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EO 12866 Meeting
"Safeguarding the Rights of Conscience as Protected by Federal Statutes"
RIN: 0945-AA18

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Thank you for the opportunity to provide comments on OIRA's review of HHS's proposed rule, "Safeguarding the Rights of Conscience as Protected by Federal Statutes," 88 Fed. Reg. 820 (Jan. 5, 2023).[1]

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

1. There is no need for federal regulatory action.

- For all rulemaking, agencies must identify a need and demonstrate how the rule meets that need. HHS has failed to do so here.

- HHS proposes to rescind the majority of the 2019 Rule entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" and maintain "the framework" from the 2011 Rule with some modifications. As an initial matter, there is no evidence that the 2019 Conscience Rule has or will cause *any* harms or burdens necessitating the need for its rescission. To justify its proposed rescission, HHS must provide *specific evidence* as to how the 2019 Conscience Rule is causing harms or burdens. We ask that OIRA ensure that HHS provide such evidence.

- HHS's given justifications in the proposed rule are wholly unconvincing. HHS claims that its proposal to rescind large portions of the 2019 Rule is justified "because those portions are redundant, unlawful, confusing or undermine the balance Congress struck between safeguarding conscience rights and protecting access to healthcare, or because significant questions have been raised as to their legal authorization."[2] It states that §§ 88.1, 88.2, 88.3, 88.4, 88.6, 88.6, 88.9, and 88.10 are "either (1) redundant and unnecessary, because they simply repeated the language of the underlying statute;

[1] As OMB cancelled a previous EO 12866 meeting EPPC had scheduled for a different HHS 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] 88 Fed. Reg. at 825.

(2) have been deemed unlawful in district court decisions that raise significant questions as to whether they exceed the scope of the Department's housekeeping authority; or (3) created confusion or harm by undermining the balance struck by Congress in the statutes themselves."[3]

- The first category of reasons does not justify any aspect of the proposed rule. Though HHS claims it is justified in rescinding large portions of the 2019 Rule "because those portions are redundant, unlawful, confusing" or "simply repeated the language of the underlying statute," the proposed rule does not apply any of these criteria to any particular aspect of the 2019 Rule.
    - The proposed rule never identifies any section or portion of the 2019 Rule as either redundant or unnecessary.
    - Nowhere does HHS provide any example of how a portion of the 2019 Rule "simply repeat[s] the language of the underlying statute," and even if it did, why repeating statutory text is harmful. Indeed, agency regulation regularly repeat statutory text.
    - Similarly, nowhere does HHS explain how the 2019 Rule has created confusion or cite a single example where any entity or person was confused by any part of the 2019 Rule.
- As we will discuss in more detail, HHS's remaining proposed justifications are likewise unsupported and unconvincing.
    - HHS states that it is deferring to three district court decisions without explaining the nuances within each case, without acknowledging contrary authority, and without waiting for any of these cases to be resolved on appeal. This wholesale deference is arbitrary and capricious where HHS has in other rulemaking summarily dismissed cases as "unconvincing."
    - HHS improperly claims the authority to "balance" Congress' unqualified instruction to respect rights of conscience with other policy goals that Congress has never endorsed, let alone set in tension with laws protecting rights of conscience.
- 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 robustly enforce conscience protection laws.

[3] 88 Fed. Reg. at 825-26.

2. HHS's proposal to remove various provisions of the 2019 Rule that have provided needed clarity is arbitrary and capricious.

- HHS claims that it is removing provisions from the 2019 rule that are confusing, including the purpose provision, definitions, applicable requirements and prohibitions, assurance and certification requirements, compliance requirements, rule of construction provision, severability provision, and enforcement authority. Yet its proposal to drop those provisions decreases clarity and creates confusion, undermining HHS's purported justification for the rescission and making HHS's actions arbitrary and capricious.

- **Purpose Provision.** HHS proposes gutting the explanatory statement of purpose in § 88.1 to merely state the names of the conscience protection laws. HHS would delete the broad explanation that the conscience protection laws "protect the rights of individuals, entities, and healthcare entities to refuse to perform, assist in the performance of, or undergo certain healthcare services or research activities to which they may object for religious, moral, ethical, or other reasons"; and "also protect patients from being subjected to certain healthcare or services over their conscientious objection." Neither of these provisions repeat the language of the underlying statutes. Rather they provide a broad overview of what the conscience protection laws do, which is helpful and adds clarity for those who are unfamiliar with federal healthcare conscience protection laws. It is arbitrary and capricious to remove these provisions. They should be retained.

