The Honorable Xavier Becerra
Secretary of Health and Human Services
Department of Health and Human Services.
200 Independence Ave SW, Washington, DC 20201
Via https://www.federalregister.gov
October 3, 2022

Reference (RIN): 0945-AA17 Docket ID: HHS-OS-2022-0012 Document Number: 2022-16217

Dear Secretary Becerra,

Introduction

This correspondence is submitted in response to the Health and Human Services' request for comments on the Notice of Proposed Rulemaking "Nondiscrimination in Health Programs and Activities" published by your department in the Federal Register on August 4, 2022. This rule addresses Section 1557 of the Affordable Care Act (ACA) which is enforced by the Office for Civil Rights (OCR) and the Centers for Medicare and Medicaid Services. Section 1557 prohibits discrimination on the basis of race, color, national origin, age, disability, and sex in covered health programs or activities.¹

Furthermore, Section 1557 of the Affordable Care Act states:

[A]n individual shall not, on the ground prohibited under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or Section 794 of Title 29, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this Title 1 (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.²

In short, Section 1557 ensures that no individual can be denied benefits in a federally funded health program or activity based on race, color, national origin, sex, age, or disability.

These protections have ensured that American's receive the assistance that they need, free of undue discrimination, based on clearly defined and commonly held descriptions of the human condition. Now, however, under the department's proposed rules, sex is redefined to include "discrimination on the basis of sex [that] includes, but is not limited to, discrimination on the

¹ 42 U.S.C. 18116

² 42 U.S.C. § 18116(a)

basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity."³

As passed by Congress, Section 1557 of the ACA does not create special privileges for new classes of people. Nor does it require insurers and physicians to cover or provide specific procedures or treatments. We are concerned that under new rulemaking, the Department would interpret Section 1557 as if it does create special privileges for new classes of people, defined in ways that are highly controversial and not empirically discernible.⁴

With this revision, the Department of Health and Human Services, in conjunction with the Office of Civil Rights and Centers for Medicare and Medicaid Services, is rewriting the federal definition of sex, pregnancy and abortion in healthcare and for health insurance providers. We are writing in strong opposition to this proposed rule.

Sexual Orientation and Gender Identity

The comment period for the Department of Education's proposed Title IX rule concluded on September 12. The Heritage Foundation submitted a number of comments in response to this rule. Given the abnormally high response rate in opposition to the department's plan, many are still waiting on the response to their comments. More importantly, no final rule has been released yet concerning Title IX's redefinition of sex, pregnancy, and abortion.

Since the proposed Title IX regulations redefine discrimination "on the basis of sex" to include "sex stereotypes, sex characteristics, pregnancy or related conditions, sexual orientation, and gender identity" in federally funded education programs and activities, it is worth noting that this proposed rule has not been finalized nor implemented.⁵

Nonetheless, the department alleges that because "Title VII and Title IX's prohibitions against sex discrimination are similar, Bostock's reasoning 'applies to Title IX, and, by extension, to Section 1557.' Thus, Section 1557 also prohibits discrimination based on 'sexual orientation and gender identity.'"⁶

As we will see, however, this is an incorrect reading of the Bostock decision and thereby removes the main precedent HHS provides for its redefinition of sex, pregnancy, and abortion. Moreover, Title IX's own proposed rule lies upon this faulty reading of Bostock, and its final rule has yet to be released.

The Bostock Supreme Court Case Ruling

³ 87 Federal Register 47824

⁴ 80 Federal Register 54218 (proposed September 8, 2015).

⁵ 87 Federal Register 41390

⁶ Rachel N. Morrison, "HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate in Health Care," The Federalist Society, September 8, 2022. https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-in-health-care-1

The Department's proposal to expand sex discrimination is based upon an erroneous application of the Bostock ruling and a failure to protect doctors and patients alike from compelled speech and action. In what seems to be an ideologically motivated move, the Department also fails to acknowledge the controversy surrounding and the harms caused by so-called gender transition. Instead of providing clarity, the Department muddies the waters by simultaneously failing to define sex while expanding its meaning to include non-observable subjective preferences that obscure in regulation the sexual difference that is the basis for Title IX itself. All people deserve to be treated with dignity and respect. Contrary to its express goal, this proposed rule would greatly multiply discrimination and harm within federally funded educational programs and activities and beyond.

The Department cites the Supreme Court's decision in *Bostock v. Clayton County* as justification for its expansion of sex discrimination to include sexual orientation, gender identity, and other categories. As we have argued before, the administration's application of *Bostock*, which exclusively focused on employment discrimination, to Title IX is erroneous.

In *Bostock v. Clayton County*, the Supreme Court's ruling proceeded "on the assumption that 'sex' signified what the employers suggest, referring only to biological distinctions between male and female." The ruling dealt with discrimination on the basis of sex in matters of employment according to Title VII of the Civil Rights Act. It did not redefine sex to include gender identity and sexual orientation. It also did not apply its ruling to any other part of the Civil Rights Act beyond Title VII.

