

April 6, 2022

**EO 12866 Meeting
Nondiscrimination in Health Programs and Activities
RIN: 0945-AA17**

**Rachel N. Morrison and Roger Severino
HHS Accountability Project
Ethics & Public Policy Center**

Thank you for the opportunity to provide comments on OIRA’s review of the Section 1557 proposed rule, “Nondiscrimination in Health Programs and Activities.”

As OMB cancelled a previous EO 12866 meeting for a different rule it had scheduled with EPPC,¹ we are glad you are willing to hear EPPC scholars’ input on this rule.

Today, we will share several points of interest to OIRA and HHS.

1. There is no need for federal regulatory action.

- We expect OCR will propose that health care practitioners and insurance companies will be required to treat people consistent with their self-identified gender identity “in all respects” without any requirement that a person so identifying has undergone any “transition” treatments or surgeries, dresses or acts in any particular manner, have any diagnosis of gender dysphoria, or have a legal name or birth certificate change. The expected changes in the proposed rule are not about people being barred from receiving healthcare due to irrelevant immutable characteristics such as race. Rather, if the proposed rule, as expected, redefines sex discrimination to include sexual orientation and gender identity the proposed rule would not be about discrimination in any traditional sense because LGBT persons are not being denied healthcare based solely on their self-identified status. Statements and actions from HHS confirm that this proposed rule will be about smuggling in a new standard of care into medicine and imposing a requirement for gender transition procedures under cover of nondiscrimination. While Director of OCR, I (Roger Severino) reviewed the evidence and found no denials of access based on identity sufficient to justify regulatory intervention. Let’s not be coy about this rule’s real goals—to require doctors to perform experimental gender transition surgeries and treatments on adults and minors and to require everyone’s insurance plans to pay for them. Because neither law, policy, nor science support such an extreme inversion of medicine, we request the Agency abandon all efforts at amending the Section 1557 Rule.

¹ Rachel Morrison, *Biden and Becerra Kill Democratic Norms in Rush to Fund Big Abortion*, NATIONAL REVIEW (Oct. 8, 2021), <https://www.nationalreview.com/bench-memos/biden-and-becerra-kill-democratic-norms-in-rush-to-fund-big-abortion/>.

- EO 12866, section 1(b) establishes the principles of regulation, including that “Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.” HHS’s forthcoming Section 1557 proposed rule will likely seek to replace the 2020 Section 1557 Rule. There is no evidence that the 2020 Rule has or will cause any harms or burdens necessitating the need for this rulemaking. To justify replacing the 2020 Rule, HHS must provide specific evidence as to how that Rule is causing harms or burdens.
- The policies HHS is proposing can have devastating impact in the real world. For example, we recommend you listen to Yaeli’s story, linked below.²

2. No regulatory action should be taken on the issue of abortion before the Supreme Court decision in *Dobbs*.

- The 2016 Section 1557 Rule included “termination of pregnancy” within its definition of “sex discrimination” and HHS has indicated it will do the same in this proposed rule.
- HHS should hold the proposed rule until after the Supreme Court issues its decision in *Dobbs v. Jackson Women’s Health Organization* (U.S. No. 19-1392). At issue in that case is the scope of lawful abortions within the United States. If, as many anticipate, the Supreme Court overturns *Roe v. Wade* and returns the issue to the legislatures, various states and perhaps Congress will have different definitions of what type of abortions are lawful. Moreover, many of the conscience protection laws, such as the Church Amendments, depend on the definition of “lawful abortion.”
- For HHS to act prior to the Supreme Court’s forthcoming decision in *Dobbs* would be arbitrary and capricious as that opinion could greatly impact the analysis, application, and enforcement of Section 1557. Publishing agency positions on an issue a short time period before the Supreme Court rules on an issue identified as being relevant can lead to legal vulnerability and potential invalidation.
- At a minimum, the public should have sufficient time to provide meaningful public comment after the Supreme Court issues its decision in *Dobbs*.

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

- To the extent the Department is planning to issue regulations related to the use of pronouns, HHS should hold this proposed rule until after the Supreme Court issues its decision in *303 Creative LLC v. Elenis* (U.S. No. 21-476). That case, which will be argued during the October 2022 term, involves the issue of government-compelled speech related to marriage and sexuality under the First Amendment.