- HHS also proposes deleting the statement of broad interpretation in the purpose provision: "Consistent with their objective to protect the conscience and associated anti-discrimination rights of individuals, entities, and healthcare entities, the statutory provisions and the regulatory provisions contained in this part are to be interpreted and implemented broadly to effectuate their protective purposes." This provision, likewise, does not repeat language of the underlying statute and does not cause confusion or harm; rather, it provides clarity to inform all of how HHS intends to interpret and implement the conscience protection and nondiscrimination laws. HHS claims that its proposal is "safeguarding the rights of conscience," "strengthen[ing] conscience and religious nondiscrimination," and "prevent[ing] discrimination."[4] Yet, its proposal to cut the statement of broad interpretation belies the Department's claim, making its purported rationale arbitrary and capricious.

- **Definitions.** HHS proposes to delete the definition in § 88.2, including "assist in the performance," "discriminate or discrimination," "entity," "federal financial assistance," "health care entity," "health service program," "recipient," "referral or refer," "sub recipient," and "workforce." Because the conscience protection laws don't define these terms, this provision is not redundant or unnecessary. Similarly, because the conscience protections laws do not provide definitions, these definitions added clarity—not confusion or harm—to the scope of protections the laws provide.

[4] Press Release, HHS, HHS Issues New Strengthened Conscience and Religious Nondiscrimination Proposed Rule (Dec. 29, 2022), https://www.hhs.gov/about/news/2022/12/29/hhs-issues-new-strengthened-conscience-and-religious-nondiscrimination-proposed-rule.html.

- **Applicable Requirements and Prohibitions**. HHS proposes deleting § 88.3, which provides detailed explanation of the applicability of and prohibitions or requirements under the different conscience protection laws. To the extent HHS believes these regulations merely repeat the language of the underlying statutes, there is no harm in having statutory language mirrored in regulations. Indeed, there is actual benefit to including the language as it ensures that entities and individuals that are looking at the regulations have an explanation of what the conscience protection laws cover in one place without having to individually look up each of the over two dozen statutes. This regulation explains clearly who the statute applies to and the scope of protections in an easy-to-understand format, which is especially helpful for those without legal expertise. Retaining this regulation would benefit all by minimizing the time needed to learn about the application and prohibitions under each of the conscience protection laws. Conversely, removing this regulation would impose costs of increased time burdens on entities and individuals to learn about their conscience protection obligations and rights and also increase the possibility of violations.

- **Assurance and certification requirements**. HHS proposes cutting § 88.4, which provides assurance and certification of compliance requirements. These requirements are not in the text of the statutes and do not cause confusion or harm. Rather, they are a necessary and important means of ensuring that entities receiving federal funds are aware of their obligations under the federal conscience protection laws and agree to abide by those obligations. Removing these requirements further undermines the Department's rationale that its proposal is strengthening and safeguarding conscience rights, making this proposed deletion also arbitrary and capricious.

- **Compliance Requirements**. HHS proposes deleting the compliance requirements at § 88.6, including requirement to maintain records, cooperate with OCR enforcement, and refrain from intimidation or retaliatory acts. These requirements are not in the text of the statutes and are necessary means to ensure compliance. No specific reasons are given why these basic requirements are to be removed, and their removal undercuts the Department's purported commitment, as stated in the proposed rule, "to ensuring compliance." It is general practice for all civil rights laws that records be maintained, entities and individuals must cooperate with government enforcement, and intimidation or retaliation are strictly prohibited and antithetical to promoting civil rights. It should be no different when it comes to conscience protection laws. For all these reasons, the proposed rescission of the compliance requirements is arbitrary and capricious; the requirements should be retained. In the alternative, HHS should adopt modified means of ensuring compliance.

- **Rule of Construction Provision.** Similar to the purpose statement, HHS proposes deleting the rule of construction provision at § 88.9, which states that the regulations will be construed "in favor of a broad protection of the free exercise of religious beliefs and moral convictions" (to the maximum extent permitted by law). This rule of construction is neither redundant, unnecessary, nor confusing. Instead, it provides much needed clarity as to the Department's interpretation and enforcement of the conscience protection laws. Again, removing this provision conflicts with HHS's purported goals of "safeguarding

the rights of conscience," "strengthen[ing] conscience and religious nondiscrimination," and "prevent[ing] discrimination," making its removal arbitrary and capricious.

- **Severability Provision**. HHS says it is rescinding the severability provision in § 88.10, but then proposes an identical severability provision at proposed § 88.4. We assume the statement that HHS is rescinding the severability provision is an error, otherwise to imply that it is rescinding the severability provision in the 2019 Rule for one or more of the three stated rationales, but then adopt the exact same language is arbitrary and capricious.