Notably, the Bostock court used the term "transgender status" *not* "sexual orientation and gender identity," as HHS erroneously posits. Bostock is limited to employment nondiscrimination and "did not adopt gender identity as a protected basis."

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

The employers worry that our decision will sweep beyond Title VII to other federal or state laws that prohibit sex discrimination. And, under Title VII itself, they say sex-segregated bathrooms, locker rooms, and dress codes will prove unsustainable after our decision today.

But none of these other laws are before us; we have not had the benefit of adversarial testing about the meaning of their terms, and we do not prejudge any such question today.

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

⁷ Bostock v. Clayton County 590 U.S., 140 S. Ct. 1731 (2020)

⁸ Morrison, "HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate in Health Care." https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-in-health-care-1

simply for being homosexual or transgender has discharged or otherwise discriminated against that individual 'because of such individual's sex.'

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

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

Reasonable judgments about biology are not "discriminatory"

Many people reasonably believe that maleness and femaleness are objective, biological realities that are integral to who we are as human beings. On the basis of religious teachings, moral reasoning, scientific evidence, and medical experience, many have strong grounds to hold that one's sex is an immutable characteristic that should be respected, not rejected or treated as a disease. Accordingly, many involved in providing medical care and those enrolled in health insurance plans have serious objections to participating in or paying for sex-reassignment surgeries or gender transitions. Yet the regulations would label these kinds of reasonable beliefs as "discriminatory" and seek to forbid them from being followed in the coverage or provision of health care services.

Gender identity and sexual orientation, unlike race or sex, can vary, are self-reported, and entirely self-defined characteristics independent of the body. Government should not grant special privileges on such bases when legal recognition of a group as a "protected class" is, with few exceptions, reserved for groups with objectively identifiable immutable characteristics.¹⁰

The Department nevertheless argues that Section 1557's uncontroversial bar on "sex discrimination" should be redefined controversially to cover gender identity and sexual orientation. ¹¹ But differential treatment based on actions related to gender identity or sexual orientation does not constitute "sex" discrimination under a plain reading of Section 1557. Indeed, there is no evidence that Congress departed from the common, objective definition of sex when drafting Section 1557.

⁹ Ryan T. Anderson, "Sexual Orientation and Gender Identity (SOGI) Laws Threaten Freedom," Heritage Foundation Backgrounder No. 3082, November 30, 2015, http://www.heritage.org/research/reports/2015/11/sexual-orientation-and-gender-identity-sogi-laws-threatenfreedom; Ryan T. Anderson, "Sexual Orientation and Gender Identity Are Not Like Race: Why ENDA Is Bad Policy," The Witherspoon Institute, Public Discourse, March 18, 2015, http://www.thepublicdiscourse.com/2015/03/14649/ (accessed October 27, 2015); John Finnis, "Law, Morality, and 'Sexual Orientation," in Human Rights and Common.

¹⁰ Anderson, "Sexual Orientation and Gender Identity (SOGI) Laws Threaten Freedom"; Ryan T. Anderson, "ENDA Threatens Fundamental Civil Liberties," Heritage Foundation Backgrounder No. 2857, November 1, 2013, http://www.heritage.org/research/reports/2013/11/enda-threatens-fundamental-civil-liberties; and Anderson, "Sexual Orientation and Gender Identity Are Not Like Race."

¹¹ See 80 FR 54176–54177

Absent clear congressional authorization, then, the Department would not be justified in replacing the commonsense understanding of sex as a permanent reality grounded in biology with its view that sex is something merely "assigned at birth" and that a person's gender may be "neither, both, or a combination of male and female," regardless of biology, and based solely on one's subjective "internal sense of gender." ¹²

Under such a radical redefinition of "sex," a person or covered entity that in conscience and good faith declines to participate in "gender transition" treatments could face unwarranted litigation and liability. ¹³ Because decisions about medical procedures, treatments, and insurance coverage made in line with reasonable medical, moral, and religious beliefs about biology and the best interests of the patient are nothing like invidious sex discrimination, they should not be treated by the federal government as such.

Unsettled questions about gender dysphoria

Serious concerns raised by respected physicians about the propriety of "gender-reassignment" operations should give the Department pause before forcing individuals, physicians, hospitals, and insurers to participate in or cover such procedures. There are a variety of reasonable medical opinions about the best treatment for gender dysphoria—a deep-seated desire to appear and be treated as a member of the opposite sex. Permanently altering, resecting, or amputating well-functioning organs of the human body is a controversial form of treatment. Indeed, several European countries who adopted such treatments early, including the UK, Sweden, and Finland, are now urging caution. This would be an inopportune time for the federal government to take a side in these debates through unaccountable agency action and then coercively impose that judgment on all medical professionals.

Paul McHugh, MD, University Distinguished Service Professor of Psychiatry at the Johns Hopkins University School of Medicine and former Psychiatrist-in-Chief at Johns Hopkins University Hospital, has written extensively about the serious medical and psychological questions surrounding sex-reassignment surgery. When Dr. McHugh arrived at Johns Hopkins in the 1970s, the hospital had become one of the leading centers for sex-reassignment surgery in the country. Yet few follow-up studies were being conducted with patients receiving sex-reassignment operations as treatment for gender identity disorder (now called gender dysphoria in the *Diagnostic and Statistical Manual of Mental Disorders*).

