ETHICS AND PUBLIC POLICY CENTER

September 26, 2024

EO 12866 Meeting
Health and Human Services, Centers for Medicare & Medicaid Services
"Enhancing Coverage of Certain Preventive Services
Under the Affordable Care Act" (CMS-9887)
RIN: 0938-AV57

Eric Kniffin and Sam Lucas
HHS Accountability Project
Ethics & Public Policy Center

Thank you for the opportunity today to provide comments on OIRA's review of the proposed rule, "Enhancing Coverage of Certain Preventive Services Under the Affordable Care Act" by the Centers for Medicare & Medicaid Services in the Department of Health and Human Services (HHS).

As HHS has not provided the public with any detail regarding this proposed rule, our comments are necessarily general in scope. The comments below are based on what we have observed about prior rulemaking under the Affordable Care Act as well as this administration's track record on rules that have a predictable impact on religious liberty, freedom of conscience, and the right to life.

My name is Eric Kniffin. I am an attorney and Fellow at the Ethics and Public Policy Center, where I serve on EPPC's HHS Accountability Project. I also served in DOJ's Civil Rights Division under Presidents George W. Bush and Barack Obama. After leaving public service, I worked for the Becket Fund for Religious Liberty and in private practice, where I have s successfully defended the rights of religious employers and healthcare institutions from HHS's contraception mandate and transgender mandate. Also contributing to this comment is Sam Lucas, a Legal Associate with EPPC's HHS Accountability Project.

EPPC's HHS Accountability Project is dedicated to monitoring the U.S. Department of Health and Human Services and holding it accountable to its mission: furthering the health and well-being of all Americans. The HHS Accountability Project's goals include: Ensuring human beings are recognized as worthy of protection from conception until natural death regardless of disability, age, or circumstances of birth; ensuring abortion and assisted suicide are never accepted or recognized as health care; and preventing ideology from distorting science on questions of human identity and human flourishing.

Today, there are six main points we would like to share with OIRA and HHS.

1. **HHS must identify a need for rulemaking and show how the proposed rule meets that need.**

   - For all rulemaking, agencies must identify a need and demonstrate how the rule meets that need. Agencies must also consider the alternative of not amending the regulation at all, which we encourage HHS to do here.
     - The goal of the Affordable Care Act's (ACA) preventative services mandate is prevention of disease. As EPPC scholars have documented in previous comments, the authority delegated by Congress to HHS under Section 2713 of the Public Health Services Act is limited, and it is arbitrary and capricious for HHS issue rulemaking to deem pregnancy a disease or transform this mandate from its statutory goal of "prevention" to "access." We continue to call on HHS to honor the text of this statutory provision and not use Section 2713 as a blank check with which to advance policy objectives that have not received support in Congress.
     - Speculative or general statements (such as HHS's claim in prior rulemaking that women need access to free contraception and that lack of access to contraception may cause harms) cannot establish need for regulatory action.
   - *Complaints*. To the extent that HHS relies on complaints in order to justify the need for the proposed rulemaking, HHS must be specific by providing an exact number of complaints and describing categories of complaints with enough detail so as to fulfill HHS's legal obligations and to provide the American public with enough information to assess the scope and significance of the problem claims to have identified. General complaints are insufficient to establish need, especially if those plans are not subject to a religious or moral exemption.
   - *Legal challenges*. The mere existence of ongoing lawsuits does not establish the need for regulatory action.
   - *Alternatives*. In any proposed rulemaking that would expand the items that must be covered under Section 2713 of the PHS Act, HHS should consider alternatives to mandating coverage through private health plans. Such alternatives should include market-based means of access, deliver through existing government programs, and also potential new government programs. If HHS judges judge that such alternatives are not economically viable or politically viable, it should explain in detail the bases for its reasoning and conclusions. Another alternative HHS should consider is educational campaigns, such as HHS's 2022 letters to insurers about the ACA's requirement to cover contraception,[1] and individual administrative or enforcement actions against any offenders.

2. **RFRA and the Supreme Court require meaningful religious exemption to any preventive services mandate.**

   - *Agency rulemaking must be in accord with law*. As noted above, given HHS's past rulemaking under the preventive services mandate, we are concerned that the proposed changes to regulations under Section 2713 of the PHS Act may include new mandates

[1] Letter from Secretaries of HHS, Treasury, and Labor to Group Health Plan Sponsors and Issuers (June 27, 2022), https://www.cms.gov/files/document/letter-plans-and-issuers-access-contraceptive-coverage.pdf.

that would substantially burden the religious exercise of religious employers, insurers, or TPAs. If this is the case, we remind HHS of its obligations under the Religious Freedom Restoration Act (RFRA) and several recent Supreme Court cases interpreting this law. RFRA "prohibits the federal government from substantially burdening a person's exercise of religion unless it demonstrates that doing so both furthers a compelling governmental interest and represents the least restrictive means of furthering that interest." *Bostock v. Clayton Cnty*., 140 S. Ct. 1731, 1754 (2020) (citing 42 U.S.C. § 2000bb-1).

