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Department of Health and Human Services
Office for Civil Rights
Attn: Section 1557 NPRM, RIN 0945-AA17
Hubert H. Humphrey Building, Room 509F
200 Independent Avenue SW
Washington, DC 20201

Submitted electronically

**Re: Proposed Rule at 87 Fed. Reg. 47,824, RIN 0945-AA17 titled
“Nondiscrimination in Health and Health Education Programs
or Activities”**



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The American Civil Liberties Union (“ACLU”) submits these comments on the proposed rule published at 87 Fed. Reg. 47,824 (proposed Aug. 4, 2022), RIN 0945-AA17, with the title “Nondiscrimination in Health Programs and Activities” (the “Proposed Rule” or “Rule”).

For more than 100 years, the ACLU has been our nation’s guardian of liberty, working in courts, legislatures, and communities to defend and preserve the individual rights and liberties that the Constitution and the laws of the United States guarantee to everyone in this country. With more than 3 million members, activists, and supporters, the ACLU is a nationwide organization that fights tirelessly in all 50 states, Puerto Rico, and Washington, D.C. for the principle that every individual’s rights must be protected equally under the law, regardless of race, religion, gender, sexual orientation, gender identity or expression, disability, national origin, or record of arrest or conviction.

The Proposed Rule takes important steps toward protecting health care access for the most vulnerable individuals and communities, guarding against discrimination and denials of care. Discrimination in health care leads to adverse health outcomes and exacerbates existing health disparities in underserved communities. The antidiscrimination protections of Section 1557 are critically important to removing barriers to care for patients who already face threats and discrimination in many other aspects of their lives, including people of color; women; lesbian, gay, bisexual, transgender, and queer (“LGBTQ”) individuals; people with disabilities; and people who seek or access reproductive health care. By strengthening and clarifying these protections, the Proposed Rule advances the important goals of Section 1557, to better reflect the statutory language and purpose.

In addition to supporting the laudable proposals put forth in the Proposed Rule, the ACLU proposes that the Department of Health and Human Services' Office for Civil Rights ("HHS" or "the Department") make the following changes to better effectuate the goals of Section 1557 and the Affordable Care Act ("ACA") itself:

- Explicitly prohibit discrimination based on transgender status, as well as based on gender identity;
- Explicitly prohibit discrimination based on termination of pregnancy;
- Harmonize the definition of pregnancy related conditions with relevant regulations in Title IX;
- Ensure the framework for reviewing exemption requests requires that the Department inquire into the circumstances underlying these requests, articulate the compelling interests served by Section 1557, and take into account the burdens that exemptions would place on beneficiaries of Section 1557's protections;
- Make public any final determinations regarding exemptions that are granted, as well as ensuring that beneficiaries have notice of any exemptions granted;
- Recognize Section 1557's application to covered entities' employment practices; and
- Expand on the prohibition on discrimination through the use of clinical algorithms.

Although the focus of this comment will be limited to certain aspects of the Proposed Rule, the ACLU supports many of the Rule's advancements in prohibiting discrimination against all individuals covered by Section 1557. The ACLU applauds the Department's efforts through this Proposed Rule to recognize that the purpose of Section 1557 is to address longstanding discrimination in health care that has created numerous barriers to quality care for communities of color, people with disabilities, the LGBTQ community, and more, but especially those who sit at the intersections of these identities.

I. THE DEPARTMENT'S DEFINITION OF SEX DISCRIMINATION SHOULD INCLUDE ADDITIONAL GROUNDS OF PROHIBITED DISCRIMINATION.

The ACLU supports the Proposed Rule's definition of discrimination on the basis of sex, which makes explicit that such discrimination 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." 87 Fed. Reg. at 47916 (to be codified at § 92.101). This provision crucially clarifies Section 1557's scope of application, and the ACLU supports the explanation that the list of types of sex-based discrimination in the provision is not exhaustive. However, particularly in light of the Supreme Court's decisions in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), and *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), the Department should be even more explicit in its definition. The Department should also consider ways to harmonize the definition with Title IX regulations.

We therefore suggest that this provision be revised as follows:

"Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions, **including termination of pregnancy**; sexual orientation; **transgender status**; and gender identity."

A. The Department Should Include Discrimination Based on Gender Identity, Sexual Orientation, and Transgender Status in the Definition of Prohibited Discrimination Based on Sex.

The ACLU lauds HHS for recognizing that Supreme Court case law, including *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989), and *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), makes clear that federal sex discrimination law includes protections against discrimination based on sex stereotypes, sexual orientation, and gender identity, including transgender status. The ACLU also supports the explicit inclusion of discrimination based on sex characteristics, including intersex traits, as such discrimination is inherently sex-based. This is a welcome change, as the Section 1557 regulations finalized in 2020, titled “Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority” (the “2020 Rule”), were yet another example of the Trump Administration’s intent to undermine access to health care and target transgender individuals. 85 Fed. Reg. 37,160 (June 19, 2020).¹ The Proposed Rule reverses course, properly recognizing the protections in place for LGBTQ individuals as required by the text and intent of Section 1557.

These protections are needed to combat the discrimination that LGBTQ patients face in accessing health care. Such discrimination can take the form of patients facing categorical exclusions from health care coverage, as well as providers mistreating patients, and in some cases even refusing to treat them altogether. As a result, fearing discrimination, people postpone or avoid seeking preventative care, and even decline to access care when they are sick or injured, which can result in serious negative health consequences. As the Proposed Rule recognizes, 87 Fed. Reg. at 47,870, these consequences are exacerbated when those individuals are also members of other disadvantaged groups.