McHugh encouraged Jon Meyer, who was a colleague, psychiatrist, and psychoanalyst, to conduct research on the psychological well-being of patients after sex-reassignment surgery to see if the procedure led to any improvements.

The results, as McHugh describes them, left much to be desired:

[Meyer] found that most of the patients he tracked down some years after their surgery were contented with what they had done and that only a few regretted it. But in every other respect, they were little changed in

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¹² Ibid., 54174 and 51477

¹³ Ibid., 54220

their psychological condition. They had much the same problems with relationships, work, and emotions as before. The hope that they would emerge now from their emotional difficulties to flourish psychologically had not been fulfilled. We saw the results as demonstrating that just as these men enjoyed cross-dressing as women before the operation, so they enjoyed cross-living after it. But they were no better in their psychological integration or any easier to live with.¹⁴

Seeing little to no positive impact on the psychological health of transgender adults, McHugh could not justify continuing to surgically alter or remove healthy and fully functioning organs at the patients' requests. McHugh concluded that Johns Hopkins's practice of sexreassignment surgeries, instead of helping patients, "was fundamentally cooperating with a mental illness" and the hospital stopped prescribing and performing the procedure. ¹⁵

Concurring with the observations made at Johns Hopkins, a 2011 long-term study of individuals who underwent sex-reassignment surgery documented sustained mental hardships of transgender-identifying individuals. Conducted over a 30-year period in Sweden, the study found that 10 years to 30 years after sex-reassignment surgery "the most striking result was the high mortality rate." This was due in significant part to post-operative transitioned individuals having suicide rates nearly 20 times higher than their peers. ¹⁶

McHugh addressed the question of proper treatment in the context of civil rights:

[P]olicy makers and the media are doing no favors either to the public or the transgendered by treating their confusions as a right in need of defending rather than as a mental disorder that deserves understanding, treatment and prevention.

Claiming that this is [a] civil-rights matter and encouraging surgical intervention is in reality to collaborate with and promote a mental disorder. 17

The proposed version of the 2016 Rule made no mention of the professionals who argue that there are serious medical and psychological concerns surrounding sex-reassignment surgery and gender-transition treatments.¹⁸ There are now even more prominent critics of the strict "gender-affirming approach. Thus, it would be negligent for a rule issued in 2022 to ignore these scientifically grounded criticisms.

We are concerned that the proposed regulation will have serious effects on the practice of medicine, freedom of conscience, and choice in health care coverage. The 2016 Rule appeared to

¹⁴ Paul R. McHugh, "Surgical Sex," First Things, November 2004, http://www.firstthings.com/article/2004/11/surgical-sex
¹⁵ Ibid.

¹⁶ Cecilia Dhejne et al., "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," PLOS ONE, Vol. 6, No. 2 (February 2011), http://www.plosone.org/article/fetchObject.action?uri=info:doi/10.1371/journal.

pone.0016885&representation=PDF (accessed October 27, 2015).
¹⁷ Paul McHugh, "Transgender Surgery Isn't the Solution," The Wall Street Journal, June 12, 2014, http://www.wsj.com/articles/paul-mchugh-transgender-surgery-isnt-the-solution-1402615120

¹⁸ 80 FR 54189–54190. Indeed, the only medical evidence cited in the preamble to the proposed regulation was a citation to an HHS Departmental Appeals Board decision to invalidate Medicare's previous exclusion of sex reassignment coverage, which in turn cites the opinion of only one medical group that advances transgender surgeries.

operate on the presumption that the question of gender-reassignment surgery is settled when respected physicians and researchers believe it is not the proper treatment for gender dysphoria. Whether or not one agrees with Dr. McHugh and other medical professionals' concerns about such procedures, they should retain the freedom to practice medicine according to their best judgments without governmental penalty.

"Conversion" or "Reparative" Therapy

42 U.S. Code § 18114 guarantees individuals' "access to therapies." It directly addresses the Department of Health and Human services, saying,

Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—

(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs. ¹⁹

As such, any ban on talk therapy violates both the First Amendment and U.S. Code. To require, or compel, health insurance companies and medical providers to provide medical or hormonal treatments for those struggling with gender dysphoria while failing to cover talk therapy coverage, is an equal rights anti-discrimination violation. Additionally, to the extent coverage of transitioning treatments is required or compelled, Section 1557 should provide for detransitioners.

Abortion

HHS's redefinition of "sex" is drawn from Title IX. The department uses Title IX's redefinition of pregnancy to include "or related conditions" which is defined as: "(1) Pregnancy, childbirth, termination of pregnancy, or lactation; (2) Medical conditions related to pregnancy, childbirth, termination of pregnancy, or lactation; or (3) Recovery from pregnancy, childbirth, termination of pregnancy, lactation, or their related medical conditions."²⁰

This proposed redefinition of pregnancy was introduced a mere three weeks after the Supreme Court's decision in Dobbs v. Jackson Women's Health Organization on June 24, 2022. This decision corrected the grave errors of *Roe v. Wade* and *Planned Parenthood v. Casey*.

