



Congress of the United States
Washington, DC

October 3, 2022

VIA ELECTRONIC TRANSMISSION

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Secretary Becerra:

We write in response to the U.S. Department of Health and Human Services' (HHS) Proposed Rule, "Nondiscrimination in Health Program and Activities," (Proposed Rule).¹ This proposed rule flagrantly flies in the face of Congressional intent and the underlying text of Section 1557 of the Patient Protection and Affordable Care Act (ACA). The Proposed Rule should be immediately withdrawn, and policies HHS has already pushed forward in anticipation of the rule's finalization, such as the notice of interpretation should be rescinded.² As we explain in the following paragraphs, HHS has failed at every turn to justify a legal basis or evidence medical necessity for coverage and reimbursement of these items and services.

This Proposed Rule makes no attempt to actually ensure equal access to health care based on race, color, national origin, sex, age, or disability. Instead, it takes an unprecedented departure from the law by requiring coverage and mandating performance of medical procedures and interventions that not only lack medical necessity, but are often harmful to the patient.

Life

Elective abortion is not health care. Rather, it is a lethal and violent procedure that intentionally destroys the life of an innocent child. The Proposed Rule, however, under the guise of nondiscrimination in health care, discriminates against unborn children and health care providers who are committed to caring for both of their patients, the pregnant mother and her unborn child.

This Proposed Rule redefines sex-based discrimination under Section 1557 to imply that health care providers must pay for, cover, or provide abortions (potentially to include abortion-inducing drugs) as a condition of participating in a Federal health care program or activity. Section 1557 incorporates by reference the prohibition on sex-discrimination under Title IX of the Education Amendments of 1972, extending to health care providers the same funding conditions that apply to educational institutions. The Proposed Rule defines sex-based discrimination to include discrimination on the basis of "pregnancy or

¹ 87 Fed. Reg. 47824 (RIN 0945-AA17).

² 86 Fed Reg. 27984.

related conditions.” While the regulatory text of the Proposed Rule itself does not use the term “abortion” or “termination of pregnancy” as the Obama administration’s 2016 final rule did, Title IX’s implementing regulations (including new proposed regulations) in turn, define “pregnancy or related conditions to include “termination of pregnancy” i.e. abortion.”³ HHS explicitly states in a fact sheet accompanying release of the Proposed Rule stating that the Proposed Rule “clarifies that sex discrimination includes discrimination on the basis of. . . pregnancy termination.”⁴

Far from conferring a right to abortion, however, Title IX expressly states, under a heading entitled “Neutrality with Respect to Abortion” that “[n]othing in this title shall be construed to require . . . 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.”⁵ Because Title IX, explicitly states that its provisions cannot be construed to impose abortion mandates, by extension, the fact that a health care provider does not provide abortion-related benefits or services cannot constitute under Section 1557 a “ground prohibited under . . . title IX.” Congress’ intent to incorporate this abortion neutrality provision into Section 1557, along with the rest of title IX’s statutory structure, can also be inferred from the use of the Latin phrase “et seq.,” meaning “and the following”, in the statute citation to Title IX in the ACA. HHS fails to justify its determination that the abortion neutrality provision does not apply to Section 1557. Such an understanding is plainly contrary to the law, as a federal district court ruled in the 2016 decision *Franciscan Alliance v. Burwell*.⁶

Conflicts with State Laws

In the Supreme Court’s decision in *Dobbs v. Jackson Women’s Health Organization*, the Supreme Court recognized that there is no Constitutional right to abortion. Consequently, HHS has no foundation to justify any purported Federal interest in promoting abortion or pre-empting State laws, including under Federal statutes like Section 1557. Far from pre-empting State laws on abortion, the ACA was clear that nothing in it, including Section 1557, would preempt State laws regarding abortion. Under a heading entitled “No preemption of State laws regarding abortion”, the ACA states in section 1303 specifically that “[n]othing in this Act 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.”⁷ The Proposed Rule fails to make clear that its erroneous policies would not preempt state abortion laws that protect life.

The ACA was likewise clear that nothing in it, including Section 1557, would “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.”⁸ The Proposed Rule fails to explain why under this Administration’s interpretation, Section 1557 would not be subjected to such statutory protections.

Section 1557 does not authorize HHS to dictate the practice of medicine. It does not give HHS the authority to demand that health care providers ignore State laws, which protect life and protect patients, especially children, from harmful, experimental, sterilizing and irreversible gender transition procedures, and it does now allow HHS to require medical professionals to violate their own medical judgments and

³87 FR 41390.

⁴ <https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/regulatory-initiatives/1557-fact-sheet/index.html>.

⁵ Section 909 of the Education Amendments of 1972 (20 U.S.C. 1688).

⁶ *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016).

⁷ ACA section 1303(c)(1) (42 U.S.C. 18023(c)(1)).

⁸ ACA section 1303(c)(2) (42 U.S.C. 18023(c)(2)).

consciences in order to comply with such lawless edicts. At a minimum, the Proposed Rule must make its limits in relation to state laws explicit.