These problems persist in 2022. Data in a new report from the Center for American Progress “reveal that LGBTQI+ communities encounter discrimination and other challenges when interacting with health care providers and health insurers, underscoring the importance of strengthening antidiscrimination protections through Section 1557 of the Affordable Care Act.”² Key findings from the report include:

- Twenty-three percent of LGBTQI+ respondents, including 27 percent of LGBTQI+ respondents of color, reported that, in the past year, they postponed or avoided getting needed medical care when sick or injured due to disrespect or discrimination from doctors or other health care providers;

¹ ACLU, Comment Re: Proposed Rule at 84 Fed. Reg. 27,846, RIN 0945-AA11 titled “Nondiscrimination in Health and Health Education Programs or Activities” (Aug. 13, 2019), https://www.aclu.org/sites/default/files/field_document/aclu_comment_to_hhs_on_1557_rin_0945-aa11.pdf.

² Caroline Medina & Lindsay Mahowald, Ctr. for Am. Progress, *Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities* (2022), <https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities>.

- Overall, 15 percent of LGBQ respondents, including 23 percent of LGBQ respondents of color, reported experiencing some form of care refusal by a doctor or other health care provider in the year prior;
- Overall, 32 percent of transgender or nonbinary respondents, including 46 percent of transgender or nonbinary respondents of color, reported that they experienced at least one kind of care refusal by a health care provider in the past year;
- Fifty-five percent of intersex respondents reported that, in the past year, a health care provider refused to see them because of their sex characteristics or intersex variation;
- Overall, 30 percent of transgender or nonbinary respondents, including 47 percent of transgender or nonbinary respondents of color, reported experiencing one form of denial by a health insurance company in the past year;
- Twenty-eight percent of transgender or nonbinary respondents, including 29 percent of transgender or nonbinary respondents of color, reported that a health insurance company denied them coverage for gender-affirming hormone therapy in the year prior; and
- Twenty-two percent of transgender or nonbinary respondents, including 30 percent of transgender or nonbinary respondents of color, reported that a health insurance company denied them coverage for gender-affirming surgery in the year prior.

Since the 2020 Rule, legal developments have only further confirmed that such discrimination against LGBTQ patients constitutes discrimination based on sex. In *Bostock v. Clayton County*, the Supreme Court held that anti-LGBTQ discrimination is a form of sex discrimination prohibited under Title VII, the workplace antidiscrimination law.³ The Court explained that discrimination against a person because of their sexual orientation or because they are transgender is discrimination “because of . . . sex” under Title VII “because it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex.”⁴ As the Department recognizes in the preamble to the Proposed Rule, 87 Fed. Reg. 47,858–59, the same reasoning applies to Title IX, because both statutes require no more than “but for” causation: Title VII prohibits discrimination “because of” sex, 42 U.S.C. § 2000e–2(a)(1); Title IX prohibits discrimination “on the basis of” sex, 20 U.S.C. § 1681(a). Thus, as with Title VII, to discriminate against an individual because of their gender identity or sexual orientation is to discriminate based on sex.⁵

It is essential that the final rule track the language in *Price Waterhouse* and *Bostock* to provide assurance to participants, beneficiaries, and enrollees as well as notice to covered entities. In *Price Waterhouse*, the Court held that discrimination based on “sex

³ 140 S. Ct. 1731 (2020).

⁴ *Id.* at 1741.

⁵ See *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 616 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *cert. denied*, 141 S. Ct. 2878 (2021); U.S. Dep’t of Health and Human Servs., Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, 86 Fed. Reg. 27,984 (May 25, 2021).

stereotyping” is discrimination “on the basis of gender.”⁶ And in *Bostock*, the court held that discrimination based on “transgender status [is] inextricably bound up with sex.”⁷

The ACLU suggests that the language in § 92.101(a)(2) be amended to explicitly include transgender status. While the terms “gender identity” and “transgender status” are often used interchangeably and protections from discrimination based on gender identity *should* encompass protections for discrimination based on being transgender, entities seeking to discriminate against transgender people have pressed distinctions between the two concepts in an effort to justify their discrimination.⁸ It is therefore preferable to enumerate both in the regulatory text to track the language used in *Bostock* and to ensure that people who face healthcare discrimination because they are transgender are not forced to litigate whether they are even protected by Section 1557.

The ACLU likewise supports restoring explicit protections against sexual orientation and gender identity discrimination in regulations governing programs run by the Centers for Medicare and Medicaid Services (“CMS”) that were inexplicably removed through the 2020 version of the regulations implementing Section 1557. However, the language around sex discrimination in these CMS “conforming amendments” does not match the proposed sex discrimination language in Section 1557 itself. We encourage HHS and CMS to adopt identical language to avoid confusion and ensure consistency of implementation, including adding protections against discrimination based on transgender status.

B. The Department Should Include Discrimination Based on Pregnancy or Related Conditions, Including Termination of Pregnancy, in the Definition of Prohibited Discrimination Based on Sex.

The ACLU strongly supports the inclusion of discrimination on the basis of “pregnancy or related conditions” in the Proposed Rule’s definition of “discrimination on the basis of sex.” 87 Fed. Reg. at 47916 (to be codified at 45 C.F.R. § 92.101(a)(2)). Since HHS’s predecessor, the Department of Health, Education, and Welfare, first promulgated Title IX regulations in 1975, HHS regulations have recognized that discrimination on the basis of sex includes discrimination based on pregnancy. Accordingly, as the preamble rightly notes, 87 Fed. Reg. at 47,858, pregnancy discrimination necessarily constitutes sex discrimination under Section 1557, as the statute incorporates the prohibited grounds of sex discrimination under Title IX.⁹ Further, Title IX, as well as other civil rights statutes,

⁶ 490 U.S. 228, 250 (1989).