² *Protecting Our Children: How Radical Gender Ideology is Taking Over Public Schools & Harming Kids*, HERITAGE FOUNDATION (Mar. 7, 2022), <https://www.heritage.org/gender/event/protecting-our-children-how-radical-gender-ideology-taking-over-public-schools-harming> (testimony of mother who lost custody of daughter after not supporting daughter’s medical transition; after medical transition, daughter took her own life by standing on railroad tracks where an oncoming train struck her and killed her).

- For HHS to act pm the issue of pronouns prior to *303 Creative* is resolved by the Court would be arbitrary and capricious as that opinion could greatly impact analysis, application, and enforcement of Section 1557 as it relates to pronouns. As we saw with *Bostock*, publishing agency positions on an issue a short time period before the Supreme Court rules on an issue identified as being relevant can lead to legal vulnerability and potential invalidation.
- At a minimum, the public should have sufficient time to provide meaningful public comment on the issue of pronouns after the Supreme Court issues its decision in *303 Creative*.

4. The Rule should recognize that “sex” under Section 1557 means “biological sex,” not “gender identity.”

- HHS’s National Institutes of Health (NIH) matter-of-factly states that “every cell has a sex.” As of this writing, NIH still requires its 80,000 research grant applicants to account for sex as a biological variable in all animal and human studies. That’s because it knows that a person’s immutable sexual biology explains in significant part why men and women respond differently to medication, vary in their experience and manifestation of pain, and have disparate susceptibility to illnesses, from heart disease and cancer to psychological conditions such as depression and anxiety. But sex in medicine and research is to be replaced by subjective “gender identity,” male and female by a never-ending spectrum, biology by placeholders assigned at birth and mothers by “birthing persons.” Indeed, in a document just issued by the HHS Office of Population Affairs it defined “gender identity” as “one’s internal sense of self as man, woman, both or neither.”³
- Section 1557 depends on Title IX as the source for its prohibition on sex discrimination and adopts Title IX’s enforcement mechanisms.⁴
- Title IX and its accompanying regulations recognize the fact of biological sexual difference and presuppose “sex” as a binary classification of male or female.⁵ This is clearly shown by the following statutory and regulatory references:
 - Title IX provisions are not to be construed as prohibiting an educational institution “from maintaining separate living facilities for the different sexes”⁶;
 - “an institution which admits only students of one sex to being an institution which admits students of both sexes”⁷;

³ Office of Population Affairs, U.S. Dep’t Health & Hum. Servs., Gender Affirming Care and Young People (Mar. 2022), <https://opa.hhs.gov/sites/default/files/2022-03/gender-affirming-care-young-people-march-2022.pdf>.

⁴ 42 U.S.C. § 18116(a) (citing Title IX, 20 U.S.C. § 1681 *et seq.*).

⁵ Office for Civil Rights, U.S. Dep’t Educ., *Title IX and Sex Discrimination* (last modified Jan. 10, 2020), https://www2.ed.gov/about/offices/list/ocr/docs/tix_dis.html.

⁶ 20 U.S.C. § 1686.

⁷ 20 U.S.C. § 1681(a)(2).

- references to “men’s” and “women’s” associations, as well as organizations for “boys” and “girls” in the context of organizations, “the membership of which has traditionally been limited to persons of one sex”⁸;
 - references to “boys” and “girls” conferences⁹;
 - “separation of students by sex within physical education classes or activities”¹⁰;
 - “classes in elementary and secondary schools that deal primarily with human sexuality may be conducted in separate sessions for boys and girls”¹¹; and
 - “separate teams for members of each sex where selection for such teams is based upon competitive skill or the activity involved is a contact sport.”¹²
- Although Title IX recognizes the binary nature of sex and its biological reality in things like sports and intimate facilities, under what we expect OCR is proposing, a person will have to be treated consistent with stated gender identity “in all respects.” This requirement would contradict enforcement under Section 1557 in the Larry Nasser sex abuse case since the resolution agreement requires that patients be offered chaperones of the sex of the patients’ choice.
 - Title IX prohibits sex discrimination except where its application would be inconsistent with the religious tenets of the institution.¹³ Section 1557’s sex discrimination prohibition likewise does not apply to religious institutions where application would be inconsistent with their religious tenets. This exemption should be fully recognized in Section 1557 regulations because it is part of the incorporation of enforcement mechanisms required by the text of Section 1557.
 - Despite all this, HHS indicated in a 2021 “notification of interpretation and enforcement” that it intends to propose rules that re-interpret “sex” under Section 1557 to include “gender identity.”¹⁴ Before HHS proceeds down that path, it must do the following:
 - Address the inherent contradiction of re-interpreting “sex” (an immutable reality) to include “gender identity” (subjective self-identifier based on a person’s rejection of their own biological sex).
 - Provide a rationale for any re-definition of “sex” in terms inherently contradictory to the statutory intent of Title IX and Section 1557.
 - Provide a legal justification for a re-interpretation that effectively privileges “gender identity” over sexual identity (biological sex) and threatens to ignore the conscience and religious rights of medical professional and faith-based health care providers.