- *Compelling interest*. Strict scrutiny first requires HHS to consider whether a proposed mandate would advance a compelling government interest. 42 U.S.C. § 2000bb-1(b)(1). The following is a list of factors HHS must consider when determining whether any proposed mandate would satisfy this test.
    - *Incompatible with Congress' will:* While there is not a clear test to determine what counts as a compelling government interest, one thing that is clear is that not all government interests are compelling. A second principle is that the branch of the federal government most responsible for expressing the government's interest is the executive branch. As such, when considering a potential mandate, agencies should consider whether Congress has considered legislation on the subject. As the Supreme Court has noted, where a proposed executive action is "incompatible with the expressed or implied will of Congress," executive branch's "power is at its lowest ebb."[2]
    - *Subject to substantial exceptions:* Another measure of whether an interest is compelling is whether an agency's proposal would include substantial exceptions. The Supreme Court noted in *Burwell v. Hobby Lobby Stores, Inc*. that the contraceptive mandate did "not apply to tens of millions of people." 573 U.S. 682, 700 (2014). Specifically, the ACA exempted over one-third of the 149 million nonelderly people in America with grandfathered employer-sponsored health plans and 34 million workers employed at firms that do not have to provide insurance at all because they employ fewer than 50 employees. *Id*.
    - *Applied to objecting religious organizations:* The Supreme Court explained in *Fulton v. City of Philadelphia* that the question "is not whether the City has a compelling interest in enforcing its non- discrimination policies generally, but whether it has such an interest in denying an exception to [the specific religious organization]." 141 S. Ct. 1868, 1881 (2021). As Justice Neil Gorsuch wrote in another case, *Fulton* explains that "strict scrutiny demands 'a more precise analysis'": a government's "general interest" in its regulations is not compelling "without reference to the specific application of those rules to [the specific party]." *Mast v. Fillmore County*, 141 S. Ct. 2430, 2432 (2021) (Gorsuch, J., concurring with decision to grant, vacate and remand). The Fulton Court thus rejected general or "broadly formulated" goals as being a compelling government interest. 141 S. Ct. at 1881. Rather, the Court framed the question around the party whose religious beliefs were burdened by the policy— whether the government has an interest in burdening the religious organization when the

[2] *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 637-38 (1952).

government's policy allowed other exceptions. *Id*. Here, any government interest in providing women access to free contraception must be considered in light of the existing exceptions to the contraception mandate and the impact on the specific employer with a conscience or religious objection.

- *Least restrictive means.*
    - Even if HHS concludes that its proposed mandate advances a compelling government interest, it must also consider whether its proposal "is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. § 2000bb-1(b)(2). As the Supreme Court in *Fulton* explained, "so long as the government can achieve its interests in a manner that does not burden religion, it must do so." 141 S. Ct. at 1881.
    - *As applied to religious employers,* HHS must take into account "'[t]he most straightforward way of [ensuring that people have access to preventive care services] would be for the Government to assume the cost of providing [such services] 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)).
    - *As applied to religious healthcare providers,* HHS must undertake a similar analysis. For example, when analyzing HHS's attempt to force religious health care providers to perform gender transition procedures, one court noted HHS could not 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).
- *Case-by-case consideration not required.*
    - In some rulemaking, HHS has claimed that it cannot make broad representations about protecting religious liberty because RFRA requires "a fact-sensitive, case-by-case analysis of [substantial] burdens and [compelling government] interests is needed under RFRA."[3] That is true in some but not all RFRA cases. In RFRA challenges against other HHS mandates, courts have found in favor of religious employers and religious healthcare institutions for reasons that do not require inquiries into entity-specific facts.[4]

[3] 87 Fed. Reg. at 47941.

[4] *See* EEOC Scholars' Comment for EO 12866 Meeting, "Nondiscrimination in Health Programs and Activities," RIN 0945-AA17 (Feb. 2, 2024) at 9-11, https://eppc.org/wp-content/uploads/2024/02/EPPC-Scholars-Comments-for-EO-12866-Meeting-Section-1557-ACA-.pdf.

- *Balancing interests and rights*.
    - HHS has also sometimes claimed the authority to balance religious liberty rights or rights of conscience against its own interests. We remind HHS that it does not have independent authority to balance interests; whether any balancing is appropriate is determined by the relevant law. For example, where HHS proposals impact religious liberty, the balancing HHS must conduct is under the strict scrutiny test set out in that law. To the extent that HHS's proposals impacts the conscience rights of health care workers and health care institutions, we note that federal conscience protection statutes do not contain any balancing tests.[5]
- *Promoting equity for religious minorities.* In accord with the administration's push for equity in federal programs as directed by President Biden in Executive Order 13985, HHS should consider the impact of its rule on religious minorities who have objections to complying with any proposed mandate.
- *No slippery slope.* One concern raised during the initial wave of litigation against the contraception mandate, is that it would lead to a floodgate of other RFRA claims. This never manifested. An empirical study of religious freedom cases found "despite claims that Christians would be the prime beneficiaries of Hobby Lobby, religious minorities are significantly overrepresented in the cases relative to their population, while Christians are significantly underrepresented. And while there was an uptick of RFRA claims challenging the contraception mandate—culminating in Hobby Lobby and Little Sisters of the Poor—those cases have subsided, and no similar cases have materialized." Luke W. Goodrich & Rachel N. Busick, *Sex, Drugs, and Eagle Feathers: An Empirical Study of Federal Religious Freedom Cases*, 48 Seton Hall L. Rev. 353, 356 (2018).