⁷ 140 S. Ct. at 1742.

⁸ See, e.g., *Bear Creek Bible Church v. Equal Emp. Opportunity Comm’n*, 571 F. Supp. 3d 571, 621 (N.D. Tex. 2021); *Making Admission or Placement Determinations Based on Sex in Facilities Under Community Planning and Development Housing Programs*, 85 Fed Reg 44811 (proposed July 24, 2020).

⁹ See, e.g., 45 C.F.R. §§ 86.21(c)(2), (3), 86.40(b)(1); see also *Pfeiffer v. Marion Ctr. Area Sch. Dist.*, 917 F.2d 779, 784 (3d Cir. 1990); *Hogan v. Ogden*, No. 06-CV-5078, 2008 WL 2954245, at *13 (E.D. Wash. July 30, 2008); *Chipman v. Grant Cnty. Sch. Dist.*, 30 F. Supp. 2d 975, 977–78 (E.D. Ky. 1998); *Hall v. Lee Coll.*, 932 F. Supp. 1027, 1033 n.1 (E.D. Tenn. 1996); *Cazares v. Barber*, No. 90-CV-0128, slip op. (D. Ariz. May 31, 1990); *Wort v.*

including Title VII, prohibit discrimination based on pregnancy itself, as well as pregnancy-related conditions.¹⁰

The ACLU encourages HHS to strengthen its approach to defining sex discrimination at § 92.101(a)(2) and throughout the regulatory text by explicitly noting that discrimination based on pregnancy or related conditions, *including termination of pregnancy*, is prohibited. The preamble to the Proposed Rule correctly notes that subjects of the Rule are required to comply with the specific prohibitions on discrimination found in the Title IX regulations, including 45 C.F.R. 86.40(b)(1), which enumerates some “pregnancy-related conditions,” including childbirth, false pregnancy, termination of pregnancy, and recovery therefrom. However, following the Supreme Court’s cataclysmic decision in *Dobbs v. Jackson Women’s Health*, more explicit language is needed.

Even prior to *Dobbs*, many people were not able to access abortion care due to the stigma against abortion and a coordinated effort by anti-abortion policymakers to restrict access to abortion care and coverage. Then, in *Dobbs*, the Supreme Court overturned *Roe v. Wade* and dismantled the constitutional protections for abortion that have existed for nearly 50 years. The decision has allowed anti-abortion legislatures across the country to pass or enforce laws that ban abortion and force women and others who can become pregnant into a second-class status by denying them control over their bodies and their futures.¹¹

Forcing someone to carry a pregnancy against their will has life-altering consequences, including enduring serious health risks from continued pregnancy and childbirth, making it harder to escape poverty, derailing education, career and life plans, and making it more difficult to leave an abusive partner. The impacts of pushing abortion out of reach fall disproportionately on the same women and other people who have always faced systemic barriers to care—communities of color, people living on low-incomes, undocumented immigrants, young people, the LGBTQ community, and people with disabilities. In particular, the harms will fall hardest on Black women, who are already three times more likely than white women to die during childbirth or shortly after.¹²

Given the pervasive nature of discrimination related to termination of pregnancy and stigma against abortion, particularly post-*Dobbs*, the ACLU urges HHS to specifically include termination of pregnancy along with “pregnancy or related conditions” throughout the final rule.

Vierling, No. 82-3169, slip op. (C.D. Ill. Sept. 4, 1984), *aff’d*, 778 F.2d 1233 (7th Cir. 1985).

¹⁰ See, e.g., 42 U.S.C. § 2000e(k); see also 29 C.F.R. pt. 1604; *Newport News Shipbuilding & Dry Dock Co. v. EEOC*, 462 U.S. 669 (1983).

¹¹ *An Overview of Abortion Laws*, Guttmacher Inst., <https://www.guttmacher.org/state-policy/explore/overview-abortion-laws> (last updated Sept. 24, 2022).

¹² Priya Krishnakumar & Daniel Wolfe, *How Outlawing Abortion Could Worsen America’s Maternal Mortality Crisis*, CNN (June 24, 2022), <https://www.cnn.com/2022/05/10/us/maternal-mortality-roe-wade-abortion-access/index.html>.

HHS does not define sex discrimination consistently in the Proposed Rule: sex discrimination includes “pregnancy or related conditions” at § 92.101(a)(2), but only “pregnancy” under § 92.101 and § 92.10. We urge HHS to be consistent throughout the final rule.

This section would also be strengthened if it were harmonized with the definition of “pregnancy or related conditions” that was recently proposed in the rulemaking titled “Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance,” published in the Federal Register on July 12, 2022. 87 Fed. Reg. 41,390, at 41,568. The ACLU applauded that Proposed Rule’s definitions of pregnancy, childbirth, and related medical conditions.¹³

Finally, the ACLU encourages the Department to include specific examples of what constitutes discrimination based on pregnancy or related conditions, such as discriminating against someone because they had previously had an abortion or denying health care to treat an underlying condition where the treatment could interfere with a person’s pregnancy or fertility.

II. THE DEPARTMENT SHOULD CONFIRM THE BROAD SCOPE OF SECTION 1557.

A. The Proposed Rule Correctly Declines to Import Title IX Exceptions into Section 1557.

The Proposed Rule is correct in declining to import Title IX’s exemptions, 20 U.S.C. § 1681(a), including the religious exemption, *id.* § 1681(a)(3), into Section 1557. *See* 87 Fed. Reg. at 47,840. Importing the religious exemption would allow religiously affiliated health care providers to discriminate based on sex and to refuse access to necessary medical care, in violation of the text and purpose of Section 1557.

