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EO 12866 Meeting
"Nondiscrimination in Health Programs and Activities"
RIN 0945–AA17

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Thank you for the opportunity[1] to provide comments on OIRA's review of HHS's proposed rule, "Nondiscrimination in Health Programs and Activities,"87 Fed. Reg. 47824 (August 4, 2002). I, Eric Kniffin, am a former attorney in the DOJ Civil Rights Division under Presidents George W. Bush and Obama. I also have also been involved in extensive civil rights litigation against HHS as counsel for the Becket Fund for Religious Liberty and in private practice, including successful lawsuits against HHS's contraception mandate and HHS's original Section 1557 transgender mandate. Attending with me are my colleagues Rachel N. Morrison, a former attorney advisor at the EEOC, and Natalie Dodson. All three of us serve as scholars in the HHS Accountability Project (Project) at the Ethics and Public Policy Center (EPPC).

This comment is the latest in a long string of comments we have submitted to the executive branch regarding this proposed rulemaking:

- On April 6, 2022, HHS Accountability Project scholars met with OIRA officials to discuss concerns with an anticipated Section 1557 proposed rule from HHS[2];
- On March 11, 2022, Project scholars wrote HHS on behalf of a coalition of more than a dozen stakeholder organizations to request a meeting to discuss shared concerns about the anticipated rulemaking[3];
- HHS granted our request, and on April 6, 2022, Project scholars met HHS officials to again express their concerns;[4] and

[1] As OMB cancelled a previous EO 12866 meeting it scheduled with EPPC on another rule, we are glad you are willing to hear EPPC scholars' input on this rule. *See* Rachel N. 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/.

[2] https://eppc.org/wp-content/uploads/2022/04/EEPC-Scholars-Comment-for-EO-12866-Meeting-on-Section-1557-Rule.pdf.

[3] https://eppc.org/wp-content/uploads/2022/03/Request-for-Meeting-on-Anticipated-Section-1557-Rulemaking.pdf.

[4] https://eppc.org/wp-content/uploads/2022/04/EEPC-Scholars-Comment-for-EO-12866-Meeting-on-Section-1557-Rule.pdf.

- On October 3, 2022, the Project submitted a public comment in response to HHS's proposed rule.[5]

For the reasons set out below, and as set out in more detail in our public comment to HHS, the proposed rulemaking is contrary to law. It reads protected bases into Section 1557 that Congress chose not to protect and it does so on some of the most controversial issues of our time. HHS's rule would harm children and negatively impact the healthcare industry and access to care. The rule also has massive implications for conscience and religious freedom rights, which HHS continues to set aside in pursuit of the administration's and Secretary Becerra's policy goals.

Given the flagrant legal problems with the proposed rule, and given that HHS already conceded defeat in legal challenges to its 2016 Section 1557 rule, we are confident this proposal awaits a similar fate. If HHS continues down the path set out in the proposed rule, this rule will be the subject of extensive litigation, just like the 2016 Rule. Plaintiffs will win these lawsuits, just like with the 2016 Rule. We urge OIRA and HHS to take this final chance to reverse course, acknowledge the fundamental problems with this proposed rule, and develop regulations under Section 1557 of the Affordable Care Act that honors the executive branch's obligations under the Constitution and federal law.

1. There is no need for federal regulatory action.

- *Purported need.* For all rulemaking, agencies must identify a need and demonstrate how the rule meets that need. Federal administrative agencies are required to engage in "reasoned decision making."[6] To justify replacing current regulations, an agency must provide specific evidence as to how the current regulations are causing harm or burdens and how the Proposed Rule would remedy the alleged defects without causing equal or greater harms and burdens.[7]
- *Confusion*. To begin, HHS has failed to explain why it has grounds to replace the 2020 Rule, 85 Fed. Reg. 37160 (June 19, 2020). HHS claims it has legal justification to replace the 2020 grounds to do so because the 2020 Rule "caused confusion in compliance by failing to provide clear procedural requirements."[8] This is mere speculation. HHS fails to cite to any entity, complaint, or enforcement action that demonstrates such confusion exists. Making such a claim without substantial concrete evidence is arbitrary and capricious.

[5] EEOC Scholars' Public Comment Opposing HHS Proposed Rule, "Nondiscrimination in Health Programs and Activities," RIN 0945-AA17, Docket ID HHS-OS-2022-0012 (Oct. 2, 2023) [hereinafter "EPPC Section 1557 Public Comment"], https://eppc.org/wp-content/uploads/2022/10/EPPC-Scholars-Comment-Opposing-1557-Proposed-Rule.pdf.

[6] *Michigan v. E.P.A*., 576 U.S. 743, 750 (2015).

[7] *Id*. at 779 (regulation is irrational if it disregards the relationship between its costs and benefits); *Alltelcorp v. FCC*, 838 F.2d 551, 561 (D.C. Cir. 1988) ("a regulation perfectly reasonable and appropriate in the face of a given problem is highly capricious if that problem does not exist").

[8] 87 Fed. Reg. at 47830.

