentation? To deny the biological female insurance coverage while giving coverage to a biological male would be discrimination based on sex. It would also be discrimination based on gender identity for denying coverage to those whose gender identity corresponds to their biological sex.

Under the insurance coverage discrimination theory of the Proposed Rule, insurance coverage would have to extend to cover medical interventions based on a qualifying disability. This too would open Pandora’s box as far as the types and number of medical interventions that would now have to be covered.

HHS must calculate the increased costs associated with insurance coverage based on sex and disability or explain why, in its view, insurance coverage under the Proposed Rule should not be extended to these other types of claims.

15. HHS should not adopt the CMS insurance regulations.

We applaud the Department for not issuing its insurance regulations proposed by HHS’s Centers for Medicare & Medicaid Services (CMS) in the January 2022 Section 1557 rule that implicated discrimination based on sexual orientation and gender identity.²⁷⁹ While disclaiming reliance on Section 1557, the nondiscrimination requirements for insurance coverage and plans proposed in the CMS rule clearly overlapped with Section 1557’s requirements for nondiscrimination in insurance coverage and plans. The Proposed Rules states that “the Department will consider all comments previously submitted regarding these proposals in issuing its final rule.”²⁸⁰ For your reference, we have attached our comments submitted in opposition to those proposals.²⁸¹ To the extent that the arguments in that comment apply to proposed insurance requirements under Section 1557, we incorporate those comments to the proposed regulations under Section 1557.

16. The Rule must be considered in conjunction with other proposed regulations affecting the scope of nondiscrimination provisions in healthcare.

There are currently several proposed rules (at various stages) that implicate nondiscrimination provisions in health care, and that should be jointly considered as a common rule with the Proposed 1557 Rule. Most obviously, since Section 1557 incorporates Title IX’s prohibition against sex discrimination,

²⁷⁸ 87 Fed. Reg. 47865-69.

²⁷⁹ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, CMS-9911-P, RIN 0938-AU65; see <https://eppc.org/publication/eppc-scholars-submit-public-comment-opposing-hhs-proposed-insurance-mandate-for-transgender-puberty-blocking-drugs-cross-sex-hormones-and-surgeries/>.

²⁸⁰ 87 Fed. Reg. 47890.

²⁸¹ Also available here: <https://eppc.org/wp-content/uploads/2022/01/EPPC-Scholars-Comment-Opposing-SOGI-Insurance-Mandate.pdf>.

the Proposed Rule should be joined with the Department of Education’s recently proposed Title IX regulations.²⁸² Both rules concern the scope of sex discrimination prohibitions under Title IX, and Title IX and Section 1557 have significant overlap concerning their application to educational institutions that receive health funding. How ED defines the ground of sex discrimination under Title IX in its proposed regulations could have direct impact for Section 1557, its regulations, and the health care context.²⁸³ It would be arbitrary and capricious for the federal government to interpret and enforce Title IX’s sex discrimination prohibition differently under different agencies.

ED is also proposed to change the scope of application of the religious exemption in Title IX. This “Free Inquiry Rule” is currently pending at OIRA.²⁸⁴ Because Section 1557 includes application of Title IX’s religious exemption, that rule should be considered jointly with ED’s proposed Title IX regulations and HHS’s Proposed 1557 Rule.

As the Proposed Rule will have implications for conscience and religious freedom rights, especially if HHS refuses to recognize Title IX’s religious exemption for religious organizations, the Proposed Rule should also be considered jointly with HHS’s proposed rescission of the 2019 Conscience Rule, which could impact the conscience and religious freedom protections recognized and enforced by the Department, including in relation to Section 1557 claims.²⁸⁵

Under Executive Order 12250, the Department of Justice is required to coordinate the implementation of any regulations implementing nondiscrimination provisions of Title IX or of “[a]ny other provision of Federal statutory law which provides, in whole or in part, that no person in the United States shall, on the ground of sex, be excluded from participation in, be denied the benefits of, or be subject to discrimination under any program or activity receiving Federal financial assistance.” Inconsistency in implementation of discrimination on the basis of sex across programs or agencies, such as between ED and HHS, could lead to legal vulnerability.

In particular, an overly simplistic legal justification for imposing nondiscrimination on the basis of sexual orientation and gender identity across different statutes that have different wording, such as Title IX and Title VII, and across different kinds of programs such as non-health programs through the Department of Education, or health programs through HHS, could lead to legal vulnerability of all of those provisions. Only through coordination by the Department of Justice and joint common rules across agencies can the administration as a whole consider the proper interpretation and application of the principles of nondiscrimination.