The statute’s plain text prohibits discrimination “on the *ground* prohibited under” Title IX. 42 U.S.C. § 18116 (emphasis added). Congress did not include a religious carve-out. Indeed, in choosing to incorporate the impermissible “ground[s]” of discrimination from other civil rights statutes, Congress expressly declined to also incorporate the attendant exemptions contained in those statutes, many of which are wholly inapposite to the healthcare context. For example, in the education context, “students and families typically make a choice to attend religious educational institutions,” whereas in the health care

¹³ That proposed rule defines “pregnancy or related conditions” to mean “(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,” as well as prohibiting discrimination based on “current, potential, or past pregnancy or related conditions.” 87 Fed. Reg. 41,390, at 41,568 (to be codified at 34 C.F.R. § 106.2); *id.* at 41,571 (to be codified at 34 C.F.R. § 106.40); *id.* at 41,579 (to be codified at 34 C.F.R. § 106.57).

context, many patients have no practical alternative to a religious health care provider. 87 Fed. Reg. at 47,840.

Incorporating Title IX's exemptions would swallow Congress's antidiscrimination rule by rendering *unprotected*, via blanket exemption, precisely those patients whom Congress sought to protect. Religiously affiliated health care providers make up a significant percentage of the health care facilities in the United States. For example, "one in six hospital beds are in a Catholic facility,"¹⁴ and religious hospitals are also increasingly the *only* healthcare option in many regions. In 2011, at least 30 regions relied on a Catholic provider as their sole community hospital (a designation for hospitals that are at least 35 miles from the next-closest equivalent provider); by 2020, there were 52 such communities.¹⁵

The Proposed Rule's approach respects the careful balance between civil rights and religious liberty, maintaining fidelity to the Establishment Clause of the First Amendment. A blanket exemption would threaten access to critical care for millions of patients, especially transgender patients and patients seeking, or who have obtained, reproductive health services.¹⁶ While the right to free exercise of religion and religious accommodation is vital and has long been supported by the ACLU,¹⁷ as the Supreme Court has made clear, "[t]he principle that government may accommodate the free exercise of religion does not supersede the fundamental limitation imposed by the Establishment clause." *Lee v. Weisman*, 505 U.S. 577, 587 (1992). Incorporating Title IX's religious exemption—which would permit significant harm to patients in the name of religious exercise—would be fundamentally at odds with the constitutional commitment to the separation of church and state. *See, e.g., Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 708–10 (1985).

The Proposed Rule comports with the statutory language and these legal principles in declining to import Title IX's broad religious exemption.

¹⁴ Samantha Liss, *How the Spread of Catholic-Owned Healthcare Facilities May Complicate Access to Reproductive Care*, Healthcare Dive (July 13, 2022), <https://www.healthcarediver.com/news/catholic-hospitals-abortion-reproductive-care-restrictions/626332>; *see also* AP, *Catholic Hospitals' Growth Has an Impact on Reproductive Health Care*, NBC News (July 24, 2022), <https://www.nbcnews.com/news/us-news/catholic-hospitals-growth-impacts-reproductive-health-care-rcna39756>.

¹⁵ Tess Solomon, Lois Uttley, Patty HasBrouck & Yoolin Jung, Community Catalyst, *Bigger and Bigger: The Growth of Catholic Health Systems* 15 (2020), <https://www.communitycatalyst.org/resources/publications/document/2020-Cath-Hosp-Report-2020-31.pdf>.

¹⁶ *See* Julia Kaye, Brigitte Amiri, Louise Melling & Jennifer Dalven, ACLU, *Health Care Denied: Patients and Physicians Speak Out About Catholic Hospitals and the Threat to Women's Health and Lives* (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

¹⁷ *See, e.g.,* ACLU Defense of Religious Practice and Expression, ACLU, <https://www.aclu.org/aclu-defense-religious-practice-and-expression?redirect=defendingreligion> (last visited Oct. 2, 2022).

B. In Evaluating Requests for Exemptions, the Department Should Transparently Conduct Thorough Reviews, Recognizing the Compelling Interest in Full Enforcement of Section 1557’s Antidiscrimination Provisions.

The Proposed Rule would create a framework for recipients of federal funding, covered by Section 1557, to notify the Department that they believe they are exempt from provisions of Section 1557’s implementing regulations under certain federal refusals laws and religious freedom laws. *See* 87 Fed. Reg. at 47,885; *id.* at 47,918 (to be codified at 45 C.F.R. § 92.302). The final rule should ensure that the process for receiving and assessing notices from entities seeking exemptions is structured to promote equity and transparency, and to ensure compliance with relevant legal requirements. Moreover, it should make clear that exemptions must be granted only if consistent with the Establishment Clause and only if otherwise required by law, so as not to conflict with the language and purpose of Section 1557.

The Establishment Clause cabins the government’s ability to grant religious exemptions or accommodations to Section 1557’s requirements, prohibiting exemptions or accommodations that would harm the beneficiaries of Section 1557’s protections, as discussed above. Moreover, granting exemptions from the antidiscrimination provisions of Section 1557, for any reason, would undercut the effectiveness of the statute by making it harder for vulnerable populations who have often faced significant barriers—particularly women, those with limited economic resources, LGBTQ people, religious minorities, nonreligious people, and other historically marginalized populations—to get access to the services they need. Exemptions would thus thwart the very goal of Section 1557, to promote equitable access to health care.

In evaluating requests for exemptions, the Department should thoroughly inquire into the circumstances underlying the requests, articulate the compelling interests served by Section 1557, and take into account the burdens that the exemption would place on beneficiaries of Section 1557’s protections. Additionally, the Department should make public any final determinations regarding granted exemption requests, and ensure that beneficiaries have notice of any exemptions granted.