- *Text of Section 1557*. HHS also claims the Proposed Rule is necessary "to better align the Section 1557 regulation with the statutory text . . . to reflect recent developments in civil rights case law, to address unnecessary confusion in compliance and enforcement resulting from the 2020 Rule, and to better address issues of discrimination that contribute to negative health interactions and outcomes." It claims its proposed regulations are "consistent with the statutory text of Section 1557 and Congressional intent."
- However, as explained in detail in our October 2022 public comment, the Proposed Rule *contradicts* 1557's statutory text (and the text of Title IX, which it incorporates by reference), *ignores* congressional intent, *ignores* relevant case law, and adds unnecessary confusion in compliance and enforcement. The Proposed Rule also arbitrarily, capriciously, and dangerously meddles in the practice of medicine and expands the scope of discrimination under 1557 beyond reasonable bounds. Indeed, the Proposed Rule fails to cite *any* legislative history indicating Congress ever contemplated application of sexual orientation, gender identity, or transgender status under Section 1557 in the Affordable Care Act (ACA).
- In short, contrary to HHS's purported need for the proposed rescission, its proposal increases confusion, decreases clarity, and undermines the Department's claim that it is seeking to honor its obligations under the Constitution, the Administrative Procedure Act, the Affordable Care Act, and the Religious Freedom Restoration Act, to name but a few.

2. **The proposed rule's claim that *Bostock* applies to Title IX, and by extension Section 1557, is arbitrary and capricious and contrary to law.**

- The proposed rule relies in substantial part on HHS's assertion that, the Supreme Court's interpretation of Title VII in *Bostock v. Clayton County*,[9] which held that discrimination on the basis of sex under that law encompasses discrimination based on sexual orientation and gender identity, applies also to sex discrimination under Title IX.[10]
- Title VII prohibits sex (and race, color, religion, national origin) discrimination in employment, a completely different context than Title IX, which bars discrimination on the basis of sex in education. Notably, *Bostock*'s Title VII analysis does not apply to Title IX because Title IX has a different sex-specific structure and, unlike Title VII, specifically uses language based on a biological binary, as detailed below.
- The Court's terminology in *Bostock* is also fundamentally different from the proposed rule. The Majority in *Bostock* used the term "transgender status," and did not adopt "gender identity" as a protected class.[11] The proposed rule, by contrast, claims that Title IX prohibits discrimination on the basis of "gender ideology," not "transgender status." It is arbitrary and capricious for HHS to proceed as if these two terms were identical and interchangeable, without even any argument as to why this shift is permissible.

[9] 140 S. Ct. 1731 (2020).

[10] 87 Fed. Reg. at 47829-30.

[11] *See id.* at 47859.

- HHS also impermissibly and inexplicably adopts only *parts* of *Bostock's* analysis. The *Bostock* Court premised its decision on the assumption that "sex" refers only to the "biological distinctions between male and female."[12] To the extent HHS relies on *Bostock*, it must likewise assume "sex" refers to "biological distinctions between male and female" and ensure that its rule reflects this understanding.
- Further, *Bostock* was a limited holding. The Supreme Court specifically cabined its decision to the hiring and firing context under Title VII, stating it was not addressing other Title VII issues, such as sex-specific bathrooms, locker rooms, and dress codes, or other laws.[13] While the Court acknowledged concerns by some that its decision could make sex-segregated bathrooms, locker rooms, and dress codes "unsustainable" and "sweep beyond Title VII to other federal or state laws that prohibit sex discrimination," the Court did not address those concerns.[14] It is arbitrary and capricious for HHS to ignore *Bostock*'s limitations and claim *Bostock* justifies its efforts to expand Section 1557.
- It is arbitrary and capricious for HHS to ignore a critical difference between Title VII and Title IX in that the latter law explicitly allows certain policies that account for biological differences between the sexes.
    - For example, 20 U.S.C. § 1686 states that Title IX does not "prohibit any educational institution receiving funds under this Act, from maintaining separate living facilities for the different sexes."
    - The proposed rule does not cite this statute and therefore offers no account of this critical difference between Title VII and Title IX.
- The proposed rule's treatment of caselaw applying *Bostock* to Title IX is also arbitrary and capricious. HHS claims the relationship between *Bostock* and Title IX is settled based on holdings from two circuit courts.[15] Yet, as shown below, two circuit courts have discovery granted religious employers and healthcare providers permanent injunctions against HHS's Section 1557 transgender and abortion mandates. Both courts found the 2016 Rule illegal under RFRA and did so without the need for discovery. If HHS were to treat these holdings with the same regard as the two decisions that endorse HHS's preferred reading of Title IS, HHS would accept that RFRA requires that any final rule include broad exemptions for entities with sincere religious objections to complying with HHS's mandates.
- Furthermore, courts are now split as to whether *Bostock* redefines sex discrimination for laws other than Title VII. Cases HHS must consider include:
    - *Pelcha v. MW Bancorp, Inc.*, 988 F.3d 318, 324 (6th Cir. 2021) ("*Bostock* extends no further than Title VII");

[12] *Bostock*, 140 S. Ct. at 1739.

[13] *Id*. at 1753.

[14] *Id.* at 1753.

[15] 87 Fed. Reg. at 47829 (citing *Doe v. Snyder*, 28 F.4th 103, 113–14 (9th Cir. 2022); *Grimm v. Gloucester Cty. Sch. Bd*., 972 F.3d 586, 616 (4th Cir. 2020), as amended (Aug. 28, 2020)).

- *L. W. by & through Williams v. Skrmetti*, 73 F.4th 408, 420 (6th Cir. 2023) ("*Bostock v. Clayton County* does not change the analysis. . . . Title VII analysis does not apply to Title IX." (cleaned up)); and
- *Neese v. Becerra*, 640 F. Supp. 3d 668, 684 (N.D. Tex. 2022) ("[B]ecause the Court finds Title IX's 'on the basis of sex' language does not include 'sexual orientation' or 'gender identity' status, the Court holds the Secretary cannot alter the phrase by administrative fiat.").