⁸ 20 U.S.C. § 1681(a)(6)(B).

⁹ 20 U.S.C. § 1681(a)(7)(A).

¹⁰ 34 CFR § 106.34.

¹¹ *Id.*

¹² 34 CFR § 106.41.

¹³ 20 U.S.C. § 1681(a)(3); 34 C.F.R. § 106.12.

¹⁴ U.S. Dep’t Health & Human Servs., Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972 3 (May 10, 2021), <https://www.hhs.gov/sites/default/files/ocr-bostock-notification.pdf>.

5. Section 1557 was not amended by *Bostock*, and *Bostock* does not support the need for regulatory action.

- Without going through the notice and comment process, on May 10, 2021, HHS unilaterally issued a “notification of interpretation and enforcement,” stating: “Consistent with the Supreme Court’s decision in *Bostock v. Clayton County* and Title IX, beginning today, OCR will interpret and enforce Section 1557’s prohibition on discrimination on the basis of sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity.”¹⁵
- To the extent HHS is relying on *Bostock* as the legal impetus for issuing the anticipated proposed rule, that basis is deficient. *Bostock* requires no such regulatory action.
- *Bostock* was neither a Section 1557 nor a Title IX case. Rather, in *Bostock* the Supreme Court held that under Title VII “an employer who fires someone simply for being homosexual or transgender has discharged or otherwise discriminated against that individual ‘because of such individual’s sex.’”¹⁶ The Court specifically cabined its decision to the hiring/firing context under Title VII, explicitly stating it was not addressing other Title VII issues or other laws and would not prejudge those questions.¹⁷
- Likewise, HHS should not prejudge those questions. *Bostock*’s Title VII analysis cannot apply to Title IX, and by extension Section 1557, because Title IX has a different sex-specific structure and, unlike Title VII, uses language based on a biological binary, as detailed above.
- Moreover, to the extent HHS chooses to rely on *Bostock*, that decision rested on the assumption that “sex” refers only to the “biological distinctions between male and female.”¹⁸ To be consistent with *Bostock*, any definition of “sex” that HHS proposes must also and continue to be “biological distinctions between male and female” and cannot assume a gender spectrum, fluidity, or non-binary.
- Further, the Majority in *Bostock* used the term “transgender status,” and did not adopt “gender identity” as a protected class. Thus, HHS cannot rely on *Bostock* to support the inclusion of the term “gender identity” within the definition of “sex discrimination” under Section 1557 (or Title IX).

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

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

¹⁵ *Id.*

¹⁶ 140 S. Ct. 1731, 1737 (2020).

¹⁷ *Id.* at 1753.