At a minimum, the Agency must evaluate this Proposed Rule in light of those other proposed rules that will have a direct impact on the scope of nondiscrimination provisions in health care.

²⁸² Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance, RIN 1870-AA16.

²⁸³ See <https://eppc.org/wp-content/uploads/2022/03/EPPC-Scholars-Comment-Title-IX-Rule-EO-12866-Meeting.pdf>.

²⁸⁴ Religious Liberty and Free Inquiry Rule, RIN 1840-AD72, *see* <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=1840-AD72>.

²⁸⁵ Rescission of the Regulation entitled “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority,” RIN 0945-AA18; *see* <https://eppc.org/wp-content/uploads/2022/04/EPPC-Scholars-Comments-for-EO-12866-Meeting-on-Proposed-Rescission-of-Conscience-Rule.pdf>.

17. The Proposed Rule’s purported preemption of state laws is contrary to law.

The Proposed Rule states that “The Department has concluded that the proposed regulation has Federalism implications but preempts State law only where the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.”²⁸⁶ Specifically, “State laws continue to be enforceable, unless they prevent application of the proposed rule.”²⁸⁷

While we agree state laws do not alleviate a recipient’s burden to comply with Section 1557 regulations to receive federal funding, Section 1557 regulations cannot preempt inconsistent or conflicting state laws. Section 1557 imposes strings on the receipt of federal funding. To the extent that a health institution is unable to follow Section 1557 regulations due to oversight, choice, or a conflicting state law requirement, it would be unable to comply with the strings attached to receipt of federal funding. The appropriate response from HHS is disallowance of federal funding. HHS does not have the power under Section 1557 to preempt state laws. To the extent HHS’s proposed regulations purport to preempt state law, they are contrary to law. The Department should also wait to finalize this Rule until the Supreme Court issues a decision in the October 2022 term case *Health and Hospital Corporation of Marion County, Indiana v. Talevski*, which involves the scope of authority under Spending Clause legislation.²⁸⁸

The Proposed Rule also states 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.”²⁸⁹ State laws that ensure girls and women have access to sex-specific private spaces free from biological males, regardless of gender identity, provide greater protection to females. Similarly, several states have laws that protect minors from harmful, sterilizing, and irreversible gender transition drugs and surgeries. To the extent the Proposed Rule would preempt or conflict with these protective state laws, it is arbitrary and capricious because these state laws provide greater protection to patients.

18. The Proposed Rule must address its federalism implications.

EO 13132 from the Clinton Administration establishes certain requirements that an agency must meet when it issues a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Section 3(c) of the EO states that “with respect to Federal statutes and regulations administered by the States, the national government shall grant the States the maximum administrative discretion possible.” Section 3(d) explains how to implement policies that have federalism implications. Specifically, agencies “shall” (1) “encourage States to develop their own policies to achieve program objectives and to work with appropriate officials in other States,” (2) “where possible, defer to the States to establish standards,” and (3)/(4) consult with States and officials. Executive Order 12866 (§ 6(a)(3)(B)) also directs that significant regulatory actions avoid undue interference with State, local, or tribal governments, in the exercise of their governmental functions.

The Proposed Rule acknowledges that it will have federalism implications.²⁹⁰ It will impact state hospitals, medical facilities, and insurance plans. In addition, it will conflict with and purports to preempt state and local laws regulating coverage and provision of gender transition services, especially for minors.

²⁸⁶ 87 Fed. Reg. 47907.

²⁸⁷ 87 Fed. Reg. 47907.

²⁸⁸ No. 21-806 (U.S.).

²⁸⁹ 87 Fed. Reg. 47907.

²⁹⁰ 87 Fed. Reg. 47907.