- We urge OIRA to ensure that HHS takes proper notice of this caselaw in the final rule and that the Department takes a consistent approach to all caselaw that bears on its proposed Section 1557 rule. We have unfortunately seen that HHS often allows its predetermined policy objectives and the Biden administration's political promises to dictate whether or not it will defer to relevant judicial decisions.
    - When HHS finds a case or two that supports its preferred policy outcome, like the two circuit cases cited in the proposed rule, it claims that the issue is settled and defers to those courts' holdings with little to no explanation.
    - But when HHS runs against cases whose holdings frustrate its policy agenda, it "respectfully disagrees" with those courts, often without any analysis at all, and sets them aside.[16]
- We encourage OIRA to examine the HHS submission now under review with this unfortunate track record in mind. We urge OIRA to ensure that HHS meets it legal obligation to rule offer a "reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy."[17]

3. HHS' failure to recognize that Section 1557 incorporates *all* of Title IX into the Affordable Care Act is arbitrary and capricious, and contrary to law.

- HHS' simplistic argument that Section 1557 did not incorporate Title IX's religious exemption and abortion neutrality provisions is contrary to law. Section 1557 incorporates *the whole* of Title IX, "20 U.S.C. 1681 ***et seq***.," not just the rule against discrimination "on the basis of sex."
- The Surplusage Canon (*verba cum effectu sunt accipienda*) precludes HHS from ignoring that Congress placed "***et seq.***" after 20 U.S.C. 1681 in Section 1557.[18]
- As noted in our public comment,[19] it is arbitrary and capricious for HHS to deny that that Section 1557, which incorporates *all* of Title IX, incorporates its religious exemption, 20 U.S.C. § 1681(a)(3).
    - Should HHS reverse course and recognize that Section 1557 requires it to incorporate Title IX's religious exemption, it is important to note that this

[16] *Id*. (citing *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015)).

[17] *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009).

[18] *See Advoc. Health Care Network v. Stapleton*, 581 U.S. 468, 477 (2017) (employing the "surplusage canon—the presumption that each word Congress uses is there for a reason").

[19] *Id*. at 34-35.

exemption is simple and straightforward and would not provide any additional justification for HHS's claimed need to evaluate religious objections to its Section 1557 mandates on a case-by-case basis.

  - According to this exemptions plain terms, when it applies it does so regardless of whether the religious entity applies to a federal agency to have its exemption recognized and regardless of whether and when an agency rules on the religious entity's application.
  - To the extent an entity might nonetheless ask HHS to recognize that it qualifies for the religious exemption incorporated through Title IX, HHS should look to the Department of Education for help. The DOE has for decades been able to issue letters in response to such applications without the need for a detailed inquiry into each religious applicant's beliefs or factual context.

- As noted in our public comment,[20] it is arbitrary and capricious for HHS to deny that that Section 1557, by incorporating all of Title IX, incorporates its abortion neutrality provision, 20 U.S.C. § 1688.
- This brings to mind yet another arbitrary and capricious aspect of the proposed rule:
  - In trying to justify its claim that *Bostock* applies to Title IX, HHS *soft-pedals critical differences* between the employment context and the educational context, and again between the employment context and the healthcare context.
  - But when HHS tries to justify its claim that Section 1557 incorporates Title IX's prohibition on sex discrimination but not its provisions honoring religious liberty and objections to abortion, hat the proposed rule *emphasizes the differences* between educational settings and healthcare care settings.[21]
- This sort of cherry picking is, again, unlawful. Here and elsewhere, we urge OIRA to ensure HHS to demonstrate that there is some common thread in its arguments *other* than the obvious: that HHS is intent on keeping President Biden's[22] and Secretary Becerra's pledges to pro-abortion and pro-LGBT advocacy groups:
  - that HHS would "double down and use every lever [it has] to protect access to abortion";[23] and

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[20] *Id*. at 40-41.

[21] 87 Fed. Reg. at 47840 ("Health care settings differ significantly from educational settings with respect to both the ability of affected parties to choose or avoid a certain religiously affiliated health care institution and the urgency of the need for services provided by the covered entities.").

[22] Rachel N. Morrison, *The Biden Administration's Post*-Dobbs, *Post*-Roe *Response*, Federalist Soc'y Blog (July 13, 2022), https://fedsoc.org/commentary/fedsoc-blog/the-biden-administration-s-post-dobbs-post-roe-response; https://thefederalist.com/2024/01/09/how-democrats-set-the-stage-in-2023-for-an-lgbt-onslaught-in-2024/.

[23] Press Release, HHS, *HHS Secretary Becerra's Statement on Supreme Court Ruling in Dobbs v. Jackson Women's Health Organization* (June 24, 2022), ''https://www.hhs.gov/about/news/2022/06/24/hhs-secretary-becerras-statement-on-supreme-court-ruling-in-dobbs-v-jackson-women-health-organization.html.

    - that HHS would put "access to the ['gender-affirming care'] . . . above the hateful and harmful beliefs of a narrow-minded few."[24]

- We urge OIRA to ensure that HHS's final rule does not reflect this pledge from HHS Secretary Becerra to place *the administration's interests* in promoting gender transitions over statutory text and *Congress' interests* in protecting religious liberty.

4. HHS's analysis ignores critical and fundamental differences between the employment context (Title VII) and the healthcare context (Section 1557).

- Leaving aside the important differences between the employment context (Title VII) and the education context (Title IX), the proposed rule overlooks critical differences between the employment context and the healthcare context (Section 1557).

- The question as to whether, and in what regards, it is prudent and necessary for insurers and healthcare providers to focus on a patient's biological sex—regardless of whether a patient identifies with his or her biological sex—is precisely the sort of issue on which HHS should be expected to offer its agency expertise. And yet the proposed rule says nothing on the matter.