- **Enforcement Authority**. HHS also proposes deleting the 2019 Rule's detailed explanation of enforcement authority, including resolution through withholding federal funds or referral to the Department of Justice for lawsuit. Instead, the proposed rule summarily states that OCR would have the authority to: "(1) Receive and handle complaints; (2) Conduct investigations; (3) Consult on compliance within the Department; (4) Seek voluntary resolutions of complaints; and (5) Consult and coordinate with the relevant Departmental funding component, and utilize existing regulations enforcement, such as those that apply to grants, contracts, or other programs and services." While we support this authority of OCR, this brief statement does not provide a needed explanation and clarity. It is unclear how HHS can claim to reduce confusion and be "committed to ensuring compliance" by deleting provisions explaining how HHS will investigate and enforce alleged noncompliance. HHS fails to explain why it is retaining the same enforcement authority as the 2019 Rule but deleting the provisions detailing that authority. This proposal is arbitrary and capricious, and those explanatory provisions should be retained.

- **Model Notice.** HHS proposes two significant changes to the model notice text in Appendix A. First, it would delete the regulation stating that "OCR will consider an entity's voluntary posting of a notice of nondiscrimination as non-dispositive evidence of compliance." Second, it would modify the model notice text to merely name the applicable laws rather than include language from the 2019 Rule model notice explaining what protections and rights the laws provide, such as "prohibiting exclusion, adverse treatment, coercion, or other discrimination against individuals or entities on the basis of their religious beliefs or moral convictions" and that individuals "may have the right under Federal law to decline to perform, assist in the performance of, refer for, undergo, or pay for certain healthcare-related treatments, research, or services (such as abortion or assisted suicide, among others) that violate your conscience, religious beliefs, or moral convictions." HHS fails to explain why it is modifying the text of the model notice, making it arbitrary and capricious. This is yet another example of the proposed rule's unfortunate trend of deleting more detailed information and explanation of conscience protection obligations and rights. This proposal further undermines the Department's purported goals of "safeguarding the rights of conscience," "strengthen[ing] conscience and religious nondiscrimination," and "prevent[ing] discrimination." HHS's model notice text should provide more explanation than just the name of the relevant statutes to better inform people of their rights. The names of the statutes—*e.g*, Church Amendments, Weldon Amendment, and Coats-Snowe Amendment—are insufficiently description to convey the important protections they provide.

3. **HHS should not rely on the flawed reasoning in the three district court decisions and defend the 2019 Rule in court.**

    - HHS does nothing to support its claim that portions of the 2019 rule are "unlawful" other than refer to three district court decisions that each enjoined the 2019 Rule in November 2019.[5] However, HHS does not explain each court's rationale or identify what HHS agrees or disagrees with in each. Instead, HHS describes all three court decisions *in a single sentence.*[6]

    - HHS's categorical deference to the decisions vacating the 2019 Rule fails to explore and account for the important shortcomings in those decisions, which we detailed in our public comment.[7]

    - HHS's simple deference here also stands in sharp contrast to what HHS has done in other recent proposed rules. For example, in proposed rules issued February 2, 2023, HHS proposes to maintain a religious exemption to its "contraceptive services" mandate but eliminate the exemption for non-religious moral exemptions.[8] HHS acknowledges that a district court "reasoned that there was no rational basis" for "distinguishing between religious and moral exemptions."[9] But HHS summarily said there that it "respectfully disagree[d]" with the court's decision. Yet it completely and without explanation defers to court decisions here. This fails to meet HHS's obligation to provide a "reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy."[10]

4. **HHS's reliance on a balance between conscience rights and other interests of access to care and nondiscrimination is contrary to law.**

    - The proposed rule repeatedly states that new rules are necessary to reflect the "balance" Congress allegedly struck in the conscience protection laws between competing interests, even though such a balance is not mentioned in the text of the laws. For example, the proposed rule states:

        > The Federal health conscience protection and nondiscrimination statutes represent Congress' attempt to strike a careful ***balance***. Some doctors, nurses, and hospitals, for example, object for religious or moral reasons to providing or referring for abortions or assisted suicide, among other procedures.

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[5] 88 Fed. Reg. at 823-24.

[6] *Id*. at 824.

[7] EPPC HHS Accountability Project, *EPPC Scholars Comment Opposing HHS's Proposed Rule "Safeguarding the Rights of Conscience as Protected by Federal Statutes," RIN 0945–AA18* (March 6, 2023) at 8-10, *available at* https://eppc.org/wp-content/uploads/2023/03/EPPC-Scholars-Comment-Opposing-HHS-Proposed-Conscience-Rule.pdf.

[8] 88 Fed. Reg. 7236, 7249 (Feb. 2, 2023).

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

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

> Respecting such objections honors liberty and human dignity. It also redounds to the benefit of the medical profession.
>
> Patients also have autonomy, rights, and moral and religious convictions. And they have health needs, sometime urgent ones. Our healthcare systems must effectively deliver services—including safe legal abortions—to all who need them in order to protect patients' health and dignity.
>
> Congress sought to ***balance*** these considerations through a variety of statutes. The Department will respect that ***balance***.[11]

- To the contrary, Congress said that the federal government must respect the conscience rights of healthcare professionals and entities, full stop. For example, nothing in the Church Amendments describes any conditions under which a public official or entity can require an individual to perform an abortion or sterilization procedure in violation of his or her religious beliefs or moral convictions.[12] More to the point, nowhere did Congress grant HHS rulemaking authority to "balance" other interests with the government interest spelled out in the text of the Church Amendments. To suggest otherwise is contrary to law.

