ETHICS AND PUBLIC POLICY CENTER

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EO 12866 Meeting
Rescission of the Regulation entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority"
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Thank you for the opportunity to provide comments on OIRA's review of HHS's proposed rescission of the rule entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (the "2019 Conscience Rule" or "2019 Rule").

As OMB cancelled a previous EO 12866 meeting EPPC had scheduled for a different HHS rule,[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.

- The 2019 Conscience Rule gives effect to 25 longstanding laws that broadly protect individuals, health care entities, and providers from discrimination in health care by government or government-funded entities because of the exercise of religious belief or moral conviction. The Rule protects the rights of diverse health care professional and faith-based institutions and helps ensure that health care professionals will not feel compelled to leave the practice of medicine because they have conscience or religious objections to patriciate in abortion, sterilization, or assisted suicide.[2]
- The 2019 Rule addressed the lack of knowledge and rights and obligations under HHS-funded or administrated health programs and corrected misunderstandings about conscience protections, which happened under the 2011 regulations. Despite HHS's duty to enforce all 25 federal constitutional and statutory protections for conscience and religious freedom rights, the 2011 regulations provided inadequate enforcement of conscience rights by only focusing on three conscience laws.[3]

[1] Rachel N. Morrison, "Biden and Becerra Kill Democratic Norms in Rush to Fund Big Abortion," *National Review*, October 8, 2021. https://www.nationalreview.com/bench-memos/biden-and-becerra-kill-democratic-norms-in-rush-to-fund-big-abortion/.
[2] https://www.hhs.gov/sites/default/files/final-conscience-rule-factsheet.pdf.
[3] *Id.*

- 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. Further, the agency must explain how it will fulfill its statutory duty to protect and enforce conscience protection laws while rescinding a Rule giving effect to those protections.
- The proposed rescission follows a disturbing trend of HHS paying lip service to conscience and religious freedom rights, while blatantly disregarding and ignoring those right, including by effectively dismantling its Conscience and religious Freedom Division and crippling its Office for Civil Rights to receive complaints and enforce religious protections under the Religious Freedom Restoration Act and the First Amendment.[4]

2. HHS should consult with and follow the recommendations of the Conscience and Religious Freedom Division.

- Considering this proposal involves HHS's statutory duty to uphold conscience protection laws, HHS should request input from the career professionals at the Conscience and Religious Freedom Division and follow their 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.

3. No regulatory action should be taken before the Supreme Court decision in *Dobbs*.

- At a minimum, HHS should hold it proposal 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. Many of the conscience protection laws, such as the Church Amendments, depend on the definition of "lawful abortion." 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. 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 analysis, application, and enforcement of the federal conscience laws at issue with HHS' proposal. At a minimum, the public should have sufficient time to provide meaningful public comment after the Supreme Court issues its decision in *Dobbs*.

[4] Rachel N. Morrison, "In Its First Year, Biden's HHS Relentlessly Attacked Christians and Unborn Babies," *The Federalist* (March 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).

4. **The Proposal must be considered in conjunction with other proposed regulations affecting conscience and religious freedom rights.**

- There are currently several proposed rules (at various stages) that implicate conscience and religious freedom rights in health care. As such, HHS must join this Proposal with those related rules, which include:
    - The CMS insurance regulations proposed in January that would mandate insurance coverage of sterilizing gender transition surgeries and hormones, including for minors.[5]
    - HHS's forthcoming Section 1557 proposed rule, currently under review at OMB, that could "redefine standards of care by requiring doctors to perform experimental transgender surgeries (including on minors) against their ethical and medical judgment, and by requiring insurance plans to pay for such dangerous interventions."[6]
    - The Department of Education's forthcoming Title IX proposed rule, also currently under review at OMB, because it has direct implications for health care since Section 1557 prohibits discrimination on the grounds prohibited by Title IX.[7]
- At a minimum, the agency must evaluate its proposed rescission in light of those other proposed rules that will have a direct impact on conscience and religious freedom rights.

5. **The Proposal must include a meaningful economic analysis and consider its costs.**

- HHS' proposed rescission an economically significant rule, that 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 proposal to rescind the 2019 Conscience Rule should take into consideration the following key inputs:
    - 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.

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[5] *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/.
[6] https://eppc.org/news/eppc-leads-coalition-to-request-meeting-with-government-health-officials-on-anticipated-section-1557-rulemaking/.
[7] *See* https://eppc.org/wp-content/uploads/2022/03/EPPC-Scholars-Comment-Title-IX-Rule-EO-12866-Meeting.pdf.