Nonetheless, Title IX did not mention the Dobbs ruling nor its impact upon the way pregnancy and abortion rulings will necessarily be interpreted in the United States. Not only does Section 1557 define sex discrimination to include "termination of pregnancy," the department goes so far as to question "what impact, if any, the Supreme Court decision in *Dobbs v. Jackson Women's*

¹⁹ 42 U.S. Code § 18114

²⁰ 87 FR 41390

Health Organization has on the implementation of Section 1557 and these regulations." The department fails to explain why they are picking and choosing only certain parts of Title IX's definition of sex, pregnancy, and abortion to implement.²¹

Applies by extension, or by convenience?

The Department of Health and Human Services, per their own admission, is relying upon the redefinition of sex, pregnancy and abortion from Title IX as the basis for their own rule.

As HHS admits, it is relying on an "applies by extension" argument from Bostock to Title IX to argue that the redefinition of sex, pregnancy, and abortion in Section 1557 has a reasonable basis.²² Nonetheless, the department is willfully and unaccountably abandoning the longstanding abortion neutrality provision in Title IX. This opens the door for Section 1557's federal funds going towards promoting, paying for, and supporting abortion. The department fails to explain its pro-abortion agenda or why federal funds should go towards an abortion.

Title VII does not require a provider to pay for an abortion, Title IX remains neutral on funds going towards abortion, and Title X bans the use of its funds going toward an abortion outright. What right or basis does Section 1557 have to include abortion in the definition of sex without extending an abortion neutrality provision? The department fails to explain its failure to include an abortion neutrality clause. It must provide a clear explanation given this obvious and weighty departure from previous rules. In addition, the department must provide an analysis of the expected cost and impact of allowing federal funds to go towards an abortion.

Assessment of impact on families

Under Section 654 of the Treasury and General Government Appropriations Act, 1999, (Pub. L. 105-277) federal agencies are required to assess the impact of proposed regulations on families. Officially known as the "Family Policymaking Assessment," agencies are required to assess their actions "before implementing policies and regulations that may affect family well-being.²³

Given the sensitive nature of Section 1557's proposed regulation, we humbly request that HHS conduct an assessment on the impact of this proposed rule on family well-being. The seven categories that qualify for assessment are:

- (1) the action strengthens or erodes the stability or safety of the family and, particularly, the marital commitment
- (2) the action strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children;
- (3) the action helps the family perform its functions, or substitutes governmental activity for the function:
- (4) the action increases or decreases disposable income or poverty of families and children;
- (5) the proposed benefits of the action justify the financial impact on the family;

²¹ HHS Announces Proposed Rule to Strengthen Nondiscrimination in Health Care, July 25, 2022. https://www.hhs.gov/about/news/2022/07/25/hhs-announces-proposed-rule-to-strengthen-nondiscrimination-inhealth-care.html

²² 87 FR 47824

²³ Section 654 of the Treasury and General Government Appropriations Act, 1999, (Pub. L. 105-277) https://www.govinfo.gov/content/pkg/PLAW-105publ277/pdf/PLAW-105publ277.pdf

- (6) the action may be carried out by State or local government or by the family; and
- (7) the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society.

We are interested in the department addressing how the Section 1557 proposed regulation "increases or decreases disposable income or poverty of families and children" and how "the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society."²⁴ Given the department's failure to conduct an analysis of how the additional cost of new surgeries will impact those who are insured, insurers, and so on, it is reasonable to be concerned that the proposed regulation could decrease the "disposable income of poverty of families and children".²⁵ Additionally, the push to provide medical and hormonal treatment for those struggling with gender identity or sexual orientation issues, it is reasonable to assume the action will establish an implicit policy concerning the "relationship between the behavior and personal responsibility of youth and the norms of society".²⁶ This same concern is reflected in the question of the degree to which this rule will erode the "authority and rights of parents in the education, nurture, and supervision of their children."²⁷

Title IX's Abortion Neutrality Clause

Title IX's statute includes an abortion neutrality provision which states that "nothing in this chapter shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion. Nothing in this section shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion." Additionally, Title IX ensures that institutions and individuals have access to strong religious liberty protections in the form of exemptions.

Relying on HHS' "applies by extension argument," the department fails to provide an explanation for why Section 1557's proposed rule *does not* include an abortion neutrality clause, nor does it import key religious exemption protections. If the department is supposedly relying upon Title IX's interpretation of sex, which includes a poorly defined use of "termination of pregnancy," then it doesn't follow for HHS to abandon the longstanding abortion neutrality clause.

Title IX's definition of sex as it relates to pregnancy is largely derived from Title VII

Title IX's abortion neutrality, and longstanding definition of pregnancy, is not an isolated ruling. Title VII's Pregnancy Discrimination Act addresses the limits of compelled abortion provisions and adds further insight into the original meaning of "or related conditions."²⁹

²⁴ Ibid., 529.

²⁵ Ibid., 529.

²⁶ Ibid., 529.