- In response to this shocking admission, our public comment draws upon the expertise of our EPPC colleague, Mary Rice Hasson, to provide HHS with evidence establishing that a person's sex is defined by biology[25] and that innate sex differences affect our health.[26] Based on these facts, we present further evidence that a conscientious healthcare provider must take a patient's sex into account, regardless of whether the patient identifies with his or her biological sex.[27]

- For example, our public comment notes that HHS's NIH required its 80,000 research grant applicants to account for sex as a biological variable in all animal and human studies.[28]

- We also noted that the 2020 Section 1557 Rule, which HHS proposes to replace, cites a case where a medical patient[29] died because an emergency room treated a pregnant female patient according to her preferred male gender identity:

  > According to HHS, "this case is not based on speculation. Rather, it involved the actual death of an unborn child and attendant trauma and anguish for those involved, all potentially because of a misdiagnosis resulting from a reliance on stated gender identity as opposed to sex. Given that life-and-death decisions are frequently made in healthcare settings and often in urgent

[24] Press Release, HHS, *Statements by HHS Secretary Xavier Becerra and HHS Principals on Pride Month* (June 12, 2023), https://www.hiv.gov/blog/statements-by-hhs-secretary-xavier-becerra-and-hhs-principals-on-pride-month/.

[25] EPPC Section 1557 Public Comment at 12-14.

[26] *Id*. at 15-16.

[27] *Id*. at 17-22.

[28] *Id*. at 17.

[29] Consistent with EMTALA, 42 U.S.C. § 1395dd, HHS's 2020 Rule recognizes an unborn child as a medical patient.

circumstances, this story serves as an example of the consequences that could result from the confusion caused by the . . . mandate to treat individuals 'consistent with' stated gender identity." HHS also found that using non-discrimination rationales to impose a gender identity rule "risked masking clinically relevant, and sometimes vitally important, information by requiring providers and insurers to switch from a scientifically valid and biologically based system of tracking sex to one based on subjective self-identification according to gender identity."[30]

- It is arbitrary, capricious, and contrary to HHS's core mission for the Department to ignore these facts in the pending proposed rule. It is incumbent on OIRA to ensure that HHS does not issue a rule that will create profound confusion for insurers and medical professionals about the circumstances under which HHS will allow them to practice good medicine by taking a patient's biological sex into account.

5. Because the proposed rule centers on Section 1557's incorporation of Title IX, HHS should not finalize this rule until the Department of Education finalizes its proposed Title IX and Title IX Athletics rules.

- As demonstrated above, HHS's proposed rule hinges on its interpretation of Title IX. This requires in part assessing the significance of the differences between the employment setting and the educational setting, and the textual and schematic differences between Title VII and Title IX. The Department of Education is the primary agency tasked to enforce Title IX.
- The Department of Education has introduced two proposed rules that purport to interpret Title IX in light of *Bostock*:
    - Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance, 87 Fed. Reg. 41390 (July 12, 2022) [Title IX Proposed Rule]; and
    - Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance: Sex-Related Eligibility Criteria for Male and Female Athletic Teams, 88 Fed. Reg. 22860 (April 13, 2023) [Title IX Athletics Proposed Rule].
- Neither of these proposed rules have been finalized.
- Given the significance of these pending rules on Title IX from the Department of Education, HHS should hold off finalizing its Section 1557 proposal until at least the general Title IX rule is finalized and HHS has an opportunity to take what that final rule states about Title IX into account.

[30] EPPC Section 1557 Public Comment at 16 (quoting 85 Fed. Reg. at 37190).

6. The proposed rule's religious liberty provisions are inadequate in light of appellate courts' unanimously judgment that the transgender and abortion mandates HHS's first Section 1557 rule are illegal under RFRA as applied to objecting religious entities and individuals.

- The proposed rule deals briefly with litigation brought by religious organizations against its 2016 Rule.[31] It is critical that any final rule also take into account what has happened in this litigation in the year and a half since HHS published its proposed rule.
- On August 26, 2022, a few weeks after the proposed rule was published, the Fifth Circuit decided *Franciscan Alliance v. Burwell*, 47 F.4th 368 (5th Cir. 2022), unanimously upholding the district court's permanent injunction barring HHS from trying to use Section 1557 to require the religious plaintiffs to perform or provide insurance coverage for gender transition services or abortion. In December 2022, the Department of Justice abandoned any attempt to appeal this decision, making the Fifth Circuit's ruling final.[32]
- On December 9, 2022, the Eighth Circuit likewise found that HHS's attempt to enforce its Section 1557 Rule against objecting religious employers was illegal under RFRA. *Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 609 (8th Cir. 2022). In June 2023, the Department of Justice let the final deadline for appealing this decision expire, making the Eighth Circuit's ruling final.[33]
- No appellate court has upheld HHS's attempt to apply the 2016 Rule to objecting religious organizations.
- OIRA and HHS should ensure that any final rule takes into account *not only **that*** its 2016 rule has been enjoined under RFRA, *but also **how*** these courts have ruled against HHS. HHS claims that "a fact-sensitive, case-by-case analysis of [substantial] burdens and [compelling government] interests is needed under RFRA."[34] That is true in some but not all RFRA cases. In this case, HHS's statement is plainly wrong and impossible to square with HHS's long history of litigating (and losing) RFRA claims brought against its contraception and transgender mandates.[35]
    - ***Substantial Burden:*** In a RFRA case, the plaintiff bears the burden of first showing that the challenged government action substantially burdens its religious exercise.

[31] 87 Fed. Reg. at 47826.

[32] Joe Davis, *Biden Admin Waives Supreme Court Review in Key Transgender Fight*, RealClearPolicy, Dec. 2, 2022, https://www.realclearpolicy.com/articles/2022/12/02/biden_admin_waves_supreme_court_review_in_key_transgender_fight_868028.html.