3. Any new religious or moral exemption process should include HHS's Conscience and Religious Freedom Division.

- HHS should not change the existing process for religious or moral exemptions. However, if HHS (based on an established need) decide to change the process, it should request input from the career professionals at the Conscience and Religious Freedom Division (CRFD) and follow their expertise and recommendations. Further, if HHS proposes to evaluate any religious freedom or moral exemption requests, that evaluation should be conducted by conscience and religious freedom law experts, namely the CRFD.
- In other regulations, the Biden administration has summarily acknowledged religious protections, but failed to explain (a) how those protections would apply in practice, (b) the process for obtaining a religious accommodation, or (c) how an organization can appeal an alleged incorrect denial of an accommodation. In this rulemaking, if HHS proposes that it will now evaluate religious or moral exemption requests, it should clearly explain the protections and process for religious and moral exemptions. This should include, at a minimum, who is responsible for evaluating the exemption, the timeline for evaluation, and the process for appeal of any denied exemptions.

[5] *See* EEOC Scholars' Comment for EO 12866 Meeting, "Safeguarding the Rights of Conscience as Protected by Federal Statutes" RIN: 0945-AA18 (Sept. 29, 2023) at 6-7, https://eppc.org/wp-content/uploads/2023/09/EPPC-Scholars-Comments-for-EO-12866-Meeting-2023-09-29-on-HHS-Rule-on-Safeguarding-the-Rights-of-Conscience-as-Protected-by-Federal-Statutes.pdf.

- Unfortunately, there has been a concerning trend by HHS to cut the career CRFD professionals out of the review process for 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. For example, Secretary Becerra removed from the HHS Office for Civil Rights (of which the CRFD is part) the delegation of authority to enforce RFRA. Further, HHS and specifically Secretary Becerra have shown a distain for conscience and religious rights even going so far as to not enforce statutory protections for those who have conscience and religious objections to providing abortion.[6]

HHS should respect the American tradition of respecting conscience rights in health care.

- HHS can and should respect rights of conscience. As the Supreme Court held in *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, HHS has "the authority to provide exemptions from the regulatory contraceptive requirements for employers with religious and conscientious objections." 140 S. Ct. 2367, 2373 (2020).

- *American tradition respects conscience rights in health care.* America has a long tradition of respecting religious and broader conscience or moral objections in health care, especially related to matters concerning end of life, such as abortion, abortifacients (which can include certain contraceptives), and euthanasia. For example:

    - The Church Amendments 42 U.S.C. § 300a-7 et seq., were enacted in the 1970s to protect the conscience rights of individuals and entities that object to performing or assisting in the performance of abortion or sterilization procedures if doing so would be contrary to the provider's religious beliefs or moral convictions.

    - The Weldon Amendment, originally passed as part of the HHS appropriation and has been readopted (or incorporated by reference) in each subsequent HHS appropriations act since 2005, provides that "[n]one of the funds made available in this Act [making appropriations for the Departments of Labor, Health and Human Services, and Education] 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." It also defines "health care entity" to include "an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan."

- HHS should continue this tradition of respecting conscience rights in healthcare.

[6] See, e.g., Rachel N. Morrison, In Its First Year, Biden's HHS Relentlessly Attacked Christians and Unborn Babies, Federalist (Mar. 18, 2022), https://thefederalist.com/2022/03/18/in-its-first-year-bidens-hhs-relentlessly-attacked-christians-and-unborn-babies/.

4. **HHS must conduct a regulatory flexibility analysis and properly consider the benefits and costs.**

   - *Regulatory Flexibility Analysis Required*. 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."

   - *Proper baseline for analysis of benefits*. The rule cannot claim a general benefit of "increased access" to contraception. It can only claim benefits for those who do not currently have access to contraception because of the current regulations that would change under the proposed rule.

   - *Costs*. HHS should consider the cost of any loss of free exercise of religion rights which results in irreparable harm.

5. **Any rule should have a meaningful public comment period.**

   - Under EO 12866, for most rules, the public should receive at least 60 days for meaningful comment. The Administrative Procedure Act suggests less than 30-days is highly suspect and problematic.

   - There has been a concerning trend by this administration of providing the public less than 30 days for comment from publication of the notification of proposed rulemaking in the federal register. For example, CMS published a 145-page, triple-columned notice of proposed rulemaking on January 5, 2022, 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 deadline was outrageously short.

   - We urge HHS to provide a minimum of 60 days (counted from publication in the federal register not public inspection of the NPRM) to allow the public time to provide meaningful input on this rule as required by law. Any shorter would suggest that HHS has prejudged the rule and are not interested in the public's input. Surely, fairness and equity suggest the public should have a reasonable amount of time to consider and comment on the proposed rule, especially for a rule that is significant.

Conclusion

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