¹⁸ *Id.* at 1739.

proposed Title IX rule.¹⁹ Both rules concern interpretation of Title IX’s application to sexual orientation and gender identity, and Title IX and Section 1557 have significant overlap concerning their application to educational institutions that receive health funding. How ED defines the ground of sex discrimination under Title IX in its proposed regulations (currently under review at OMB) could have direct impact for Section 1557, its regulations, and the health care context.²⁰

- The insurance regulations proposed by HHS’s Centers for Medicare & Medicaid Services (CMS) in January that would, in part, mandate under various nondiscrimination provisions insurance coverage of sterilizing gender transition surgeries and hormones, including for minors, should also be joined with the Section 1557 rule.²¹ While disclaiming reliance on Section 1557, the nondiscrimination requirements for insurance coverage and plans proposed in the CMS rule clearly overlap with Section 1557’s requirements for nondiscrimination in insurance coverage and plans. At a minimum, the portions of the CMS rule dealing with sexual orientation and gender identity should be held for finalization until the finalization of this rule.
- Because this proposed rule will have implications for conscience and religious freedom rights, it should be considered jointly with HHS’s proposed rescission of the 2019 Conscience Rule, which could impact the conscience and religious freedom protections recognized and enforced by the Department, including in relation to Section 1557 claims.²²
- Under Executive Order 12250, the Department of Justice is required to coordinate the implementation of any regulations implementing nondiscrimination provisions of Title IX or of “[a]ny other provision of Federal statutory law which provides, in whole or in part, that no person in the United States shall, on the ground of sex, be excluded from participation in, be denied the benefits of, or be subject to discrimination under any program or activity receiving Federal financial assistance.”
- Inconsistency in implementation of discrimination on the basis of sex across agencies, across programs, or in this case within an agency between CMS and OCR, could lead to legal vulnerability.
- In particular, an overly simplistic legal justification for imposing nondiscrimination on the basis of sexual orientation and gender identity across different statutes that have different wording, such as Title IX and Title VII, and across different kinds of programs such as non-health programs through the Department of Education, or health programs through HHS, could lead to legal vulnerability of all of those provisions.

¹⁹ Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance, RIN 1870-AA16.

²⁰ See <https://eppc.org/wp-content/uploads/2022/03/EPPC-Scholars-Comment-Title-IX-Rule-EO-12866-Meeting.pdf>.

²¹ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, CMS-9911-P, RIN 0938-AU65; see <https://eppc.org/publication/eppc-scholars-submit-public-comment-opposing-hhs-proposed-insurance-mandate-for-transgender-puberty-blocking-drugs-cross-sex-hormones-and-surgeries/>.

²² Rescission of the Regulation entitled “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority,” RIN 0945-AA18; see <https://eppc.org/wp-content/uploads/2022/04/EPPC-Scholars-Comments-for-EO-12866-Meeting-on-Proposed-Rescission-of-Conscience-Rule.pdf>.

- Only through coordination by the Department of Justice and joint common rules across agencies can the administration as a whole consider the proper interpretation and application of the principles of nondiscrimination
- At a minimum, the Agency must evaluate this proposed rule in light of those other proposed rules that will have a direct impact on the scope of nondiscrimination provisions in health care.

7. The Rule must be analyzed in conjunction with other laws.

- *Section 1554*. The proposed rule, as anticipated, would violate Section 1554 of the Affordable Care Act (42 U.S.C. § 18114), which provides: “the Secretary of Health and Human Services shall not promulgate any regulation that—
 - (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
 - (2) impedes timely access to health care services;
 - (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
 - (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
 - (5) violates the principles of informed consent and the ethical standards of health care professionals; or
 - (6) limits the availability of health care treatment for the full duration of a patient’s medical needs.”
 - Specifically, the Rule would violate:
 - (1), (2), and (6) by pressuring health care providers out of federally funded health programs and the practice of health care;
 - (3) and (4) by requiring health care providers to speak contrary to their medical, ethical, and religious beliefs, such as by requiring affirmation of gender identity or abortion and prohibiting speech that is “negative: towards gender transition or in accord with patient’s biological sex; and
 - (5) by requiring health care providers to deprive patients of informed consent by preventing them from warning patients of the risks associated with abortion or gender transition surgeries, cross-sex hormones, and puberty blockers, and by forcing providers to violate moral and medical standards as health care professionals.
- *RFRA*. In proposing this Rule, HHS must analyze its regulatory action under the Religious Freedom Restoration Act (RFRA) and refrain from imposing a substantial burden on religious exercise absent a compelling interest imposed by the least restrictive means. The government does not have a compelling interest in forcing health care providers to end the life of another human being through abortion or assisted suicide, or to sterilize adults or minors, including through gender transition surgeries and hormones. As the Supreme Court made clear in *Fulton v. City of Philadelphia*, 141 S. Ct. 585 (2021), the government does not have a compelling interest in enforcing its nondiscrimination policies generally. Rather any interest must reference the specific

application of the requirements to those specifically affected. Indeed, the Court in *Fulton* stated: “so long as the government can achieve its interests in a manner that does not burden religion, it must do so.”