[33] Press Release, The Becket Fund, Federal government backs down on transgender mandate (June 21, 2023) https://www.becketlaw.org/media/federal-government-backs-down-on-transgender-mandate/.

[34] 87 Fed. Reg. at 47941.

[35] Though HHS's contraception mandate and its transgender mandate were created through different sets of regulations and HHS has purported to justify them through different parts of the Affordable Care Act, there is a great deal of similarity in the way that the RFRA claims against each mandate have been structured, the way these claims have been argued in court, the reasons why courts have found in these religious organizations' favor, and the nature and scope of the permanent injunctive relief the courts have entered against HHS.

- HHS has sometimes argued that these plaintiffs have not articulated a substantial burden on religious exercise, but to our knowledge HHS has always lost these claims. In one of these cases, the Supreme Court took HHS to task for claiming that a religious plaintiff's alleged burden was "too attenuated": it held that the First Amendment (which applies equally to executive agencies and to courts) precludes government from determining whether "the religious beliefs of the plaintiffs are mistaken or unreasonable. . . . The Court's narrow function . . . is to determine whether the plaintiffs' asserted religious belief reflects an honest conviction."[36]
- As to the "honest conviction" inquiry, it is important to note that for more than a decade HHS has been willing to accept a religious organization's sincere religious objection to its contraption mandate based on the entity's submission of a one-page form that says, in part, "I certify that, on account of religious objections, the organization opposes providing coverage for some or all of any contraceptive services that would otherwise be required to be covered; the organization is organized and operates as a nonprofit entity; and the organization holds itself out as a religious organization."[37]
- In light of this CMS-10459-Certification form, HHS cannot plausibly claim that it needs to conduct a factual inquiry into each entity that raises religious objections to complying with HHS's proposed Section 1557 mandates. It would be arbitrary and capricious for HHS to fail to create a comparable form in this context that would allow religious entities to certify that they have a sincere religious objection to cooperating with HHS's Section 1557 mandates.
- ***Strict Scrutiny*:** Under RFRA, if a plaintiff can demonstrate a substantial burden on religious exercise, HHS will lose unless it can prove that its attempt to coerce the plaintiff satisfies strict scrutiny. This can be a fact-intensive inquiry in many RFRA cases, but that has not been the case in litigation over HHS's Section 1557 transgender and abortion mandate. Courts have found in favor of religious employers and religious healthcare institutions for reasons that do not require inquiries into entity-specific facts:
  - ***As applied to religious employers,*** HHS's attempted transgender mandate cannot pass strict scrutiny, as "'[t]he most straightforward way of [ensuring that people have financial support] would be for the Government to assume the cost of providing' gender-transition procedures for those 'unable to obtain them under their health-insurance policies due to their employers' religious objections.'" *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1148–49 (D.N.D. 2021), aff'd in relevant part *Religious Sisters of Mercy v. Becerra*, 55 F.4th 583 (8th Cir. 2022) (quoting *Hobby Lobby v. Sebelius*, 573 U.S. 682, 728 (2014)). The same applies, of course, to any HHS abortion mandate.

[36] *Hobby Lobby v. Burwell*, 573 U.S. 682, 686 (2014).

[37] HHS, CMS-10459-Certification, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cms-10459-certification.pdf.

        - ***As applied to religious healthcare providers,*** the outcome is the same: HHS cannot pass the least restrictive means test because the government could always "assist transgender individuals in finding and paying for transition procedures available from the growing number of healthcare providers who offer and specialize in those services. . . . [T]he government has numerous less restrictive means available to provide access and coverage for transition and abortion procedures." *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 693 (N.D. Tex. 2016), aff'd in relevant part *Franciscan Alliance v. Burwell*, 47 F.4th 368 (5th Cir. 2022).
    - For all these reasons, it would be arbitrary and capricious for HHS to ignore its losses in court over its Section 1557 mandate and maintain the claim in the proposed rule that it is unable to establish clear guidelines to determine when a religious entity is entitled to an exemption from its mandates under RFRA.

7. The proposed rule's religious liberty provisions ignore the plain text of the Church Amendments.

- HHS's proposed case-by-case approach also fails to honor its legal obligations under the Church Amendments, 42 U.S.C. § 300a-7. This law prohibits public officials and covered entities from punishing or otherwise discriminating against entities or individuals that refuse to perform or participate in abortions or sterilizing procedures for religious or moral reasons.
- While we are glad to see that HHS acknowledges in the proposed rule that its Section 1557 mandates are subject to the Church Amendments, it is arbitrary and capricious for HHS to say absolutely nothing about *how* that law applies to these proposed regulations.
- The test to determine whether the Church Amendments preclude HHS's efforts to enforce its regulatory mandate in a given case is simple:
    - Does the mandate require the objecting entity to perform or assist in the performance of an abortion or sterilizing procedure?
    - Does the objecting entity have a religious or moral objection to this requirement?
        - To the extent the entity proffers a religious objection, HHS's role is cabined by the Supreme Court's caution in *Hobby Lo*bby, noted earlier: its "narrow function . . . is to determine whether the plaintiffs' asserted religious belief reflects an honest conviction." *Hobby Lobby v. Burwell*, 573 U.S. 682, 686 (2014). HHS's role is also cabined by its conduct under the contraception mandate, which allows an entity to certify in writing that it sincerely opposes cooperating with the HHS's mandate.
- Neither of these inquiries requires a detailed factual inquiry. To the extent that HHS disagrees and maintains that it cannot provide any bright-line rules about how the Church Amendments apply to its proposed Section 1557 mandates, HHS is obligated to explain in detail why this is the case.