²⁷ Ibid., 529.

²⁸ 20 U.S.C. § 1681(a)

²⁹ 42 U.S.C. 2000e(k)

Title IX relies on guidance from the Pregnancy Discrimination Act, an amendment of Title VII, for their definition of "sex". The Act bars employers from "discriminating against employees on the basis of pregnancy, childbirth, or related medical conditions". As the Department of Education clarifies in this proposed rule, "the fact that Congress did not amend Title IX's definition of 'sex' to explicitly include pregnancy, as it did for Title VII in 1978, does not signal Congress's intent to exclude pregnancy coverage under Title IX." Title VII's definition of sex, then, is the basis of Title IX's own interpretation.

Unlike Title IX, Title VII does not have an explicit abortion neutrality clause. It states that a company is not required to cover the cost of an abortion on their health insurance, as a benefit or otherwise. They are, however, expected to cover medical issues that may arise from an abortion complication-like excessive hemorrhaging- as it may result in subsequent surgeries or medical care beyond the scope of the abortion. Additionally, employers are required to provide medical insurance coverage when the life of the mother is at risk.

Title VII does not provide a clear definition as to what falls under the "or related medical conditions" clause, though subsequent district court rulings and guidance announcements have clarified that it includes breastfeeding and complications arising from abortion.

By following the Department of Education's own reasoning as it relates to Title VII and Title IX definitions and protections, Title IX's proposed definition of "or related conditions" is derived from Title VII's "related medical conditions." The department defines Title IX's "pregnancy or related conditions" as: "(1) Pregnancy, childbirth, termination of pregnancy, or lactation; (2) Medical conditions related to pregnancy, childbirth, termination of pregnancy, or lactation; or (3) Recovery from pregnancy, childbirth, termination of pregnancy, lactation, or their related medical conditions."³²

In this, #2 and #3 follows the logic of Title VII as it relates to abortion: namely, categorizing abortion as a subsequent medical condition that warrants medically directed accommodations; providing necessary periods of recovery without discrimination or penalty. The first definition, however, breaks with Title VII's definition of sex and changes Title IX's current definition of pregnancy.

The Proposed Rule Equates Pregnancy and Abortion

Title IX's proposed rule defines pregnancy itself as "pregnancy, childbirth, termination of pregnancy, or lactation." This is a shift from listing conditions protected from discrimination, as the current rule does: "pregnancy, childbirth, false pregnancy, termination of pregnancy, or recovery therefrom." It's a distinction that makes all the difference. Under the department's new definition, abortion is given equal status with pregnancy and childbearing. This requires an acceptance of abortion as morally equivalent to pregnancy and childbirth. From a moral (and for that matter, medical) standpoint, this could not be further from the truth.

³¹ Ibid.

³⁰ Ibid.

³² 87 Federal Register 41390

A pregnancy is a natural process in which new life begins at the moment of conception when an ova and sperm bond; the single-celled zygote quickly develops into an embryo. This embryo – a new, separate and distinct human being – implants on the uterine wall where it continues to grow and born after about nine months. This human being is just that – a human being – from its earliest stage of development.

Lactation is the natural response of a mother's body to the needs of her baby as she provides milk and essential nutrients for her newborn child.

Abortion, on the other hand, is the intentional, direct destruction of preborn human life. It kills the preborn baby and halts the natural process of pregnancy.

In short, Title IX's proposed definition erroneously conflates pregnancy and lactation, a natural and lifegiving process, with abortion, a medically induced procedure intended to kill preborn life. The department has not explained why the current definition is insufficient, nor has the department sufficiently demonstrated its reason for changing it. The department must explain its reasoning and justification.

Religious Freedom and Conscience Rights

Regarding religion, the proposed rule states that HHS is "fully committed to respecting the conscience and religious freedom laws when applying this rule, including an organization's assertion that the provision of this rule conflict with their rights under Federal conscience and religious freedom laws." ³³

As Rachel Morrison, Fellow at the Ethics and Public Policy Center, argues, "the NPRM proposes a process for application of such laws. Proposed regulations would provide a specific means for recipients to notify HHS of their views regarding the application of federal conscience or religious freedom views. HHS would be required to 'promptly consider those views,' pause any agency investigation or enforcement activity during consideration and made a 'case by case' determination about any applicable legal protections. HHS notes that a 'case-by-case approach to such determinations... will allow it to account for any harm an exemption could have on third parties."³⁴

The harm to religious liberty and freedom of conscience

In the preamble to the 2016 Proposed Rule, the Department acknowledged that its recommended nondiscrimination rule may conflict with religious beliefs. Although the Department said the regulation would not displace the federal Religious Freedom Restoration Act or laws and regulations protecting people from having to perform, pay for, or refer for abortion against their will, it provided no guidance as to how the proposed regulations would be limited, if at all, by

³³ 87 Federal Register 47824

³⁴ Morrison, "HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate in Health Care." https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-in-health-care-1

those laws and regulations. Moreover, it proposed no moral or religious accommodations. It is unlikely that a religious exemption, even if proposed at some later date, would have adequately protected the freedom of conscience of physicians, insurers, employers, health care providers, and taxpayers given the breadth of the rule.³⁵

We anticipate that the new rule will have the same problems.