- Since HHS recently withdrew the delegation of authority from OCR to enforce RFRA,²³ any perfunctory statement that HHS will comply and follow RFRA and other conscience protection laws, such as in the 2021 notification, is suspect. HHS must explain *specifically* how it intends to uphold its duty to enforce conscience and religious freedom protection laws in relation to its proposed regulations.
- *Title VII*. HHS must also consider its rule in connection with Title VII’s religious nondiscrimination and accommodation requirements. Employers cannot create a hostile work environment based on religion and are generally required to reasonably accommodate an employee’s sincerely held religious belief, observance, and practice. These protections are in addition to protections under the federal conscience protection laws.
- *Civil Rights Restoration Act*. The Civil Rights Restoration Act of 1987 (CRRA) delineates the scope of coverage of several of the civil rights statutes that are incorporated into Section 1557.²⁴ As discussed in the preamble to the 2020 Rule, with respect to scope of “program or activity,” the CRRA made certain the above-mentioned statutes apply to the “all the operations” of certain federally funded entities but only if they are (as relevant here) “principally engaged in the business of providing . . . health care.”²⁵ That limitation should be fully respected and preserved as set forth in the 2020 Rule.

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

- Religious health care professionals and faith-based health care organizations live out their faith-based vocation to love and care for the sick and suffering through health care based on the biological scientific reality of the human person and the human body. These professionals and organizations are vital to health care access for the poor and vulnerable, especially where Catholic health care alone provides over 15 percent of all health care delivery in America.
- Regulations that fail to uphold federal protections for medical conscience and religious liberty in health care will lead to decreasing access to care to poor communities and racial minority communities throughout much of the country—this should never occur generally and especially not during the “public health emergency” declared by HHS Secretary Becerra to still exist.²⁶
- At a minimum, federal regulations should uphold existing medical conscience and religious freedom protections under federal law.

²³ 86 Fed. Reg. 67,067.

²⁴ Pub. Law 100–259, 102 Stat. 28 (Mar. 22, 1988).

²⁵ 85 Fed. Reg. 37,160, 37,171.

²⁶ *Cf.* EPPC Scholars Call on HHS Secretary Becerra to End Covid-19 Public Health “Emergency” (Mar. 15, 2022), <https://eppc.org/news/eppc-scholars-call-on-hhs-secretary-becerra-to-end-covid-19-public-health-emergency/>.

- HHS acknowledges that its Section 1557 interpretation will implicate conscience and religious freedom concerns. For instance, in its 2021 notification, HHS stated: “In enforcing Section 1557, as stated above, OCR will comply with the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq.*, and all other legal requirements.”²⁷
- Since the proposed rule would implicate conscience and religious freedom concerns, HHS should request input from the career professionals at the Conscience and Religious Freedom Division and follow their expert recommendations.
- There has been a concerning trend by HHS to cut the Division out of review of proposed rules that implicate conscience and religious freedom rights. Indeed, HHS has only made it more difficult across the board for the Agency to enforce vital conscience and religious protections in healthcare. It should not do so here.
- While HHS has paid lip service to conscience and religious freedom rights in its proposed rules, it has blatantly disregarded and ignored those right, including by effectively dismantling its Conscience and religious Freedom Division and crippling its Office for Civil Rights (OCR) to receive complaints and enforce religious protections under the Religious Freedom Restoration Act and the First Amendment.²⁸ And most recently, by proposing to rescind the 2019 Conscience Rule.²⁹
- The removal of the delegation of authority from OCR to enforce RFRA and the First Amendment said that “Department components, in consultation with OGC, have the responsibility, and are best positioned, to evaluate RFRA-based requests for exemptions, waivers, and modifications of program requirements in the programs they operate or oversee. Department components, further, are best situated to craft exemptions or other modifications when required under RFRA and to monitor the impact of such exemptions or modifications on programs and those they serve. Moreover, they are best positioned to evaluate how their programs must be run to comply with the Free Exercise Clause and the Establishment Clause of the First Amendment.”³⁰
 - But OCR is the “department component” for this rule. Despite its withdrawn authority, HHS must explain whether OCR has RFRA and First Amendment authority to evaluate any violations and receive complaints under this OCR rule.
- In the proposed rule, the Agency must explain how it will fulfill its statutory duty to protect and enforce conscience protection laws within its 1557 regulations, while at the same time proposing to rescind the Conscience Rule giving effect to those protections.