- The increase in discrimination and marginalization, especially for those with minority religious viewpoints.
- The cost to the health care profession by requiring professionals violate the Hippocratic Oath, which requires they "do no harm" and refrain from participating in abortion.
- The number of health care 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 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 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 health care and health care professionals who do not share a patient's values.
- The overall impact on public health and access to health care services.
- The impact on other HHS-funded programs, such as Medicare, Medicaid, Global Health Programs.
- The impact on health care facilities, especially in rural and low-income areas.
- The economic losses, as well as unemployment payments, as a result of health care professionals leaving the profession.
- The additional burdens losing staff will cause for health care systems that are already suffering and understaffed after the COVID pandemic.
- The number of additional health care professionals that will leave the profession with those increased burdens.
- The impact on labor shortages, especially in health care.
- The amount health care and insurance expenses will increase due to decreased supply.
- The number of patients that will lose access to care.
- The number of people that will choose not to enter the health care profession.
- The government's interest is in supporting and enable existing and new medical professionals to care for their patients.
- 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.
- 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 (because 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.

- The analysis must consider as the baseline, 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.
- 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.

6. The Proposal must evaluate alternative regulatory approaches.

- In addition to the numerous costs of its Proposal, HHS must consider alternatives, including not regulating, and provide a reasoned explanation of why its proposal is better than those alternatives.
- Some alternatives the agency must consider and evaluate are:
    - Issuing similar regulations to the 2019 Rule.
    - Adopting the Obama-era 2011 conscience regulations.
    - Modifying the 2011 regulations, such as by covering all 25 conscience protection laws.
    - Rescinding only portions of the 2019 Rule, while leaving other portions in place, such as the procedural regulations.[8]
    - Evaluating any rescission or modifications to the 2019 Rule on a statute-by-statute basis instead of whole cloth.
    - Waiting until after the *Dobbs* decision is issued by the Supreme Court to make its proposal.

7. The Proposal 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 anticipated HHS rescission 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.

[8] *See* https://www.hhs.gov/sites/default/files/final-conscience-rule-factsheet.pdf (summarizing the 2019 Conscience Rule's procedural regulations).

- 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.

8. 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 "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 as it will impact state hospitals, medical facilities, and insurance plans. In addition, it will likely preempt state and local laws protecting conscience and religious freedom rights. These impacts must be addressed.
- HHS must also consult with states before issuing a rule that imposes a substantial cost and impact on states.

9. The Proposal must be analyzed in conjunction with other laws.

- *Section 1554.* The proposed rescission of the 2019 Conscience Rule 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."

- The proposal 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 beliefs, such as in affirmance of abortion or gender identity, and refrain from speaking according to a patient's biological sex and medical needs; 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 and treatments, and by forcing providers to violate moral and medical standards as healthcare professionals.

- *RFRA.* In proposing to rescind the 2019 Conscience 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 in 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 intertest in enforcing its non-discrimination 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."
    - HHS recently withdrew the delegation of authority from OCR to enforce RFRA, and so any perfunctory statement that HHS will comply and follow RFRA and other conscience protection laws is suspect. HHS must explain *specifically* how it intends to uphold its duty to enforce conscience and religious freedom protection laws.

- *Title VII.* HHS must also consider its proposed rescission in connection with Title VII's religious accommodation requirement, which generally requires employers to reasonably accommodate an employee's sincerely held religious belief, observance, and practice. Specifically, Title VII does not preempt the Church Amendments, which were passed *after* Title VII. Rather the conscience protection laws provide *additional* protections to Title VII.

10. HHS appears to have prejudged the Proposal by rushing review at OMB.

- We are concerned with the apparent fast tracking of this rule at OMB and the apparent disregard for democratic norms and meaningful public comment at this stage. The rule was received at OMB a week ago on Friday, March 25. When EPPC requested a meeting on Tuesday, March 29 for two weeks later (which would allow me sufficient time to prepare substantive comment), the meeting was instead scheduled for the very next day, Wednesday, March 30. This is absurd. The rule is economically significant and there is no legal deadline. It appears HHS is trying to rush the rule through OMB review and

avoid substantive and meaningful public input, suggesting that it has prejudged the outcome and is not interested in public participation.

11. The Proposal 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 2019 Rule had a 60-day comment period. As mentioned earlier, this proposal is economically significant and there is no legal deadline. As such, I ask that for this Proposal the Department provides a minimum of 60 days, if not 90 days since the Proposal would take away benefits, to allow the public time to provide meaningful input as required by law.
- I 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. SKIP For example, HHS's Centers for Medicare & Medicaid Services (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 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 Proposal has sufficient legal and economic analysis that is rationale and reasoned, not political, rushed, or prejudged.