1. *HHS Should Weigh Requests for Exemptions Against Section 1557’s Compelling Purpose, Granting Exemptions Only If Unambiguously Required by Law.*

Exemptions to the antidiscrimination requirements of Section 1557 should be narrowly circumscribed so as not to jeopardize the quality and availability of the services beneficiaries seek, thereby undermining the efficacy of the health programs covered by the law. The framework proposed by the Department allows covered entities to argue that complying with antidiscrimination requirements, providing all the required services, or serving everyone who meets neutral criteria would burden their religious exercise in violation of the Religious Freedom Restoration Act (“RFRA”),¹⁸ among other federal refusals laws and religious freedom laws. *See* 87 Fed. Reg. at 47,841. When an exemption under RFRA is sought, the Department is permitted—indeed required—to inquire into the

¹⁸ 42 U.S.C. § 2000bb *et seq.*

circumstances underlying the request. Such inquiries should be conducted in a manner that respects and does not evaluate the merits of the religious beliefs. The Department must ensure that:

- there is a logical tie between the asserted burden and a religious belief;¹⁹
- the religious belief is sincerely held;²⁰
- the burden is “substantial” as a legal matter;²¹ and
- the requested exemption is tailored to address the burden.

The Department *may not* take the covered entity at its word without any review, nor may it create broad categorical exemptions for hypothetical burdens. Doing so would violate the strictures of RFRA.

As an initial matter, RFRA applies only where a law imposes a “substantial burden” on the exercise of sincerely held religious beliefs.²² Minimal burdens do not trigger RFRA protection, and RFRA requires a careful, individualized review as to the substantial burden question.

If the Department verifies that a substantial burden exists on a particular claimant’s religious exercise, the rest of RFRA comes into play: The government regulation must “further a compelling government interest” using the “least restrictive means.”²³ Given the sheer import of the protections offered by Section 1557, the Department should—in most instances—be able to meet its burden in denying a requested accommodation. For Section 1557’s antidiscrimination requirements, there is a compelling interest in eradicating, and not using taxpayer money to subsidize, discrimination.²⁴ Moreover, the

¹⁹ See, e.g., *Mahoney v. Doe*, 642 F.3d 1112, 1121 (D.C. Cir. 2011).

²⁰ Agencies may make inquiries into the sincerity of the asserted beliefs, although they may not pass judgment on whether those beliefs are correct or reasonable, as a religious matter. See, e.g., *Holt v. Hobbs*, 574 U.S. 352, 369 (2015) (emphasizing under RFRA’s sister statute, RLUIPA, it was proper to investigate whether inmate was using religious claim to “cloak illicit conduct”); see also EEOC Compliance Manual on Religious Discrimination, §§ 12-I(A)(2)-(A)(3) (2021) (explaining that employers may inquire into sincerity of religious beliefs of employees or applicants who request religious accommodation).

²¹ See, e.g., *EEOC v. R.G. & G.R. Harris Funeral Homes, Inc.*, 884 F.3d 560, 588 (6th Cir. 2018) (“Most circuits . . . have recognized that a party can sincerely believe that he is being coerced into engaging in conduct that violates his religious convictions without actually, as a matter of law, being so engaged.”), *aff’d*, *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731 (2020) (RFRA claims were not at issue in Supreme Court case); see also, e.g., *Bowen v. Roy*, 476 U.S. 693, 702–03 (1986); *Hernandez v. C.I.R.*, 490 U.S. 680, 699 (1989) (noting that while it “is not within the judicial ken to question the centrality of particular beliefs or practices to a faith, . . . [we] have doubts whether the alleged burden imposed . . . is a substantial one”).

²² See 42 U.S.C. § 2000bb-1(a)

²³ 42 U.S.C. § 2000bb-1(b).

²⁴ See *Roberts v. U.S. Jaycees*, 468 U.S. 609, 623 (1984).

Department has a compelling interest in specifically meeting the ACA’s goals “of expanding access to affordable and quality health care,” by ensuring that Section 1557’s antidiscrimination protections apply broadly. 87 Fed. Reg. at 47,870. When responding to a notice or request for exemption that must be denied, the Department should clearly and thoroughly explain these asserted interests, including supporting them with empirical evidence where possible. Officials should detail why, under the particular circumstances presented, granting an exemption would impede the Department’s ability to achieve its compelling interests, and officials must be prepared to explain how granting that *particular* exemption would undermine those interests. Department officials will also need to demonstrate that these requirements are narrowly tailored to meet the governmental interests under the ACA and Section 1557, specifically, and why an exemption could not be granted under the circumstances before them.

Notably, prior court cases granting exemptions to Section 1557 pursuant to RFRA do not control the Department’s future determinations, where the government never asserted a compelling governmental interest in denying the exemptions Section 1557 during the course of the litigation.²⁵

The government’s ability to provide religious accommodations and exemptions—including under RFRA—is not unlimited. When considering an exemption, the Department “must take adequate account of the burdens” that the exemption would place on third parties and must ensure that the exemption is “measured so that it does not override other significant interests.”²⁶ The individuals protected by Section 1557 are harmed if they are denied health care or insurance coverage, or they may be discouraged from seeking them in the first place because they could face discrimination when doing so.²⁷ These vulnerable

²⁵ See, e.g., *Franciscan All., Inc. v. Becerra*, 553 F. Supp. 3d 361, 376 (N.D. Tex. 2021), *amended*, No. 7:16-CV-00108-O, 2021 WL 6774686 (N.D. Tex. Oct. 1, 2021), and *aff’d in part, dismissed in part*, 47 F.4th 368 (5th Cir. 2022); *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1148 (D.N.D. 2021), *judgment entered sub nom. Religious Sisters of Mercy v. Cochran*, No. 3:16-CV-00386, 2021 WL 1574628 (D.N.D. Feb. 19, 2021).