For example, Alabama, Arizona, Arkansas, and Tennessee have all passed laws protecting children from harmful and irreversible gender transition treatments.²⁹¹

In April 2022, Florida’s Department of Health issued guidelines clarifying that the treatment of gender dysphoria for children and adolescents should not include social gender transition, puberty blockers, cross-sex hormones, or sex reassignment surgeries based on “the lack of conclusive evidence, and the potential for long-term, irreversible effects.”²⁹² In February 2022, the Texas Attorney General issued an opinion letter stating sterilizing and other permanent “sex-change procedures” “can constitute child abuse when performed on minor children,” including —“(1) sterilization through castration, vasectomy, hysterectomy, oophorectomy, metoidioplasty, orchiectomy, penectomy, phalloplasty, and vaginoplasty; (2) mastectomies; and (3) removing from children otherwise healthy or non-diseased body part or tissue.”²⁹³ HHS has already indicated in a March 2 guidance that it disagrees with this determination and will use Section 1557 to invalidate state action.²⁹⁴ But a federal district court just enjoined that guidance as being “arbitrary and capricious” and “unlawful.”²⁹⁵

In addition, overriding state laws concerning nondiscrimination in health and using a novel interpretation of Title IX and Section 1557 to override those laws risks a coercive impact under *NFIB v Sebelius*.²⁹⁶ When states agreed to accept federal funding under health programs and activities, they were only aware of the text of Title IX prohibiting sex discrimination and specifically in the statute using language showing a male and female binary application of sex. Consequently, implementing sexual orientation and gender identity nondiscrimination through Section 1557 can only be binding on states’ acceptance of federal financial assistance if states had clear notice under *Pennhurst State School and Hospital v. Halderman*²⁹⁷ that they were accepting that condition by the plain meaning of the text of the statute. They had no such notice.

All these federalism impacts must be addressed, and HHS must consult with states before issuing a rule that imposes a substantial cost and impact on them.

19. HHS’s expansion of federal financial assistance is arbitrary and capricious and contrary to law.

Despite the absence of direction in the ACA to redefine long-standing definitions of federal financial assistance, proposed § 92.2 would expand Section 1557 application to “(1) every health program or activity, any part of which receives Federal financial assistance, directly or indirectly, from the Department; (2) every health program or activity administered by the Department; and (3) every program or activity administered by a Title I entity.”²⁹⁸ HHS also proposes to apply Section 1557 regulations to

²⁹¹ See Ala. S.B. 184 (2022); Ariz. S.B. 1138 (2022); Ark. H.B. 1570 (2021); Tenn. H.B. 0578 (2021).

²⁹² Office of the State Surgeon Gen., Fla. Dep’t of Health, Treatment of Gender Dysphoria for Children and Adolescents (Apr. 20, 2022), <https://www.floridahealth.gov/documents/newsroom/press-releases/2022/04/20220420-gender-dysphoria-guidance.pdf>.

²⁹³ Tex. Att’y Gen. Op. Letter No. KP-0401, from Ken Paxton, Attorney General, to Matt Krause, Chair, House Committee on General Investigating, Texas House of Representatives 1–2 (Feb. 18, 2022), <https://www.texasattorneygeneral.gov/sites/default/files/opinion-files/opinion/2022/kp-0401.pdf>.

²⁹⁴ Press Statement, U.S. Dep’t Health & Hum. Servs., Statement by HHS Secretary Xavier Becerra Reaffirming HHS Support and Protection for LGBTQI+ Children and Youth (Mar. 2, 2022), <https://www.hhs.gov/about/news/2022/03/02/statement-hhs-secretary-xavier-becerra-reaffirming-hhs-support-and-protection-for-lgbtqi-children-and-youth.html>.

²⁹⁵ *Texas v. Equal Emp’t Opportunity Comm’n*, No. 2:21-cv-194, at *32 (N.D. Tex. Oct. 1, 2022).

²⁹⁶ 567 U.S. 519 (2012).

²⁹⁷ 465 U.S. 89 (1984).

²⁹⁸ 87 Fed. Reg. 47838.

include health insurance²⁹⁹ and Medicare Part B payments.³⁰⁰ “The Department’s longstanding position has been that Medicare Part B funding does not constitute Federal financial assistance for the purpose of Title VI, Title IX, Section 504, the Age Act, and Section 1557.”³⁰¹ HHS fails to demonstrate a need to make this change, as well as account for the costs associated with providers no longer accepting Medicare Part B funds to avoid the strings of this regulation.

As stated earlier, the CRRA limits the application of the program or activities. This proposed change would radically expand the notion of Federal financial assistance to ultimate beneficiaries of the funding which would have significant effects on other civil rights laws dealing with funding including Title VI, Title IX, and others. At a minimum HHS must calculate how many other covered entities the Proposed Rule would now cover and the additional costs and benefits of such a radical change. To fail to do so would be arbitrary and capricious.

20. HHS should clarify that tax-exempt status is not federal financial assistance, subjecting an institution to Title IX or 1557 liability.

