ETHICS AND PUBLIC POLICY CENTER

August 2, 2022

EO 12866 Meeting
Coverage of Certain Preventive Services Under the Affordable Care Act (CMS-9903)
RIN: 0938-AU94
Comments by Rachel N. Morrison & Roger Severino

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

The abstract states: "This rule would propose amendments to the final rules regarding religious and moral exemptions and accommodations regarding coverage of certain preventive services under title I of the Patient Protection and Affordable Care Act" (ACA). Preventative services include contraception, and it appears proposed rule would make changes to the existing regulations for religious and moral exemptions to the ACA's contraception mandate.

My name is Rachel Morrison. I am an attorney and Fellow at the Ethics and Public Policy Center (EPPC), where I serve on EPPC's HHS Accountability Project. Also on the call is Roger Severino, Senior Fellow at HHS, member of EPPC's HHS Accountability Project, and former director of the HHS Office for Civil Rights.

OMB cancelled a previous EO 12866 meeting EPPC had scheduled for a different rule,[1] so we are glad you are willing to hear our input on this rule.

Today, there are seven main points we want to share with OIRA and the three agencies.

1. **The agencies 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. The agencies must also consider the alternative of not amending the regulation at all, which we encourage the agencies to do here.
   - *Need*. The agencies must demonstrate with specific evidence three things:

     1) that qualifying women who want access to contraception have been unable to obtain access to contraception *but for* the existing regulations;

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

2) that such women became pregnant due to #1 and aborted their child (or continue to regret having their child); and

3) that any proposed regulatory amendments would significantly reduce both #1 and #2, in a manner that is the least restrictive means possible with respect to burdening religious exercise of regulated parties.

- The goal of the preventative services mandate (which HHS made to include a contraceptive mandate) is prevention of disease. Although it is arbitrary and capricious to deem pregnancy a disease, having done so, the agency cannot now transform the mandate from its statutory goal of "prevention" to "access."
- It has been several years since the 2018 regulations went into effect allowing the departments sufficient time to assess the "on-the-ground" impact. Speculative or general statements that women need access to free contraception, that lack of access to contraception may cause harms, or that the 2018 regulations may lead to these "harms" cannot establish need for regulatory action.
- If the agencies believe they are compelled to mandate contraceptive access to exempt entities under the existing rule, the agencies must at the same time eliminate the exemption for all grandfathered plans that currently do not have to provide contraceptive access in order to fulfill this alleged compelling interest.

- *Complaints*. HHS should be able to provide an exact number of how many complaints it has received from women unable to access contraception through their insurance plans and the number of those women who became pregnant and regretted it as a result. General complaints that insurance plans do not cover contraception are insufficient to establish need, especially if those plans are not subject to a religious or moral exemption. Likewise, failure of women to utilize existing alternative mechanisms by which they can receive free or low-cost access to contraception when their plan is subject to a religious or moral exemptions does not establish the need for regulatory action to modify the religious and moral exemptions.
- *Legal challenges.* The mere existence of ongoing lawsuits does not establish need for regulatory action. There are no adverse final judgments in the existing legal challenges to the 2018 regulations, and the court in Massachusetts upheld the religious and moral exemptions under constitutional and statutory claims. *See Massachusetts v. U.S. Dep't of Health & Human Servs*., 513 F. Supp. 3d 215 (D. Mass. 2021).
- *Dobbs.* The Supreme Court's recent decision in *Dobbs v. Jackson Women's Health Organization*, No. 19-1392 (U.S. Jun. 24, 2022), does not create a need for this rulemaking. As the Majority made clear that opinion was *not* about contraception. Rather, it was about whether there is a right to abortion in the U.S. Constitution. There is not. The Court explained, "*Roe's* defenders characterize the abortion right as similar to the rights recognized in past decisions involving matters such as intimate sexual relations, contraception, and marriage, but abortion is fundamentally different, as both *Roe* and *Casey* acknowledged, because it destroys what those decisions called 'fetal life' and what the law now before us describes as an 'unborn human being.'" *Id.*
- *Alternatives.* The agencies should consider not regulating and allow market forces to fill the gap for any lack of access to contraception. If the agency establishes a market failure,

the agencies should also consider how other regulations can provide access to contraception for women not through a religious or morally-objecting organization, such as through the Title X program. Another alternative the agencies should consider are educational campaigns, such as their recent letters to insurers about the ACA's requirement to cover contraception,[2] and individual administrative or enforcement actions against any offenders.