²⁶ *Cutter v. Wilkinson*, 544 U.S. 709, 720, 722 (2005).

²⁷ See Off. of Disease Prevention & Health Promotion, U.S. Dep’t of Health & Hum. Servs., *Healthy People 2030: Discrimination*, <https://health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/discrimination#cit9> (last visited Sept. 26, 2022); Jaime M. Grant et al., *Nat’l Gay & Lesbian Task Force & Nat’l Ctr. for Transgender Equality, Injustice at Every Turn: A Report of the National Transgender Discrimination Survey 72* (2011), https://transequality.org/sites/default/files/docs/resources/NTDS_Report.pdf (transgender and nonbinary patients experiencing discrimination delayed needed medical care); Lambda Legal, *When Health Care Isn’t Caring: Lambda Legal’s Survey on Discrimination Against LGBT People and People Living with HIV 12* (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf (“[P]erceived bias by health care providers can cause LGBT people and people living with HIV to become . . . reluctant to seek care.”); see also Mark L. Hatzenbuehler, Jo C. Phelan & Bruce G. Link, *Stigma as a Fundamental Cause of Population Health Inequalities*, 103 *Am. J. Pub. Health* 813 (2013),

individuals lose out on getting the critical services they need and to which they are entitled under the ACA; and they have to deal with the humiliation and stigma of discrimination. Exemptions that would materially harm those protected from discrimination by Section 1557 are not and cannot be required under RFRA because they would violate the Establishment Clause by forcing individuals to suffer harm to facilitate another's religious practices.²⁸

Finally, the Department should always handle requests for religious exemptions neutrally and respectfully. The Department should be mindful not to disparage religious beliefs and should not treat religiously affiliated applicants differently from other applicants.²⁹

2. HHS Should Make Public Any Exemptions Granted and the Grounds for Those Determinations.

The Department should make publicly available any exemptions from the antidiscrimination mandates of Section 1557 that are granted under proposed § 92.302, as well as the grounds for those determinations. In addition to generally promoting transparency, this would provide guidance both to providers and patients regarding their rights and responsibilities under Section 1557, reducing confusion that can inhibit equitable access to care, particularly for the vulnerable populations the Rule is designed to protect.

It is important that individuals seeking care and coverage know whether the providers they are considering will, in fact, provide the services they need—including whether they will be presented with all available care options—and whether they will feel accepted and welcome by the provider they see. As the Department notes, “health care consumers are not always aware that the health care entities from which they seek care may be limited in the care they provide.” 87 Fed. Reg. at 47,840–41. It is thus important to make public the Department's determinations under § 92.302 that a covered entity is entitled to an exemption, including the reasoning and relevant factual circumstances underlying the final disposition. Accordingly, such determinations should be made public within 10 days by notice in the Federal Register and posting on the Department's website. The notice should be accompanied by an electronic link to documents that specifically state the nature, scope, and duration of the exemption granted.

As discussed above, any exemptions should be narrowly drawn, only to the extent required by law. The scope of these exemptions should be made clear to individuals who may be unsure of their rights in seeking care or insurance coverage with a covered entity.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3682466> (examining the health consequences of stigma).

²⁸ See, e.g., *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 693, 729 n.37 (2014); *id.* at 739 (Kennedy, J., concurring); *Cutter*, 544 U.S. at 720, 726; *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989); *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 708–10 (1985).

²⁹ See *Masterpiece Cakeshop, Ltd. v. Colorado C.R. Comm'n*, 138 S. Ct. 1719, 1731 (2018).

In this context, transparency surrounding the grant of exemptions under § 92.302 would promote equitable access to care.

In the same vein, the notice of nondiscrimination requirement in § 92.10 should include a provision that any entity receiving any exemption under § 92.302—whether religious or other—include the existence and scope of such exemption in its notices to patients and prospective patients. It would be misleading and inaccurate to require entities to tell participants, beneficiaries, and the public that the entity does not discriminate if the entity does, in fact discriminate, in certain circumstances and has been granted permission to do so.

C. Section 1557’s Scope of Application Is Broad, Including Health Insurance.

The ACLU supports the Proposed Rule’s application of Section 1557’s antidiscrimination protections to “[e]very health program or activity, any part of which receives Federal financial assistance, directly or indirectly, from the Department.” 87 Fed. Reg. at 47,911 (to be codified at 45 C.F.R. § 92.2). The Department is correct to roll back the 2020 Rule’s limitations on the type of entities covered by the provision, as that rule sanctions discriminatory denials of coverage, causing confusion and serious harm to those unable to access care.

With the Proposed Rule, the Department properly recognizes that health insurers are “engaged in the business of providing healthcare.” 45 C.F.R. § 92.3(c). The 2020 Rule’s exclusion of health insurance was contrary to the text of the statute and the broader antidiscrimination purpose of the law. Congress spoke clearly in passing Section 1557: “[A]n individual shall not . . . be excluded from participation in, be denied the benefits of, or be subject to discrimination under, *any* health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance” 42 U.S.C. § 18116 (emphasis added). Congress meant what it said. The purpose of Section 1557 is to provide broad antidiscrimination protections to patients in all aspects of health care delivery, and the Proposed Rule reflects that purpose.