8. **It would be arbitrary and capricious for HHS to fail to acknowledge that "gender transition" interventions are covered by the Church Amendments.**

- In our public comment to HHS regarding its proposed rule under federal conscience protection laws, [38] we asked HHS to recognized that the Church Amendments; protections for religious and moral objections apply to medical "gender transition" interventions.[39]
- Drawing on the expertise of EPPC scholar Mary Rice Hasson, we provided HHS with substantial evidence that many so-called "gender affirming" interventions—puberty blockers, cross-sex hormones, and surgeries on gonads and reproductive organs—are sterilizing.
    - For example, our comment quoted Diane Ehrensaft, PhD, a leading clinician-advocate for "gender affirming" medical interventions for adolescents, who describes in stark term the sterilizing nature of the one-two combination of pubertal suppression followed by cross-sex hormones: "[A] child who begins puberty blockers at Tanner Stage 2 and proceeds directly to cross-sex hormones will be rendered infertile."[40]
- Based on the scientific record we provided, we urged HHS "to acknowledge the application of conscience protections under conscience protection laws to individual and institutional religious and moral objections related to the performance, participation, or assistance in sterilizing gender transition procedures."[41]
- We were surprised and disappointed that HHS did not acknowledge, let alone respond to, our comment in its final conscience rule, which was published in January: the phrase "gender transition" does not even appear in the final rule.[42]
- We ask OIRA to ensure that HHS addresses this important question in the context of this rulemaking.
- If HHS contends that the Church Amendments do not provide legal protections to covered individuals and entities with moral and religious objections to participating in or providing sterilizing procedures, we ask OIRA to ensure that HHS provides a detailed explanation for this conclusion.

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[38] EEOC Scholars' Public Comment Opposing HHS Proposed Rule, "Safeguarding the Rights of Conscience as Protected by Federal Statutes," RIN 0945–AA18 (Jan. 5, 2003) [hereinafter "EPPC Conscience Rule Public Comment"] https://eppc.org/wp-content/uploads/2023/03/EPPC-Scholars-Comment-Opposing-HHS-Proposed-Conscience-Rule.pdf.

[39] *Id*. at 12-17.

[40] *Id*. at 15 (quoting Ehrensaft D. *Gender nonconforming youth: current perspectives*, 8 Adolesc Health Med Ther. 57-67 (May 25, 2017), doi: 10.2147/AHMT.S110859. PMID: 28579848; PMCID: PMC5448699. https://pubmed.ncbi.nlm.nih.gov/28579848).

[41] *Id*. at 17.

[42] *See* 89 Fed. Reg. 2078 (Jan. 11, 2024).

9. HHS must recognize that post-*Dobbs* neither the Constitution nor federal law assert a governmental interest in promoting access to abortion.

- HHS's proposed rule was issued shortly after the Supreme Court decided *Dobbs v. Jackson Women's* Health *Organization*.[43] The Department therefore did not have adequate occasion to absorb the impact of the Court's decision, which held that *Roe v. Wade*, "like the infamous decision in *Plessy v. Ferguson*, [] was also egregiously wrong and on a collision course with the Constitution from the day it was decided,"[44] and which affirmed that "the Constitution does not prohibit the citizens of each State from regulating or prohibiting abortion."[45]
- Instead, HHS's proposed rule merely asked for comment on "what impact, if any, the Supreme Court decision in *Dobbs v. Jackson Women's Health Organization* has on the implementation of Section 1557 and these regulations."[46]
- Our public comment answered this call, explaining that *Dobbs* is a game-changer for HHS.[47] Before *Dobbs*, HHS could point to Supreme Court cases to support its claim that the executive branch had an important interest in ensuring that women could exercise the right to abortion that these cases said was guaranteed by the Constitution. Now, after *Dobbs*, that is no longer the case.
- However, there are two critical facts about abortion that remains true both before and after *Dobbs*:
    - First, *Congress has never asserted an interest in providing women with access to abortion*. No federal law has ever claimed a governmental interest in providing abortion access, either before *Roe*, after *Roe*, or after *Dobbs.* Since the Supreme Court decided *Dobbs*, legislators have introduced many bills aimed at changing this fact, but Congress has rejected them all:
        - Women's Health Protection Act of 2022 (HR 8296), aimed at preserving access to abortion nationwide at the federal level;
        - Ensuring Access to Abortion Act of 2022 (HR 8297), intended to protect the right to travel to seek access to abortion and would prohibit anyone from restricting or hindering an individual's ability to cross state lines to obtain an abortion in a state where it is legal to do so.
        - Travel for Care Act (H.R.3132)
        - Reproductive Health Travel Fund Act (S.2152)
        - Protecting Service Members and Military Families' Access to Reproductive Care Act of 2023 (S.1610)

[43] 597 U.S. 215 (2022).

[44] *Id*. at 218.

[45] *Id*. at 302.

[46] 87 Fed. Reg. at 47879.

[47] EPPC Section 1557 Public Comment at 41.