²⁷ U.S. Dep’t Health & Human Servs., Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972 3 (May 10, 2021), <https://www.hhs.gov/sites/default/files/ocr-bostock-notification.pdf>.

²⁸ Rachel N. Morrison, *In Its First Year, Biden’s HHS Relentlessly Attacked Christians and Unborn Babies*, THE FEDERALIST (Mar. 18, 2022), <https://thefederalist.com/2022/03/18/in-its-first-year-bidens-hhs-relentlessly-attacked-christians-and-unborn-babies/> (listing the anti-religion and pro-abortion acts of the Biden-Becerra HHS).

²⁹ Rescission of the Regulation entitled “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority,” RIN 0945-AA18.

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

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

- HHS' proposed rule is economically significant, which means it requires meaningful economic analysis under EO 12866 and OMB Circular A-4. EO 12866 states:
 - “In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.”
- As part of its regulatory impact and economic analysis of the costs, benefits, and transfers, the Rule should take into consideration the following key inputs:

Costs of Coverage of Gender Transition and “Detransition” Services

- Which services, procedures, treatments, drugs, surgeries, etc. will be required to be covered by insurance or provided by health care professionals.
- Whether coverage includes services for those who wish to “detransition” according to their gender identity “realigning” with their biological sex.
- The number of gender transition or “detransition” surgeries/treatments expected to be covered by insurance
- The cost of each gender transition or “detransition” service to be covered.
- The costs of any follow-up/complications.
- The number of people covered and their ages, and whether it includes minor children.
- The increase in premium costs to cover such services.
- The number and qualifications of doctors that are willing to perform such services, especially on minor children.

Harm to Health Care Profession

- Whether doctors will be required, despite their best medical judgment, to perform sex-reassignment surgeries and prescribe puberty blockers and cross-sex hormones, including for minor children.
- The cost to the health care profession by requiring professionals to violate the Hippocratic Oath, which requires they “do no harm” and refrain from participating in abortion.
- The resulting lack of trust in public health care and health care professionals who do not share a patient’s values.

- The number of people that will choose not to enter the health care profession as a result of the rule.
- The government's interest is in supporting and enable existing and new medical professionals to care for their patients by not driving them out of the profession.

Harm to Conscience and Religious Freedom Rights

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

Harm to Free Speech Rights and Doctor-Patient Relationship

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

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

- The number of health care professionals or faith-based health care institutions that will stop providing certain categories of services or treatments, such as obstetrics and gynecology if abortion is required.
- The demographics of health care professionals that will stop providing certain categories of services or treatments, and the impact that will have on patients who can no longer find a provider from their community.
- The number of health care professionals that will leave the profession altogether.

- The burdens losing additional staff will cause for health care systems that are already suffering and understaffed after the COVID pandemic.

Loss of Access to Health Care

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

Economic Harm

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

Baseline for Analysis

- The baseline for analysis must be the 2022 reality of a post-COVID pandemic health care landscape. Pre-pandemic numbers won't accurately reflect the strain on the health care community from professionals to institutions.

Effective Date

- The impact of the effective date of the rule, especially if the date is mid-plan year or after benefit plans designs have already been determined or approved.
- The benefits of delaying the effective date of the rule to correspond with the next plan year, such as avoiding significant costs associated with last-minute changes.
- All of these things, and more, must be taken into consideration, and quantified or estimated to the maximum extent possible for a sufficient analysis of impact, costs, benefits, and transfers.