The practical impact of the proposed regulation could spread across the field of health care and to employers and taxpayers generally:

- **Physicians.** Doctors, gynecologists, psychologists, and counselors, among others, could be forced to participate directly in treatments or procedures in violation of their moral or religious beliefs.
- Hospitals, health clinics, nursing homes, and other health care organizations. The impact on many health care entities would be twofold. Like physicians, they could be forced to participate directly in procedures in violation of their moral or religious beliefs. They would also be forced to pay for coverage of the same procedures in their own employee health plans. The proposed regulations could require health care organizations to open their bathrooms, locker rooms, and shower facilities to everyone regardless of sex or to provide "comparable" facilities, regardless of an organization's religious beliefs on the matter. The series of the same procedures in their own employee health plans.
- Employers and individuals purchasing health insurance. As previously noted and also discussed in more detail in a subsequent section of these comments, if the proposed regulations require private insurers that receive any enrollee subsidy on an Obamacare exchange or any other type of federal financial assistance to make all of their health insurance products comport with the gender identity mandate it would make it much more difficult (and in some cases, practically impossible) for private employers and individuals to avoid paying for coverage of sex-reassignment surgeries and treatments through their insurance plans contrary to their religious belief or moral convictions.
- **Taxpayers.** We anticipate that because the proposed regulation would apply to all insurance plans receiving taxpayer-funded subsidies on Obamacare exchanges and to all state Medicaid plans, which are funded with both state and federal tax dollars, the proposed regulation would make American taxpayers complicit in funding coverage of controversial surgeries and treatments.

³⁵ The Department asked for comment "on whether the regulation should include any specific exemptions" and, if so, whether any should track the exemption process for certain religious institutions found in Title IX regulations. Ibid., 54173.

³⁶ The proposed regulation listed specific covered entities that would be required to ensure their own employee health benefits program abide by the proposed nondiscrimination policy. Ibid., 54220.

³⁷ The preamble to the proposed regulations noted, "HHS does not propose to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex." Ibid., 54181. Presumably, if a covered entity failed to provide such "comparable facilities," regardless of sex, it could be found in violation of the proposed regulations. Notably, the Department made no estimate of the cost to covered entities for ensuring compliance with the proposed regulations in this respect.

Instead, HHS should incorporate Title IX's religious exemption status, given that it's "applicable by extension." The existing approach default exempts religious organizations. This is the preferred approach, too. Even the Obama-era rule acknowledges the Religious Freedom Restoration Act and respects it on a case-by-case basis. The Trump administration incorporated Title IX's religious institution exemption to the Section 1557 rule. It stated that sex discrimination does not apply if it conflicts with your sincerely held religious beliefs. This precedent is wholly removed from the current department's Section 1557 proposed rule. The department does not provide an explanation for why the existing religious exemption process is inadequate, nor does the department provide a justification for why this proposed process will better protect religious individuals and institutions.

Conflict with existing federal right to conscience

Health care policy, at bottom, should concern itself with the well-being of patients and providers. And a basic moral principle is at stake for health care providers: their central duty to do no harm.

Our society has long recognized that medical care involves two parties—the patient and the doctor. Patients should be free to seek treatment, and doctors should be free to exercise their judgment about the right treatment for patients.

We are concerned that the proposed rule on Section 1557 will violate this principle. Using it, the state could force doctors to offer treatment they oppose.

As noted above, many doctors reasonably believe that to remove healthy organs, or to give young people puberty-blocking drugs, would harm their patients—whatever the subjective wishes of the patient. Healthy organs are not deadly tumors, and puberty is not a disease.

Proposed regulations may violate conscience concerning abortion

In addition to the preceding concerns, the proposed regulation may threaten the freedom of conscience of physicians, health care entities, and individuals who have religious or moral objections to abortion. For nearly four decades, the federal government has prohibited discrimination against individuals and health care providers who do not wish to pay for, cover, or perform abortions. However, the proposed regulation could prohibit discrimination in health care "on the basis of sex" further defined to include discrimination on the basis of "termination of pregnancy," i.e., abortion.³⁸

In the preamble to the 2016 regulation, the Office for Civil Rights cited existing conscience protections for individuals, physicians, and other health care entities. Yet those conscience laws were not explicitly applied in the text of the proposed regulations, and it was unclear how the regulations would have interacted with those existing policies.

It was also unclear what "discrimination" based on termination of pregnancy would look like in practice. Would it prevent any differential treatment of a woman who has had an abortion, is

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³⁸ Ibid., 54216

seeking one, or both? Would the regulation have prohibited pro-life obstetricians from declining to refer patients for abortions? Or would it have required coverage and provision of abortions, as with sex-reassignment surgeries? Because of this extreme ambiguity, the proposed 2022 regulation could risk serious conflict with long-standing and widely accepted law and policies protecting conscience.³⁹

Scope of Section 1557

Section 1557 is expanding its scope to include health insurance issuers for the first time. As recently as the 2020 Section 1557 rule, the department reasoned that health insurance providers are not "principally engaged in the business of providing health care." Now, however, under the proposed rule, the department is changing their stance to include health insurance issuers. This means that health insurance issuers will be subject to Section 1557's redefinition of sex, pregnancy, and abortion as a consequence of receiving federal funds. This is a hefty departure from previous rulings and will have far-reaching conclusions for health insurance issuers.