- Second, *Congress has passed many laws to protect employers and healthcare providers*—the subjects of HHS's intended Section 1557 mandate—*from a federal abortion mandate.* The following are illustrative examples of how clearly and how emphatically Congress has declared its interests in this area:
  - ***Hyde Amendment***: "None of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for any abortion."
  - ***Greenwood Amendment***: "That amounts provided to said projects under such title shall not be expended for abortions, that all pregnancy counseling shall be nondirective, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office."
  - ***Weldon Amendment***: "None of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions."
  - ***Livingston Amendment***: "That in awarding grants for natural family planning under section 104 of the Foreign Assistance Act of 1961 no applicant shall be discriminated against because of such applicant's religious or conscientious commitment to offer only natural family planning."
  - ***Lowey Amendment***: "Nothing in this section shall be construed to require coverage of abortion or abortion-related services."
  - ***Humphrey Amendment***: "None of the funds appropriated under this title shall be used to require any person to perform, or facilitate in any way the performance of, any abortion."
- These declarations of Congressional intent are all the more important because they are not one-time deals; the amendments listed above have been passed every fiscal year by Congress since their first enactment.

- In sum, although President Biden and Secretary Becerra have made clear that *they* would like a federal abortion mandate, the American people have spoken even more clearly through their elected representatives in Congress: the American people do not want a federal abortion mandate.
- We urge OIRA to ensure that HHS has properly absorbed this state of affairs and that the final rule acknowledges and reflects that HHS's zeal for creating an abortion mandate finds no support in either Congress or the Constitution.

10. HHS must conduct a meaningful economic analysis and consider the proposed rule's costs and impacts.

- In accord with EO 12866 and OMB Circular A–4, HHS agrees the proposed rule is an "economically significant rule," that requires meaningful economic analysis.[48] 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.

- We ask OIRA to ensure that HHS takes into consideration each of the economic and cost concerns referenced on pages 52 to 57 of our public comment.
- Additionally, HHS should take into account the social costs and the harm to HHS's policy goals that would occur if doctors make fundamental changes to their practices to avoid the proposed HHS gender transition mandate under Section 1557.
    - Some doctors might respond by stopping taking Medicaid patients.
    - Other doctors might respond by changing the nature of their practice.
    - Other doctors might respond by ceasing to practice medicine.
- HHS should undertake a study so that it can estimate how many doctors will change their practice in reaction to the proposed gender transition mandate and how these changes will affect the public's access to health care.
- If HHS does not have data on this question and is not inclined to collect evidence on this matter, it should at least request public comments on this question so it can better understand the economic impact and broader societal impact that would come from a new attempt to coercing covered entities into cooperating with its Section 1557 mandates.

11. The Proposal 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.

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[48] 88 Fed. Reg. at 827.

- 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.

- HHS's proposal will clearly have federalism implications:
  - It will impact state hospitals, medical facilities, and insurance plans.
  - In addition, there are state and local laws protecting conscience and religious freedom rights, which could be impacted.
  - As noted above, the proposed rule was unable to take into account the *Dobbs* decision's impact on its proposals and arguments. This includes the substantial federalism implications of the Supreme Court's decision in *Dobbs*, which held that "health and welfare laws" (such as laws restricting abortion and gender transitions on minors) are "entitled to a strong presumption of validity" and "must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests."[49]
  - Twenty-three states have passed laws restricting or banning the provision of "gender transition" interventions on minors and twenty of these were passed in the past year. The federalism implications of HHS's proposed gender transition mandate are thus far more profound than they were when HHS published its proposed rule in August 2022.[50]
  - Around 21 states have passed laws restricting abortion.[51]
- The proposed rule acknowledges that HHS's proposed rule has federalism implications, but the final rule must do more and ensure that the legal requirements set out above are applied to each of the federalism issues summarized here.

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[49] 597 U.S. at 221 (cleaned up).

[50] Ohio becomes latest state to restrict gender-affirming care for minors, PBS Newshour (Jan. 25, 2024), https://www.pbs.org/newshour/show/ohio-becomes-latest-state-to-restrict-gender-affirming-care-for-minors ("A total of 23 states have passed trans healthcare bans with 20 approved just in the past year.").

[51] Tracking Abortion Bans Across the Country, NY Times (Jan. 8, 2024), https://www.nytimes.com/interactive/2022/us/abortion-laws-roe-v-wade.html ("Twenty-one states ban abortion or restrict the procedure earlier in pregnancy than the standard set by Roe v. Wade.").

- For example, HHS must address whether its rule will preempt state law.
    - Specifically, HHS should state whether it contends that its regulatory mandate preempts state laws that protect unborn human life against abortion.
    - HHS should likewise state whether it contends that its regulatory mandate preempts state laws that protect minor children from irreversible gender transition interventions.
- To the extent that HHS asserts that its Section 1557 Rule preempts state pro-life laws, HHS should take into account the status of the administration's other efforts to preempt state pro-life laws.
    - For example, the Department of Veterans Affairs issued an interim final rule on abortion benefits, claiming that it was permitted to perform abortions in pro-life states in violation of state law.[52]
    - The Department of Justice also sued Idaho claiming the Emergency Medical Treatment and Active Labor Act (EMTALA)[53] preempts the state's abortion law, even though EMTALA itself explicitly creates a legal duty to look after the best interests of an unborn child.
    - The Supreme Court stayed the preliminary injunction against Idaho's law and will hear oral arguments in the case in April to determine "whether EMTALA preempts state laws that protect human life and prohibit abortions, like Idaho's Defense of Life Act."[54]
- In the proposed rule, HHS implies that EMTALA could preempt state abortion laws:

> The Department also notes in this regard that the Emergency Medical Treatment and Active Labor (EMTALA) provides rights to individuals when they seek examination or treatment and appear at an emergency department of a hospital that participates in Medicare. If that person has an 'emergency medical condition,' the hospital must provide available stabilizing treatment, including abortion, or an appropriate transfer to another hospital that has the capabilities to provide available stabilizing treatment, notwithstanding any directly conflicting state law s or mandate that might otherwise prohibit or prevent such treatment."[55]

- To the extent HHS's intended federal rule continues to rely on this claim that EMTALA preempts state laws, it should hold its rule until the Supreme Court rules this term in *Idaho v. U.S.* and *Moyle v. U.S.* where the Question Presented will be "whether

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[52] Rachel N. Morrison, *Department of Veterans Affairs Interim Final Rule on Abortion*, Federalist Soc'y Blog (Oct. 14, 2022), https://fedsoc.org/commentary/fedsoc-blog/department-of-veterans-affairs-interim-final-rule-on-abortion.