Gender Identity

The Proposed Rule attempts to implement an over-reaching policy change to Section 1557 that would force health care providers to provide, and health insurance to cover, experimental gender transition procedures and drugs such as puberty blockers, cross-sex hormones, and gender-reassignment surgeries – regardless of a physician’s best medical judgment or conscience objections. The Proposed Rule expands this requirement not only for adults, but also for minors. Medical and surgical gender transition procedures, especially for children, lack scientific, medical, and legal justification. Imposing such mandates in the Proposed Rule is irresponsible, rash, and contradicts the scientific method consistently used in medicine and throughout our various regulatory processes. Despite the bias, one-sided reports HHS relied upon for its rule, use of these drugs cause irreparable harm to patients, including sterilization.

In the underlying statute, Congress did not delegate discretionary authority to HHS to implement such a sweeping change in policy through the regulatory process. The lack of HHS’ existing authority to implement the Proposed Rule is made clear by the fact that there have been numerous attempts in Congress to enact similar policies legislatively, but those attempts have failed every time. For example, in 2021, Members of Congress reintroduced H.R. 5/S. 393, The Equality Act, which would expand public accommodation laws to prohibit discrimination on the basis of “sex (including sexual orientation and gender identity)”, in any “establishment that provides health care.” If Congress already enacted such prohibition in the ACA, why would it have legislation pending to implement such action?

HHS violates its mission, which 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.” HHS needs to be focused on evidence-based science and medicine to promote the health and well-being of all Americans. Instead, this Proposed Rule purports to eradicate the difference between men and women in health care. It should go without saying that men and women are different, both inherently and biologically. That means they have different health care needs. HHS lacks any sufficient scientific evidence to promote health care that disregards the differences between men and women. As evidenced by the harms of the 2016 rule, health care professionals are unable to care adequately for patients when they do not know they are caring for a man or woman.

Beyond a denial of the biological difference between men and women, it is worth noting that the U.S. Food and Drug Administration (FDA) has not approved any drug for the purpose of gender transition. Further, no drug sponsor has filed a new drug application or supplemental application to modify its existing label for the treatment of gender transition in minors or adults. This could be in part because there are no clear clinical endpoints for these experimental treatments. The studies cited in the Proposed Rule that do affirm such care beg to question HHS’ assessment of such research. While there are many studies featured in ideologically biased and aggressive journals, HHS ignores other peer-reviewed publications that contradict those findings and conclude that more research is necessary before determining standards of care. Moreover, HHS fails to consider contrary studies demonstrating the harms of medicalized transitioning and fails to demonstrate significant reasoning as to why it relied upon only studies that affirmed its actions.

Tragically, the FDA has also abdicated its responsibility to caution health care providers and consumers about the dangers of the experimental, off-label use of these drugs.

HHS has similarly failed to provide an explanation for pushing a medical standard of care when no manufacturer has demonstrated that its drug is approved safe and effective. Nor has HHS provided an

analysis on how this impact of the Proposed Rule impacts current federal and state laws and implementing regulations for making unapproved use of drugs commonplace as it relates to coverage determination and reimbursement. As a result, this regulation will harm patients. Further, even if the FDA and HHS gave in to the ideologically-charged pressure to approve these drugs for the purported use of gender transition, HHS still would lack the statutory ability to implement the mandates the Proposed Rule attempts to impose.

Federal Conscience and Religious Freedom Laws

Besides failing to incorporate the abortion neutrality provision in Title IX, the Proposed Rule also refuses to apply Title IX's religious exemption. The law clearly states that Title IX "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."⁹ In referencing Title IX in Section 1557, Congress stated discrimination in health programs and activities is prohibited "on the grounds prohibited under.... Title IX."¹⁰ Section 1557 did not exclude application of the Title IX's religious exemption. Nevertheless, the Proposed Rule dismisses the existence of such protection. The Proposed Rule fails to explain how it has determined what parts of Title IX to enforce and when.

Further, while the Proposed Rule acknowledges and anticipates conflicting Federal conscience laws, it fails to comply with these very laws. The Proposed Rule's provisions for "notification of views" on Federal conscience and religious freedom laws are wholly inadequate. As written, the ambiguity of the Proposed Rule leaves conscience exemptions to be determined on a case-by-case basis by the Office for Civil Rights (OCR). In addition to being arbitrary and capricious, this wrongfully imposes burdens and uncertainty on health care providers to notify HHS of their objections to the pro-abortion and pro-sterilization implications of the Proposed Rule, which in turn, could be evaluated by agency officials with little to no oversight as to how those evaluations should be conducted. The process itself will impose a chilling effect on many health care providers.