The Department considered any explicit or categorical exclusions of coverage for "gender transition" treatment as "unlawful on its face." Although the Department claimed that the proposed regulations would not "affirmatively require" coverage of such treatment, this claim was undercut by the Department's more concrete statements on the matter:

In evaluating whether it is discriminatory to deny or limit a request for coverage of a particular service for an individual seeking the service as part of transition related care, OCR will start by inquiring whether and to what extent coverage is available when the same service is not related to gender transition. If, for example, a health plan or State Medicaid agency denies a claim for coverage of a hysterectomy that a patient's provider says is medically necessary to treat gender dysphoria, OCR will evaluate the extent of the plan's coverage of hysterectomies under other circumstances.⁴³

³⁹ Specifically, the Church Amendments prevent the government from forcing any individual or entity receiving certain federal dollars to "perform or assist in the performance of any sterilization procedure or abortion" or make its facilities available for such procedures if doing so would violate religious or moral beliefs about abortion. 42 U.S. Code § 300a-7 et seq. Likewise, the Weldon Amendment, attached to every HHS appropriations bill since fiscal year 2004, prohibits any government receiving certain federal dollars from discriminating against health care entities (including health insurance plans) because it "does not provide, pay for, provide coverage of, or refer for abortions." For example, see the Consolidated Appropriations Act, 2010, Public Law No. 111–117. Even the ACA prohibits qualified health plans offered on state and federal exchanges from "discriminat[ing] against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions." Public Law 111–148 as amended by Public Law 111–152. See also U.S. Department of Health and Human Services, "Overview of Federal Statutory Health Care Provider Conscience Protections," http://www.hhs.gov/ocr/civilrights/faq/providerconsciencefaq.html

⁴⁰ The Department of Health and Human Services, "Section 1557: Frequently Asked Questions," question #17. https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html

⁴¹ Any "covered entity shall not," among other things, "[c]ategorically or automatically exclude from coverage, or limit coverage for, all health services related to gender transition" or "[o]therwise deny or limit coverage, or deny a claim, for specific health services related to gender transition if such denial or limitation results in discrimination against a transgender individual." Ibid., 54190 and 54220.

⁴² Ibid., 54190.

⁴³ Ibid.

A provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to perform the procedure on transgender individuals in the same manner it provides the procedure for other individuals.⁴⁴

Under these guidelines, if a covered physician administered treatments or performed surgeries that *could* further gender transitions, that physician would *have to* provide them for gender transitions on the same terms, and insurance had to cover it, regardless of the independent medical judgment of the physician. ⁴⁵ Furthermore, the Department proposed no religious accommodation or exemption to its gender identity mandate or any other aspect of its proposed regulations.

Thus, the regulation, once finalized, would have forced many physicians, hospitals, and other health care providers to participate in "gender-reassignment" surgeries and treatments, even if it violated their religious beliefs or their best medical judgment. Moreover, because it applied so broadly, the regulation proposed could also force employers, individuals, and taxpayers to fund coverage for such procedures even if doing so conflicted with their sincere beliefs. However, those conflicts were averted by the revisions made in the subsequent 2020 Rule.

Medical Providers

Forcing physicians to act against their medical judgment and insurance to pay for it

The proposed regulations would disregard reasonable medical decisions and instead open medical professionals to extensive litigation and potential liability if they decline to participate in a transgender-identified individual's demands for a "sex change."

In 2016, the Department explained how a hypothetical gynecologist's office would be required to change its policy under the proposed regulations to "provide a medically necessary hysterectomy for a transgender man...in the same manner it provides the procedure for other individuals." What constitutes a "medically necessary" procedure was not defined.

However, in a preceding section of the preamble of the 2016 Proposed Rule, the Department suggested that health insurance plans could be forced to cover procedures involved in sexreassignment surgeries provided at least one medical professional deems the procedure "medically necessary" to treat gender dysphoria.

The Department explained:

⁴⁴ Ibid., 54204.

⁴⁵ According to the Department, "if a provider is not accepting new patients, the provider does not have to accept a new patient request from a transgender person." Ibid., 54205. However, all existing patients must be treated in a "nondiscriminatory" manner, and it was unclear whether a physician could stop taking new patients in response to the regulations or if the Department would consider that illegal discrimination as well.

⁴⁶ Ibid., 54204.