The 2020 Rule’s limitations contravene not only the text of the statute, but also the approach Congress adopted in the Civil Rights Restoration Act of 1987 (“CRRA”), which amended the four civil rights laws referenced in Section 1557. In the CRRA, Congress defined “program or activity” to mean “all of the operations of . . . an entire corporation, partnership, or other private organization, or an entire sole proprietorship . . . which is principally engaged in the business of providing,” *inter alia*, a range of social and health services. Pub. L. 100-259, 102 Stat. 28 (1988). Congress thus made clear that if any part of a program or activity receives Federal financial assistance, the *entire* program or activity must comply with the antidiscrimination mandates that form the basis of Section 1557. *See generally* 81 Fed. Reg. at 31,385. The Proposed Rule’s rejection of the 2020 Rule’s arbitrary distinctions more consistently furthers the statutory purpose of Section 1557 by protecting more individuals from being denied coverage of and access to health care.

D. Section 1557 Should Apply to Covered Entities' Employment Practices.

The Proposed Rule provides that the protections against discrimination offered by Section 1557 do not apply to the employment practices of entities covered by Section 1557. 87 Fed. Reg. at 47,911 (to be codified at 45 C.F.R. § 92.2(b)). Neither the language nor the spirit of Section 1557's directive warrants such selective applicability, and such selectivity will come at the expense of those the statute aims to protect.

Section 1557's antidiscrimination provision is written broadly, and incorporates Title IX and Section 504 of the Rehabilitation Act—both of which cover employment discrimination. There is thus no statutory reason to limit Section 1557's application to the employment practices of covered entities. Conversely, there is a crucial gap in antidiscrimination protections that Section 1557 can remedy: For example, Title VII assures no protections against discrimination with respect to employees' dependents in health insurance.³⁰ As Section 1557 was intended to remedy longstanding disparities in access to critical health services, disparities not remedied by existing antidiscrimination laws, this is the exact type of disparity that should be covered by Section 1557. For instance, an employer that objects to teenagers becoming parents could exclude coverage for maternity care for dependents without running afoul of Title VII's ban on sex discrimination, while Section 1557 would prohibit such an exclusion if construed as recommended here. Other objections to certain healthcare for minors, from access to contraception to treatment for gender dysphoria, also would be beyond the reach of Title VII's existing discrimination provision.

In proposing to limit the reach of Section 1557, the Department rests on concerns about avoiding confusion by individuals as to which law offers them protection. But that is not justification for a rule that would actually eliminate antidiscrimination protections in some cases. These administrative concerns should not override Section 1557's purpose and the health of those who will continue to be denied care under the Department's proposal.

Accordingly, the Department should not limit the applicability of Section 1557 to exclude employers' employment practices, *in particular* employers' provision of health benefits.

III. THE DEPARTMENT SHOULD EXPAND ON THE PROHIBITION ON DISCRIMINATION THROUGH THE USE OF CLINICAL ALGORITHMS.

The ACLU supports the Proposed Rule's prohibition on discrimination through the use of clinical algorithms. 87 Fed. Reg. 47918 (to be codified at 45 C.F.R. § 92.210). Of particular concern is the use of race-based clinical algorithms, which have no place in health or medical care. Many clinical algorithms are biased in that patients of color must be more ill than white patients before they can receive treatment for a range of life-threatening conditions, including for kidney disease, heart failure, and pregnancy-related complications. Race is not an appropriate proxy for genetics nor does it represent any kind

³⁰ See, e.g., *Tovar v. Essentia Health*, 857 F.3d 771, 774-79 (8th Cir. 2017); *Scott v. St. Louis Univ. Hospital*, --- F. Supp. 3d ---, 2022 WL 1211092, at *3-6 (E.D. Mo. Apr. 25, 2022); *Kadel v. Folwell*, 446 F. Supp. 3d 1, 11-12, 17 (M.D.N.C. 2020).

of “objective biological reality.”³¹ This bias directly leads to discrimination. The ACLU’s recently published white paper, entitled “AI in Health Care May Worsen Medical Racism,” discusses this as well as other necessary changes to curb discrimination in care.³² In addition to medical racism, the white paper outlines other scenarios where discrimination on the basis of disability status, immigration status, income, sex, and gender identity may occur through the use of medical artificial intelligence (“AI”).³³ For instance, an algorithm that allocates treatments with the goal of extending patients’ lifespans could decide to recommend treatments only to women since women tend to live longer than men do. Examples of similar algorithms that raise concerns about discriminatory impact in other contexts abound due to the fact that AI learns from past data that are often biased.³⁴

While the Proposed Rule represents a vital and long overdue step towards combating bias in health and clinical care, it still falls short of addressing the ubiquity of algorithmic decision-making in medical and clinical care. To start, HHS must define the term “clinical algorithms” because it may otherwise be construed too narrowly. Additionally, the Proposed Rule does not address the many other ways in which algorithmic decision-making outside the scope of the term “clinical algorithm” may also be leading to discriminatory outcomes. The Department must broaden the provision to prohibit discrimination through the use of any form of automated decision-making system, including AI or machine learning tools. These tools can lead to discrimination just as clinical algorithms can: A recent study found that an AI tool trained on medical images, like x-rays and CT scans, had unexpectedly learned to discern patients’ self-reported race.³⁵ It learned to do this even when it was only trained with the goal of helping clinicians diagnose patient

³¹ Koffi N. Maglo, Tesfaye B. Mersha & Lisa J. Martin, *Population Genomics and the Statistical values of Race: An Interdisciplinary Perspective on the Biological Classification of Human Populations and Implications for Clinical Genetic Epidemiological Research*, 7 *Frontiers in Genetics* 1 (2016).

³² Crystal Grant, ACLU, *AI in Health Care May Worsen Medical Racism*, https://www.aclu.org/sites/default/files/field_document/algo_health_white_paper_draft_final_v4.pdf.