Recently, two district courts have held that a private school which is tax exempt, and did not otherwise receive federal financial assistance, was nevertheless receiving federal financial assistance based on its tax-exempt status and thus subject to Title IX.³⁰² This is absurd. Under these strained rulings, any organization that Congress does not choose to tax could be subject to all federal spending legislation. HHS should clarify that tax-exempt status is not “federal financial assistance” under Title IX.

21. The Proposed Rule must include a meaningful economic analysis and consider its costs.

The Proposed Rule specifically mentions “gender affirming surgery” and “hormone therapy”³⁰³ as example of services that have not been covered, but HHS does not provide a comprehensive list of what services and treatments it considers “medically necessary care, including gender-affirming care.”³⁰⁴ HHS must provide a list of such procedures to provide clarity and ensure coverage. Not doing so is capricious.

In October 2021, HHS approved Colorado’s EHB benchmark plan to require coverage for “gender affirming” services and the proposed rule cited Colorado’s EHB-benchmark plan as an example of a plan that is in compliance with the updated nondiscrimination policies. 87 Fed. Reg. at 707. CMS’s press release praising Colorado’s new EHB benchmark plan claimed: “Gender-affirming care is considered a standard level of care by the American Medical Association, the American Academy of Family Physicians, the American Academy of Pediatrics, and the American Psychiatric Association.”³⁰⁵ But what is considered “gender-affirming care”?

²⁹⁹ 87 Fed. Reg. 47829.

³⁰⁰ 87 Fed. Reg. 47828.

³⁰¹ 87 Fed. Reg. 47887.

³⁰² *E.H. v. Valley Christian Acad.*, 2:21-cv-07574-MEMF, 10 (C.D. Cal. Jul. 25, 2022) (“Accordingly, the Court holds that Valley Christian’s tax-exempt status confers a federal financial benefit that obligates compliance with Title IX.”); *Buettner-hartsoe v. Balt. Lutheran High Sch. Ass’n*, No. RDB-20-3229, 6 (D. Md. Jul. 21, 2022) (“The tax-exempt status of a private school subjects it to the same requirements of Title IX imposed on any educational institution. CPS cannot avail itself of federal tax exemption but not adhere to the mandates of Title IX.”).

³⁰³ 87 Fed. Reg. 47834.

³⁰⁴ 87 Fed. Reg. 47828.

³⁰⁵ Press Release, CMS, Biden-Harris Administration Greenlights Coverage of LGBTQ+ Care as an Essential Health Benefit in Colorado (Oct. 12, 2021), <https://www.cms.gov/newsroom/press-releases/biden-harris-administration-greenlights-coverage-lgbtq-care-essential-health-benefit-colorado>.

The Colorado EHB plan notes that “[s]urgical services and hormone therapy for medically necessary gender-affirming care are EHB under this EHB-benchmark plan,” and thus the plan design covers the following “gender-affirming” interventions, “at a minimum”:

1. Blepharoplasty (eye and lid modification)
2. Face/forehead and/or neck tightening
3. Facial bone remodeling for facial feminization
4. Genioplasty (chin width reduction)
5. Rhytidectomy (cheek, chin, and neck)
6. Cheek, chin, and nose implants
7. Lip lift/augmentation
8. Mandibular angle augmentation/creation/reduction (jaw)
9. Orbital recontouring
10. Rhinoplasty (nose reshaping)
11. Laser or electrolysis hair removal
12. Breast/chest augmentation, reduction, construction³⁰⁶

Colorado states that this list is the “minimum.” But are all these procedures considered “medically necessary gender-affirming care” and by whom? Will the proposed addition of “gender identity” to the various ACA nondiscrimination provisions require coverage of all twelve of these procedures or only some, and if so which ones? Are there any additional procedures or treatments that HHS will consider “medically necessary gender-affirming” care under the Proposed Rule?

Plan issuers, states, and the insured need to know the answers to these questions. Otherwise the HHS’s requirements are not only vague and unknown, but also arbitrary and capricious.