Of great concern, is that HHS has also notified the public of its intent to rescind the final rule "Protecting Statutory Conscience Rights in Health Care."¹¹ As you know, that final rule clarified what covered entities need to do to comply with the two dozen conscience protections in federal law and required applicants for HHS federal financial assistance to provide assurances and certifications of compliance. The rule also specified compliance obligations for covered entities, including cooperation with OCR, maintenance of records, reporting, and non-retaliation requirements. Further, it established an internal process for investigating, handling, and resolving complaints. The Proposed Rule fails to address how OCR will ensure conscience protections are upheld and enforced, particularly if and when the agency moves forward with the recession of the Conscience Rule.

Federal conscience laws including Church Amendments, Coats-Snowe, and the Weldon Amendment unambiguously protect health care providers from violating their consciences in the practice of medicine. The Church Amendments, which have been in place for 50 years, protect the rights of individuals and entities that object to performing abortion or sterilization procedures if doing so would be against the provider's religious or moral beliefs.¹² Many of the items and procedures that would be required under the Proposed Rule would result in sterilization, and the agency fails to properly protect health care providers in accordance with the nearly 50-year-old law.

⁹ 20 U.S.C § 1681 (a)(3).

¹⁰ 42 U.S.C. § 18116(a).

¹¹ RIN 0945-AA18.

¹² 42 U.S.C. § 300a-7.

Additionally, the Weldon Amendment states, among other things, that a “Federal agency or program” may not receive any funds under the Labor/HHS appropriations bill, if the agency or program “subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.”¹³ On its face, the Proposed Rule, runs afoul of the Weldon Amendment, because, per HHS’ previous interpretation, “the plain text of the Weldon Amendment prohibits discrimination against protected individuals and entities for being unwilling to take certain actions or to provide certain support in relation to abortion without requiring a specifically religious or moral motive for that decision or position.”¹⁴ This covers “individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.”

The Coates–Snowe amendment, likewise prohibits the federal government from discriminating against any “health care entity” on the basis that “the entity refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions.”¹⁵

Citing its decision not to incorporate the abortion neutrality provision and Title IX’s religious exemption, HHS shows hostility to religion by stating in the preamble that “[t]here are an increasing number of communities in the United States with limited options to access health care from non-religiously affiliated health care providers.” The Religious Freedom Restoration Act also protects health care providers from abortion and gender transition mandates. Forcing doctors to provide patients with an abortion or “gender affirming care” is not a compelling governmental interest. Any such governmental interest in patients obtaining abortions or gender transition treatments cannot justify substantially burdening a health care provider’s religious beliefs.

HHS further cites articles highly critical of Catholic hospitals for not participating in certain medical interventions, consistent with their religious and ethical principles. The Proposed Rule’s overt hostility toward health care providers who affirm the sanctity of human life and the biological difference between men and women prejudices any supposed case-by-case application for health care providers to receive religious exemptions from the rule’s mandates regarding abortion and gender transition procedures.

While we maintain that the Proposed Rule as a whole should be withdrawn, at a minimum, the Department must clearly define in the regulation that recipients of federal financial assistance will not be compelled to perform, cover, or promote procedures or medical interventions including off-label use of drugs, with which they disagree.

Conclusion

In conclusion, the Proposed Rule seeks to unilaterally expand the scope of the law contrary to the text of Section 1557 and Congressional intent. The proposal promotes abortion and ideologically-motivated health care, would harm patients, and flies in the face of existing protections for health care providers. The Department of Health and Human Services should promptly withdraw the Proposed Rule and instead focus on upholding existing law and regulations consistent with the law to ensure access to legitimate health care.

¹³ Section 507 of Division H of Public Law 117-103.

¹⁴ 83 FR 3890.

¹⁵ 42 U.S.C. § 238n.

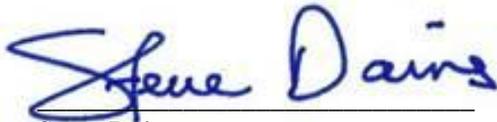
Sincerely,



Roger Marshall, M.D.
U.S. Senator



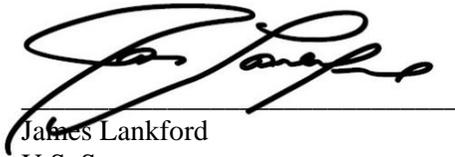
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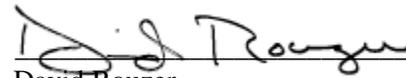
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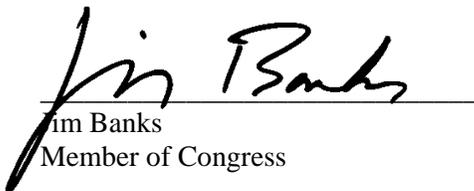
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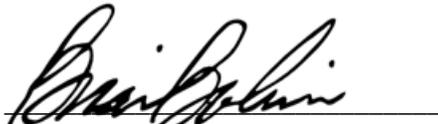
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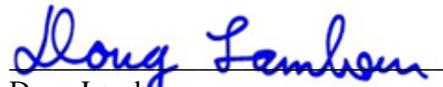

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