10. The Rule must evaluate alternative regulatory approaches.

- In addition to the numerous costs of the Rule, HHS must fully consider alternatives, including not regulating, and provide a reasoned explanation of why its proposal is better than those alternatives.
- The best alternative we urge the Department to adopt is to not act without Congressional action. Any updates to the scope of Section 1557 (and Title IX) should be done legislatively, not through agency action.
- Other alternatives the Agency must consider and evaluate are:
 - Issuing similar regulations to the 2020 Rule.
 - Modifying the 2020 regulations.
 - Rescinding only portions of the 2020 Rule, while leaving other portions in place.
 - Waiting until after the *Dobbs* and *303 Creative* decisions are issued by the Supreme Court to make its proposal.

11. The Rule must address its major impact on small health care entities.

- As you are aware, the Regulatory Flexibility Act (RFA) (5 U.S.C. § 605(b)), requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities and prepare a regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless “the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.” The Act requires that “the agency shall publish such certification in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a statement providing the factual basis for such certification.”
- It seems clear that the proposed Rule will have a significant impact on small health care providers across the country. The proposal will impact state, private, and religious health care institutions either because the provider has employees that have conscience and

religious objections to certain participating with procedures or the provider is itself religiously affiliated. HHS must explain the impact on these small health care entities, including religiously entities, and why this impact is justified.

- If, however, HHS somehow does not think that the rule will have such a significant impact, then Secretary Becerra *must* certify there is no such impact and provide sufficient factual analysis supporting such a claim.

12. The Rule must address its federalism implications.

- As you are familiar, EO 13132 from the Clinton Administration establishes certain requirements that an agency must meet when it issues a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.
 - Section 3(c) of the EO states that “with respect to Federal statutes and regulations administered by the States, the national government shall grant the States the maximum administrative discretion possible.”
 - Section 3(d) explains how to implement policies that have federalism implications. Specifically, agencies “shall” (1) “encourage States to develop their own policies to achieve program objectives and to work with appropriate officials in other States,” (2) “where possible, defer to the States to establish standards,” and (3)/(4) consult with States and officials.
- Executive Order 12866 (§ 6(a)(3)(B)) also directs that significant regulatory actions avoid undue interference with State, local, or tribal governments, in the exercise of their governmental functions.
- The proposed Section 1557 rule will clearly have federalism implications as it will impact state hospitals, medical facilities, and insurance plans. In addition, it will likely conflict with and claim to preempt state and local laws regulating coverage and provision of gender transition services, especially for minors.
 - For example, in February 2022, the Texas Attorney General issued an opinion letter stating sterilizing and other permanent “sex-change procedures” “can constitute child abuse when performed on minor children,” including — “(1) sterilization through castration, vasectomy, hysterectomy, oophorectomy, metoidioplasty, orchiectomy, penectomy, phalloplasty, and vaginoplasty; (2) mastectomies; and (3) removing from children otherwise healthy or non-diseased body part or tissue.”³¹ HHS has already indicated that it disagrees with this determination and will use Section 1557 to invalidate state action.³²

³¹ Tex. Att’y Gen. Op. Letter No. KP-0401, from Ken Paxton, Attorney General, to Matt Krause, Chair, House Committee on General Investigating, Texas House of Representatives 1–2 (Feb. 18, 2022), <https://www.texasattorneygeneral.gov/sites/default/files/opinion-files/opinion/2022/kp-0401.pdf>.

³² Press Statement, U.S. Dep’t Health & Hum. Servs., Statement by HHS Secretary Xavier Becerra Reaffirming HHS Support and Protection for LGBTQI+ Children and Youth (Mar. 2, 2022), <https://www.hhs.gov/about/news/2022/03/02/statement-hhs-secretary-xavier-becerra-reaffirming-hhs-support-and-protection-for-lgbtqi-children-and-youth.html>.

- In addition, overriding state laws concerning nondiscrimination in health and using a novel interpretation of Title IX and Section 1557 to override those laws risks a coercive impact under *NFIB v Sebelius*, 567 U.S. 519 (2012). When states agreed to accept federal funding under health programs and activities, they were only aware of the text of Title IX prohibiting sex discrimination and specifically in the statute using language showing a male and female binary application of sex. Consequently, implementing sexual orientation and gender identity nondiscrimination through Section 1557 can only be binding on states' acceptance of federal financial assistance if states had clear notice under *Pennhurst State School and Hospital v. Halderman*, 465 U.S. 89 (1984), that they were accepting that condition by the plain meaning of the text of the statute. They had no such notice.
- All these federalism impacts must be addressed, and HHS must consult with states before issuing a rule that imposes a substantial cost and impact on them.