If, for example, a health plan or State Medicaid agency denies a claim for coverage of a hysterectomy that a patient's provider says is medically necessary to treat gender dysphoria, OCR will evaluate the extent of the plan's coverage of hysterectomies under other circumstances. OCR will also carefully scrutinize whether the covered entity's explanation for the denial or limitation of coverage for transition-related care is legitimate and not a pretext for discrimination.⁴⁷

Without further clarification, such regulatory language could force gynecologists who perform hysterectomies for some purposes, such as to treat uterine or ovarian cancer, to perform the surgery for gender-reassignment purposes if the patient has a referral from a psychologist. Gynecologists who decline to perform hysterectomies in such cases because of conscientious objections or because they judge them medically inappropriate could nevertheless face litigation under the proposed regulations, as would insurers that decline to pay for the procedures.

Similarly, physicians or insurers who regularly prescribe or cover hormones for some purposes, for example, to treat conditions associated with aging in men and women, could face liability under the proposed regulation if they refuse to provide or pay for such hormones for gender-transition reasons. Could psychologists or counselors who recommend, in their best medical judgment, that patients with gender dysphoria *affirm*, rather than reject, their sex be liable for supposed "discrimination" under the proposed regulation?

Similarly, may an endocrinologist recommend that patients with gender dysphoria try hormone treatments that reinforce instead of counteract their sex without being subject to a lawsuit under the regulation? At the very least, the lack of clarity would likely invite expensive litigation on these and similar questions. As a result, the proposed regulation could very well subordinate professional medical judgments to the rulings of HHS bureaucrats or federal judges.

Procedural Concerns

The department considers how its proposed regulation in Section 1557 will interact with state law—that is, how Section 1557 (a federal agency ruling) may or will preempt conflicting state laws:

Conflicts could include state laws protecting minors from sterilizing and irreversible gender transition interventions or state conscience and religious freedom protection laws. It is unclear how strings attached to federal financial assistance could unilaterally preempt incompatible state laws, instead of the standard disallowance of federal funds from entities that are unable to comply—either by oversight, choice, or due to a state law.⁴⁸

Again, judging from the 2016 Rule, the proposed regulation would apply to any "health programs or activities any part of which receives Federal financial assistance administered by

⁴⁷ Ibid., 54190.

⁴⁸ Morrison, "HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate in Health Care." https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-in-health-care-1

HHS" as well as any health programs or activities administered by HHS or those established under Title I of the ACA, including federally facilitated and state-based insurance exchanges.⁴⁹

This includes any "hospital, health clinic, group health plan, health insurance issuer, physician's practice, community health center, nursing facility, residential or community-based treatment facility, or other similar entity" that receives HHS funds.⁵⁰

The proposed regulation would therefore apply to:

- Approximately 133,000 health care facilities;
- "[A]lmost all practicing physicians in the United States...because they accept some form of Federal remuneration or reimbursement";
- All state Medicaid programs; and
- All the businesses and activities of a private insurer if any of its businesses receive any federal financial assistance either directly (such as a through a Medicaid managed care contract) or indirectly (through subsidies provided to its customers as is the case with Medicare Advantage and exchange plans). However, the 2020 Rule narrowed the scope of application to insurers.⁵¹

Because the federal government now extensively subsidizes both medical care and health insurance coverage it would be nearly impossible for medical professionals to work free from these regulations.

Cost of proposed regulations

Given the Regulatory Flexibility Act, which requires an analysis of the costs and harms associated with a given rule, HHS must adequately address the potential costs/harms of its proposed Section 1557 regulation. If the department does not do so, it will open for the door for lawsuits. In addition, before a rule is finalized, the department must provide an analysis of how much insurance will cost for insurers, employers, small businesses, states, and the insured. Which procedures will now be covered? What are the costs associated with these approved procedures? Given the Biden Administration's stated interest in promoting "equity," especially among minorities, a failure to account for these costs will disproportionately harm rural hospitals and those living in poorer areas. The department has failed to answer these questions or provide the essential reports for how it will impact the insured and medical providers alike.

Conclusion

Section 1557 is a solution in search of a problem. The current anti-discrimination protections, that include biological sex, race, color, national origin, age, or disability, are more than sufficient. By redefining sex to include "sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity" the department is at risk of creating a new, and unjustified, class of protected citizens based on a fluid and illdefined understanding of sexuality. Given the lack of research on the impact of medical,

⁴⁹ 80 Federal Register 54218 (proposed September 8, 2015).

⁵⁰ Ibid., 54216.

⁵¹ Ibid., 54174–54175 and 54195.

hormonal, and social treatments for individuals struggling with gender dysphoria, the department would be wise to conduct in-depth, good-faith studies into the research provided in this comment.

Additionally, the inclusion of abortion in the definition of pregnancy and the subsequent failure to include Title IX's abortion neutrality provision makes abortion morally and scientifically equivalent to pregnancy. Without the abortion neutrality provision, the Department is creating an opportunity where HHS can promote and ensure abortion access through a federal agencybreaking with every major Title (VII, IX, X) ruling and taxpayer protection (like the Hyde Amendment). This raises key questions of federal agencies preempting state laws.

The final concern lies in religious liberty and conscience protections for physicians, insurers, employers, health care providers, and taxpayers given the breadth of the rule. Without careful reconsideration, the Department is setting itself up for a slew of religious liberty lawsuits for violations of individual and institutional conscience rights.

Respectfully submitted,

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