³³ *Id.* at 3.

³⁴ See, e.g., Jeffrey Dastin, *Amazon Scraps Secret AI Recruiting Tool That Showed Bias Against Women*, Reuters (Oct. 10, 2018), <https://www.reuters.com/article/us-amazon-com-jobs-automation-insight/amazon-scraps-secret-ai-recruiting-tool-that-showed-bias-against-women-idUSKCN1MK08G> (noting that AI-based hiring tool developed by Amazon penalized resumes that included the word “women’s” and downgraded graduates of all-women’s colleges); Rhema Vaithianathan et al., *Implementing a Child Welfare Decision Aide in Douglas County: Methodology Report 15* (2019), https://csda.aut.ac.nz/_data/assets/pdf_file/0009/347715/Douglas-County-Methodology_Final_3_02_2020.pdf (reporting that a screening tool in Colorado considers participation in public benefit programs like Temporary Assistance for Needy Families in recommending whether to investigate a referral about possible child maltreatment).

³⁵ *AI Systems Can Detect Patient Race, Creating New Opportunities to Perpetuate Health Disparities*, Emory Univ. News Ctr. (May 27, 2022), https://news.emory.edu/stories/2022/05/hs_ai_systems_detect_patient_race_27-05-2022/story.html.

images. Such a tool could unintentionally direct worse care to communities of color without detection or intervention.

Additionally, the Department should specify actions covered entities can take to mitigate discriminatory outcomes. Such actions include the following:

Consider whether tools are used as intended. When using clinical tools, covered entities should consider whether: they are being used for clinical applications without FDA approval or clearance, they are being used on patient populations they were not intended for, and cleared tools are being used outside of their intended use cases—something the FDA recently cautioned against.³⁶ A 2019 study shows how employing a tool outside of its use case can lead to discrimination. The study found that a clinical algorithm many hospitals were using to decide which patients need care was showing racial bias— Black patients had to be deemed much sicker than white patients to be recommended for the same care.³⁷ This happened because the algorithm had been trained on past data on health care spending, which reflect a history in which Black patients had less to spend on their health care compared to white patients, due to longstanding wealth and income disparities. Further, an algorithm with a specific use—determining the likely expenses incurred by a patient—was being employed outside of this use, to infer medical needs of the patient. Covered entities should be warned against employing such algorithms and other tools outside of their use cases to avoid such outcomes.

Requiring that tools be assessed prior to use. If the covered entity is using a commercial clinical tool not regulated by the FDA, they should, at minimum, ensure the tool has been evaluated in a peer-reviewed study on a population representative of their patient population and has not been shown to reflect racial and ethnic bias. For non-commercial tools like those developed in-house, entities should at minimum perform assessments around the effects of the tool’s use in different patient populations and the potential sources of bias in the training data. This requirement can be made part of the covered entity’s accreditation process and quality monitoring metrics in order to ensure compliance.

Providing resources and databases to evaluate whether tools are discriminatory. HHS should partner with other government agencies to provide guidance on which tools are not discriminatory as well as resources to allow covered entities to test their in-house tools for biases. HHS should also maintain a central database of instances (litigation, academic research, patient and clinician feedback, etc.) suggesting that an algorithm may be discriminatory and must include information on changes made to the tool post-market including errors detected and how and when those errors were addressed. These data on real-world performance of these tools post deployment will be vital in determining if they have begun to cause discriminatory effects.

³⁶ *Intended Use of Imaging Software for Intracranial Large Vessel Occlusion – Letter to Health Care Providers*, FDA (Apr. 11, 2022), <https://www.fda.gov/medical-devices/letters-health-care-providers/intended-use-imaging-software-intracranial-large-vessel-occlusion-letter-health-care-providers>.

³⁷ Ziad Obermeyer, Brian Powers & Sendhil Mullainathan, *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations*, 366 *Sci.* 447 (2019).

Continuing education in the proper use of algorithms and AI tools. Medical and clinical educators, professional societies, and covered entities must establish some proficiency in algorithmic decision-making and AI topics for clinical staff in order to standardize the use of these clinical tools. These teachings must mention sources of bias already in medicine and ways this bias will be encoded into AI tools and clinical algorithms; this could help providers exercise caution before using a tool on a population or in a context for which it wasn't originally designed. Clinicians, their education around technology, and the use of this technology in health care all form an interconnected system. Incorporating lessons about the inner workings of AI and algorithmic decision-making tools and their limitations into clinical education may also help lessen the human tendency to attribute too much authority to decisions made by algorithms.³⁸ Moreover, as clinical algorithms begin to change,³⁹ clinicians will need to be trained in the details of applying the updated algorithms.

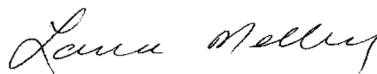
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We greatly appreciate the efforts by HHS to undo the harmful aspects of the 2020 Rule, and end discrimination in healthcare. Once put in place through a final rule, these protections will positively impact the health and well-being of millions of people in the United States. We look forward to our continued work with HHS to implement our proposed changes and ensure swift implementation of the final rule.

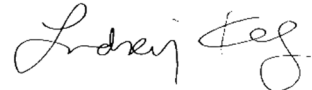
Sincerely,



Christopher E. Anders
Federal Policy Director



Louise Melling
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Lindsey Kaley
Staff Attorney

³⁸ Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, 185 Sci. 1124 (1974).

³⁹ *U.S. Laboratories Endorse Race-Free Equations*, Nat'l Kidney Found. (Feb. 8, 2022), <https://www.kidney.org/news/u-s-pathology-and-laboratory-society-leadership-endorses-nkf-asn-joint-task-force>.