[53] 42 U.S.C. § 1395dd.

[54] *See* Rachel N. Morrison, *Supreme Court to Decide Whether EMTALA Preempts State Abortion Laws:* Idaho v. U.S. and Moyle v. U.S., Federalist Soc'y Blog (Jan. 25, 2024), https://fedsoc.org/commentary/fedsoc-blog/supreme-court-to-decide-whether-emtala-preempts-state-abortion-laws.

[55] 87 Fed. Reg. at 47879.

EMTALA preempts state laws that protect human life and prohibit abortions, like Idaho's Defense of Life Act."[56]

- In addressing the federalism concerns that advance legitimate state interests in protecting unborn human life from abortions and protecting minors from irreversible gender transition procedures, HHS must acknowledge and take into consideration that no federal law asserts an interest in providing access to either abortion or gender transition procedures.

12. HHS must square its rule with the major questions doctrine.

- HHS's proposed rule raises serious questions under the major questions doctrine. The Supreme Court most recently spoke to this doctrine in *Biden v. Nebraska*, where it expressed its "concerns over the exercise of administrative power"[57] and clarified the criteria courts and federal agencies must use when determining whether Congress has delegated authority to a federal agency to address "questions of deep economic and political significance."[58]
- The major question doctrine is rooted in the basic premise that Congress normally "intends to make major policy decisions itself, not leave those decisions to agencies."[59] Or, as Justice Breyer once observed, "Congress is more likely to have focused upon, and answered, major questions, while leaving interstitial matters [for agencies] to answer themselves in the course of a statute's daily administration."[60]
- The major questions doctrine is also rooted in the separation of powers, a basic feature of the federal government. Most relevant here, the Constitution vests Congress with "[a]ll legislative Powers." Art. I, § 1.[61]
- Under the major questions doctrine, it would be absurd for HHS to claim that the bipartisan Congress that passed the Affordable Care Act sought to impose an abortion or a gender transition mandate.
- Furthermore, in the wake of *Dobbs* and the Court's decision to return the issue of abortion "to the people and their elected representatives,"[62] and in light of vastly different state pro-life laws and minor gender transition procedure laws, whether the federal government should coerce private organizations into providing access or "gender transition" interventions is certainly a major question of vast political and economic significance—one that Congress must explicitly speak to under the major questions doctrine.

[56] Order, *Moyle v. United States*, No. 23-35450 (Jan. 5, 2024).

[57] 143 S. Ct. 2355, 2372 (2023).

[58] *Id*. at 2375.

[59] *United States Telecom Assn. v. FCC*, 855 F.3d 381, 419 (CADC 2017) (Kavanaugh, J., dissenting from denial of reh'g en banc).

[60] S. Breyer, Judicial Review of Questions of Law and Policy, 38 Admin. L. Rev. 363, 370 (1986).

[61] *See also West Virginia v. EPA,* 142 S. Ct. 2587, 2609 (2022) (explaining that the major questions doctrine rests on "both separation of powers principles and a practical understanding of legislative intent").

[62] *Dobbs*, 597 U.S. at 302.

- To the extent that HHS's arguments that it can legally issue such expansive regulations under Section 1557 rely on *Chevron* deference, HHS should wait for the Supreme Court's decisions in *Relentless* and *Loper Bright*. The Supreme Court just heard oral argument in these cases on January 17, 2024.[63]
    - At issue in these cases is whether the Supreme Court should "overrule *Chevron v. Natural Resources Defense Council*, or at least clarify that statutory silence concerning controversial powers expressly but narrowly granted elsewhere in the statute does not constitute an ambiguity requiring deference to the agency."[64]
    - Depending on how the Court rules, these cases could have major impact on the deference given to HHS's efforts to create draconian and controversial mandates through regulations under Section 1557 and other provisions of the Affordable Care Act.

13. HHS should respond with clarity to the following questions.

- Finally, we submit that HHS must address the following questions with clarity in its final rule.
    - For compliance requirements and costs under the rule, will every provider be required to adopt a new policy individually and send out notices in addition to the business when a provider bills in his or her own name separate from facility?
    - Regarding assurance of compliance from prior contracts that are still in effect, will that mean their agreements to comply with HHS regulations automatically transfer into an agreement to comply with updated regulations?
- We also ask that HHS provide clarity regarding when specific medical interventions will be required. For example,
    - If a doctor performs a D&C for miscarriage, will a doctor also have to perform a D&C for abortion?
    - If a doctor prescribes estrogen to women for birth control or for menopause, does that mean the doctor will have to proscribe estrogen for males seeking to "transition"?

Conclusion

We urge OIRA to ensure that the statutory and regulatory process is upheld, and that HHS's proposed rule has sufficient legal and economic analysis that reflects its obligations under the Constitution, the Administrative Procedure Act, federal laws protecting rights of conscience and religious liberty, and all other relevant legal authority.

[63] *See* Amy Howe, *Supreme Court Likely to Discard* Chevron, SCOTUSblog (Jan. 17, 2024), https://www.scotusblog.com/2024/01/supreme-court-likely-to-discard-chevron/.

[64] Order, *Loper Bright Enterprises v. Raimondo*, No. 22-451 (May 1, 2023).