Costs. HHS agrees that its proposed rule is economically significant.³⁰⁷ As part of its regulatory impact and economic analysis of the costs, benefits, and transfers, the Rule should take into consideration the following key inputs:

Costs of Coverage of Gender Transition and “Detransition” Services

- Which services, procedures, treatments, drugs, surgeries, etc. will be required to be covered by insurance or provided by health care professionals.
- Whether coverage includes services for those who wish to “detransition” according to their gender identity “realigning” with their biological sex.
- How many issuers and plans already cover these procedures.
- How many individuals will seek health insurance coverage of “gender affirming” procedures.
- The number of gender transition or “detransition” surgeries/treatments expected to be covered by insurance
- The cost of each gender transition or “detransition” service to be covered.³⁰⁸
- The costs of any follow-up/complications.
- The number of people covered and their ages, and whether it includes minor children.

³⁰⁶ COLORADO BENEFITS FOR HEALTH CARE COVERAGE 38, <https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb> (listing covered “Gender Affirming Care”).

³⁰⁷ 87 Fed. Reg. 47898.

³⁰⁸ See, e.g., Dr. Shayne Taylor, *Convinced Nashville To Get Into The Gender Transition Game*, YouTube, <https://www.youtube.com/watch?v=xoTLMY8No6M> (stating chest reconstruction surgery costs \$40,000, routine hormone treatment costs several thousand dollars, vaginoplasty surgery costs more than \$20,000 (without cost for hospital stay, post-operative care visits, and anesthesia), and female-to-male “bottom surgery” can cost up to \$100,000).

- The increase in premium costs to cover such services.
- The number and qualifications of doctors that are willing to perform such services, especially on minor children.

Harm to Health Care Profession

- Whether doctors will be required, despite their best medical judgment, to perform “gender-affirming” surgeries and prescribe puberty blockers and cross-sex hormones, including for minor children.
- The cost to the health care profession by requiring professionals to violate the Hippocratic Oath, which requires they “do no harm” and refrain from participating in abortion.
- The resulting lack of trust in public health care and health care professionals who do not share a patient’s values.
- The number of people that will choose not to enter the health care profession as a result of the rule.
- The government’s interest is in supporting and enable existing and new medical professionals to care for their patients by not driving them out of the profession.

Harm to Conscience and Religious Freedom Rights

- The impact on reliance interests by health care professionals.
- The irreparable loss of conscience and religious freedom rights of health care professionals and religiously affiliated institutions.
- The increase in discrimination and marginalization, especially for those with minority religious viewpoints.
- The costs to health care professionals who are unable to vindicate their conscience and religious freedom rights since many federal conscience protection laws lack a private cause of action (if HHS does not enforce the laws, no one can).
- How HHS will otherwise ensure compliance with its mandatory duty to enforce the 25 conscience and religious freedom laws.
- The compounding harms of removing conscience protections while at the same time mandating performance of procedures that violate the conscience of health care professionals.
- The government’s lack of countervailing interest in coercing medical professional to participate in procedures that violate their conscience or religious beliefs.

Harm to Free Speech Rights and Doctor-Patient Relationship

- Whether preferred pronouns will be required.
- Whether coerced pronoun usage creates a chilling effect or leads to the irreparable loss of First Amendment Free Speech rights.
- The harms of requiring health care professionals and doctors to use language that does not reflect science.
- The creation of a hostile work environment for religious professionals that have different views on gender or sexuality.
- The harm of interfering with the doctor-patient relationship.

Cost of Driving Out Health Care Professionals and Faith-Based Health Care Institutions

- The number of health care professionals or faith-based health care institutions that will stop providing certain categories of services or treatments, such as obstetrics and gynecology, if abortion is required.

- The demographics of health care professionals that will stop providing certain categories of services or treatments, and the impact that will have on patients who can no longer find a provider from their community.
- The number of health care professionals that will leave the profession altogether.
- The burdens losing additional staff will cause for health care systems that are already suffering and understaffed after the COVID pandemic.

Loss of Access to Health Care

- The number of patients that will lose their provider of choice and will be less likely to seek or receive timely care.
- The overall impact on public health and access to health care services.
- The impact on health equity for those groups the Proposed Rule purports to help.
- The impact on health care facilities, especially in rural and low-income areas.
- The number of additional health care professionals that will leave the profession with those increased burdens.
- The number of patients that will lose access to care.