13. HHS appears to have prejudged the Rule by acting outside the public rulemaking process.

- Both the Obama and Trump administrations followed the legally required public comment and rulemaking process in issuing their Section 1557 regulations in 2016 and 2020, respectively.
- Yet on May 10, 2021, HHS unilaterally issued a “notification of interpretation and enforcement,” stating: “Consistent with the Supreme Court’s decision in *Bostock* and Title IX, beginning today, OCR will interpret and enforce Section 1557’s prohibition on discrimination on the basis of sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity.”³³
- First, as discussed above, *Bostock* did not apply to Title IX or Section 1557, and the Supreme Court made clear in its *Bostock* decision that it was not deciding any issue outside the hiring/firing context under Title VII.³⁴
- Second, ED likewise has not yet issued new Title IX regulations interpreting Title IX’s prohibition against sex discrimination to cover gender identity through the public notice and comment process.
- Third, HHS (as well as ED and DOJ) cannot issue such commands outside the public rulemaking process. Indeed, one judge called HHS’ notification an act of “administrative fiat.”³⁵
- HHS issued an additional “guidance” document on March 2, 2022, in which it reiterated that OCR is investigating and enforcing Section 1557 cases involving discrimination on

³³ U.S. Dep’t Health & Human Servs., Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972 3 (May 10, 2021), <https://www.hhs.gov/sites/default/files/ocr-bostock-notification.pdf>.

³⁴ 140 S. Ct. 1731, 1753 (2020).

³⁵ *Franciscan Alliance, Inc. v. Becerra*, No. 7:16-cv-00108, at 8 (N.D. Tex. Aug. 9, 2021).

the basis of sexual orientation and gender identify.³⁶ The document stated: “Categorically refusing to provide treatment to an individual based on their gender identity is prohibited discrimination. Similarly, federally-funded covered entities restricting an individual’s ability to receive medically necessary care, including gender-affirming care, from their health care provider solely on the basis of their sex assigned at birth or gender identity likely violates Section 1557.”³⁷

- By unilaterally issuing these documents outside the public rulemaking process, it appears HHS has already prejudged the outcome and we are afraid the Agency will not seriously consider contrary views and is not interested in public input.

14. The Rule should have a meaningful public comment period of at least 60 days.

- As you know, under EO 12866, for most rules, an agency should give the public at least 60 days for meaningful comment. For reference, the 2020 Rule had a 60-day comment period. As mentioned earlier, this proposal is economically significant and there is no legal deadline. As such, we ask that for this Rule the Department provides a minimum of 60 days, if not 90 days since the Proposal would greatly impact health care access, to allow the public time to provide meaningful input as required by law.
- We also ask that these dates be from publication at the Federal Register, not public inspection. There has been a concerning trend by this administration and HHS specially of providing the public less than 30 days for comment from publication of the notification of proposed rulemaking in the federal register. For example, CMS published a 145-page, triple-columned notice of proposed rulemaking on January 5 with a public comment deadline on January 27—a mere 22 days to provide input on a complex, major, and economically significant proposed rule. That comment period was outrageously short and should not be repeated.
- The Administrative Procedure Act (APA) suggests less than 30-days is highly suspect and problematic. Any shorter would further suggest that the Department has prejudged the rule and is not interested in the public’s input. Surely fairness and equity require that the public should have a reasonable amount of time of at least 60 days to consider and comment on the proposal, especially for one that is certainly to be major and economically significant.

Conclusion

We urge OIRA to ensure that the statutory and regulatory process is upheld, and that the proposed rule has sufficient legal and economic analysis that is rationale and reasoned, not political, rushed, or prejudged.

³⁶ Office for Civil Rights, U.S. Dep’t Health & Hum. Servs., HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy I (Mar. 2, 2022), <https://www.hhs.gov/sites/default/files/hhs-ocr-notice-and-guidance-gender-affirming-care.pdf>.

³⁷ *Id.* at 2.