- Nothing in the Constitution and nothing in federal law established a federal right to abortion, let alone as a right that is to be balanced against the compelling governmental interest in protecting rights of conscience described explicitly in the federal conscience protection laws that Congress has charged this Department with enforcing. As the Supreme Court recognized in *Dobbs v. Jackson Women's Health Org*, "the Constitution does not confer a right to abortion."[13] "The inescapable conclusion is that a right to abortion is not deeply rooted in the Nation's history and traditions. On the contrary, an unbroken tradition of prohibiting abortion on pain of criminal punishment persisted from the earliest days of the common law until 1973," when the Supreme Court improperly removed that question from the democratic process.[14] Laws regulating abortion 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."[15] Such "legitimate interests include respect for and preservation of prenatal life at all stages of development; the protection of maternal health and safety; the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability.[16]

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[11] 88 Fed. Reg. at 826 (emphases added).

[12] *See* 42 U.S.C. § 300a-7(b).

[13] 142 S. Ct. 2228, 2279 (2022).

[14] *Id*. at 2253-54.

[15] *Id*. at 2284.

[16] *Id*. (cleaned up).

5. **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,[17] HHS agrees the proposed rule is an "economically significant rule," that requires meaningful economic analysis.[18] 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.

- HHS must take into consideration the following key inputs as part of its regulatory impact and economic analysis of the costs, benefits, and transfers:

  Impact on Healthcare Professionals
  - The impact on reliance interests by healthcare professionals.
  - The irreparable loss of conscience and religious freedom rights of healthcare professionals and religiously affiliated institutions.
  - The increase in discrimination and marginalization, especially for those with minority religious viewpoints.
  - The costs to healthcare professionals who are unable to vindicate their conscience and religious freedom rights since many federal conscience protection laws lack a private cause of action (because if HHS does not robustly enforce the laws, no one can).
  - The compounding harms of not robustly enforcing conscience protections while at the same time mandating performance of procedures that violate the conscience of healthcare professionals.

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[18] 88 Fed. Reg. at 827.

Impact on Healthcare Profession

- The cost to the healthcare profession by requiring professionals violate the Hippocratic Oath, which requires they "do no harm" and refrain from participating in abortion.
- The number of healthcare professionals or religiously affiliated institutions that will stop providing certain categories of services or treatments, such as obstetrics and gynecology if abortion is required.
- The demographics of healthcare 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 healthcare professionals that will leave the profession altogether.
- The number of people that will choose not to enter the healthcare profession.
- The additional burdens losing staff will cause for healthcare systems that are already suffering and understaffed after the COVID pandemic.

Impact on Access to Healthcare, Especially for Underserved

- The number of patients that will lose their provider of choice and will be less likely to seek or receive timely care.
- The resulting lack of trust in public healthcare and healthcare professionals who do not share a patient's values.
- The overall impact on public health and access to healthcare services.
- The number of patients that will lose access to care.
- The impact on other HHS-funded programs, such as Medicare, Medicaid, Global Health Programs.
- The impact on healthcare facilities, especially in rural and low-income areas.
- The specific costs on poor, rural, and underserved communities due to shortages or lack of medical providers in those communities.
- The cost of perpetuating healthcare disparities and inequities.

Economic Impact

- The economic losses, as well as unemployment payments, as a result of healthcare professionals leaving the profession.
- The number of additional healthcare professionals that will leave the profession with those increased burdens.
- The impact on labor shortages, especially in healthcare.
- The amount healthcare and insurance expenses will increase due to decreased supply.

Government Interests

- The government's interest is in supporting and enabling existing and new medical professionals to care for their patients.

    - The government's lack of countervailing interest in coercing medical professionals to participate in procedures that violate their conscience or religious beliefs.

- The analysis must consider as the baseline, the 2022 reality of a post-COVID pandemic healthcare landscape. Pre-pandemic numbers won't accurately reflect the strain on the healthcare community from professionals to institutions.

- We urge OIRA to ensure that HHS takes all of these factors, and more, into consideration, and quantified or estimated to the maximum extent possible for a sufficient analysis of impact, costs, benefits, and transfers.

6. 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.
    - 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 "<u>shall</u>" (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 as 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. Yet HHS's proposal contained no discussion of federalism impacts. We urge OIRA to ensure these impacts are addressed in the final rule.

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 is rationale and reasoned, not political, rushed, or prejudged.