Economic Harm

- The economic losses, as well as unemployment payments, as a result of health care professionals leaving the profession.
- The impact on labor shortages, especially in health care.
- The amount health care and insurance expenses will increase due to decreased supply.
- The impact on other HHS-funded programs, such as Medicare, Medicaid, and Global Health Programs.
- The specific costs on poor, rural, and underserved communities due to shortages or lack of medical providers in those communities.
- The cost of perpetuating health care disparities and inequities.
- Increased insurance costs if categorical exclusions of care are now prohibited.
- Increased costs for the government, practitioners, and insurers associated with specifying every particular biological characteristic or system affected by being deprived to use “male” or “female” as a distinguishing factor.
- Increased costs associated with updating research studies, medical charts and forms, health databases, etc. to distinguish between gender identity and any relevant biological factors normally attributed to biological sex.
- The harms of gender identity interfere with the practice of medicine, research, and diagnoses when there is no single distinguishing biological feature. For example, it is well known that biological women have higher rates of anorexia than biological men, while biological men have higher rates of autism than biological women. But we anticipate under the proposed rule all patients and research subjects must be treated according to gender identity in all respects, which suggests that biological men that identify as women must be included in any study of women and anorexia, thereby skewing the results. The converse is true with women identify as men in studies of autism and males.

Baseline for Analysis

- The baseline for analysis must be the 2022 reality of a post-COVID pandemic health care landscape. Pre-pandemic numbers won’t accurately reflect the strain on the health care community from professionals to institutions.
- HHS must analyze the benefits of each proposed protected category of sex discrimination separately, rather than in the aggregate. It cannot group together any benefits associated with

adding gender identity to those with adding sexual orientation or sex characteristics, and vice versa.

Effective Date

- The impact of the effective date of the rule as is contemplated by the Proposed Rule,³⁰⁹ especially if the date is after benefit plans designs have already been determined or approved, but before the next plan year.
- The benefits of delaying the effective date of the rule to correspond with the next plan year, such as avoiding significant costs associated with last-minute changes.

All of these things, and more, must be taken into consideration, and quantified or estimated to the maximum extent possible for a sufficient analysis of impact, costs, benefits, and transfers.

Alternatives. In addition to the numerous costs of the Rule, HHS must fully consider alternatives, including not regulating, and provide a reasoned explanation of why its proposal is better than those alternatives. The best alternative we urge the Department to adopt is to not act without Congressional action. Any updates to the scope of Section 1557 (and Title IX) should be done legislatively, not through agency action. Other alternatives the Agency must consider and evaluate are:

- Issuing similar regulations to the 2020 Rule.
- Modifying the 2020 regulations.
- Rescinding only portions of the 2020 Rule, while leaving other portions in place.
- Delaying implementation of the insurance portions of the proposed rule for two plan years to give insurance providers time to adjust their plans, especially if the rule is published in the federal register before a plan year, but after benefit plans designs have already been determined or approved.
- Waiting until after Department of ED publishes its Title IX regulations since Section 1557 incorporated Title IX and HHS is relying on Title IX regulations for several of its proposals.
- Waiting until after the *303 Creative* decision is issued by the Supreme Court to make its proposal.

Joint rulemaking. HHS should also consider the Proposed Rule jointly with ED's proposed Title IX rule and the pending Free Inquiry Rule, which would change the scope of Title IX's religious exemption. Both the Title IX and Section 1557 rules concern interpretation of Title IX's application to sexual orientation and gender identity, and Title IX and Section 1557 have significant overlap concerning their application to educational institutions that receive health funding. How ED defines the ground of sex discrimination under Title IX in its proposed regulations could have direct impact for Section 1557, its regulations, and the health care context. Inconsistency in implementation of discrimination on the basis of sex across agencies and across programs, such as Title IX and Section 1557, could lead to legal vulnerability and make the varying interpretations arbitrary and capricious.

Under Executive Order 12250, the Department of Justice is required to coordinate the implementation of any regulations implementing nondiscrimination provisions of Title IX or of "[a]ny other provision of Federal statutory law which provides, in whole or in part, that no person in the United States shall, on the ground of sex, be excluded from participation in, be denied the benefits of, or be subject to discrimination under any program or activity receiving Federal financial assistance." Only

³⁰⁹ 87 Fed. Reg. 47837 ("This section provides an exception to the start date for provisions of this part that require changes to health insurance or group health plan benefit design. Such provisions will have a delayed implementation date of the first day of the first plan year (in the individual market, policy year) beginning on or after the year immediately following the effective date of the Final Rule in the Federal Register.").

through coordination by DOJ and joint common rules across agencies can the administration as a whole consider the proper interpretation and application of the principles of nondiscrimination.

Conclusion

We urge HHS to abandon and withdraw the Proposed Rule.

Sincerely,

/s

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