2. RFRA and the Supreme Court require a meaningful religious exemption to the contraceptive mandate.

- Agency rulemaking must be in accord with law. The agencies must apply the Religious Freedom Restoration Act (RFRA) and several recent Supreme Court cases to this rulemaking. 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*. It is hard for the government to claim it has any compelling interest in requiring organizations with religious (or moral) objections to provide women with free contraception when it exempts others from doing so and removes alternative methods for women to receive access.
    - In *Burwell v. Hobby Lobby Stores, Inc.*, the Supreme Court pointed out 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.*
    - The 2019 Title X Rule defined "low-income family" to include "cases involving 'payment for contraceptive services only,' where the woman's employer 'does not provide the contraceptive services sought by the woman because the employer has a sincerely held religious or moral objection to providing such coverage.'" 84 Fed. Reg. 7714, 7734. This definition, consistent with *Hobby Lobby*, provided one of the lesser restrictive means for the government to provide contraception to women directly instead of requiring employers to violate their sincerely held religious beliefs. This is a win-win solution was removed in the final Title X Rule issued in 2021 under the Biden administration. The 2021 Rule removed (over objections[3]) that part of the definition of "low-income family." 86 Fed. Reg. 56144, 56156. It is arbitrary and capricious for the government to claim that

[2] 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.

[3] 86 Fed. Reg. 56144, 56156 ("Two comments opposed removing women who cannot receive contraception from their employer because they have a religious or moral objection from the definition of low-income."); *see, e.g.*, EPPC Scholar Comment Opposing Proposed Rule "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services," RIN 0937-AA11 (May 17, 2021), https://eppc.org/wp-content/uploads/2021/05/EPPC-Comment-Opposing-Title-X-Proposed-Rule.pdf ("This provision should be retained in the definition of 'low income family.'").

providing access to contraception is a compelling interest while simultaneously removing methods of obtaining it.

  - 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 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*.
  - 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. There are numerous other ways the agencies can provide access to free contraception without using those who have religious or moral objections as "middlemen."
  - As the *Hobby Lobby* Court explained, "The effect of the HHS-created accommodation on the women employed by Hobby Lobby and the other companies involved in these cases would be precisely zero. Under that accommodation, these women would still be entitled to all FDA-approved contraceptives without cost sharing." 573 U.S. at 693. The same is true here.
- *Balancing interests and rights.* Regarding balancing the government's and women's interests in access to free contraception with religious organizations' free exercise rights, the First Amendment and RFRA have struck that balance. The agencies cannot disregard constitutional and statutory free exercise rights for interests in free contraception provided by an objecting third party. Access to free contraception is not a constitutional right nor a statutory right, but rather an interest recognized in regulations.
- *Regulating insurers as end-run.* We are concerned the agencies may try to create an end-run of RFRA's requirements by opting to instead require the insurance provider, who does not have any religious objections to contraception, to provide plans with coverage for contraception. This requirement would be suspect, a form of religious targeting, and cause direct harm. *Cf. Cedar Park Assembly of God of Kirkland, Washington v. Kreidler*, No. 20-35507, *1 (9th Cir. Jul. 22, 2021) (Church "plausibly alleged that, due to the enactment of [state law requiring insurance coverage for abortion], its health insurer (Kaiser Permanente) stopped offering a plan with abortion coverage restrictions and [the

church] could not procure comparable replacement coverage. This is sufficient to state an injury in fact that is fairly traceable to [the state law].").

- *Alternative.* One alternative method of providing religious protections is providing an accommodation for individuals to opt out of paying for insurance coverage of contraception when they have a religious (or moral) objection. This would not prevent any woman from obtaining contraception or impinge on any government interest of providing women with contraception as the person opting out would not want access to contraception. It would also respect the religious rights of the insured.
- *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, the agencies should consider the impact of their rule on religious minorities who have objections to contraception in general or certain contraceptives that can act as abortifacients.
- *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.

- The agencies should not change the existing process for religious or moral exemptions. However, if the agencies (based on an established need) decide to change the process, HHS should request input from the career professionals at the Conscience and Religious Freedom Division (CRFD) and follow their expertise and recommendations. Further, if the agencies propose 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 the agencies propose that they will now evaluate religious or moral exemption requests, they 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.
- 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, earlier this year, 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.[4]

4. **The agencies should keep moral exemptions to the contraceptive mandate consistent with the American tradition of respecting conscience rights in health care.**

- We anticipate the agencies may try to remove the moral exemption. However, in *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, the Supreme Court held that 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). The moral exemption should be kept.
- *Lack of need.* Any changes to the existing moral exemption must be supported by need. According to the 2018 regulation, the department estimated that "approximately 15 women may incur contraceptive costs due to for-profit entities using the expanded moral exemption provided for in these final rules." 83 Fed. Reg. 57592, 57627. The agencies should provide a concrete number of what has happened since the inception of the moral exemption. Absent evidence, this does not necessitate proposed rulemaking.
- *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."

[4] *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/.

The agencies should continue this tradition of respecting conscience rights in healthcare.

- *Targeting pro-life groups.* Eliminating the moral exemption will likely have a disproportionate impact on pro-life organizations, many of which oppose certain forms of contraception that could act as an abortifacient. For example, the March for Life is a pro-life organization and presumably those who work there share the organization's pro-life views. No organization should be required to pay for abortifacients that could end the life of a child in the womb.
- *Alternative.* An alternative to eliminating the moral exemption (if proposed) is to allow the same process for woman to receive access to contraception as those with plans with religious objectors.
- *Opening the door for legal challenges.* Any removal of the moral exemption would open the door for additional challenges to the ACA, particularly an Administrative Procedure Act (APA) challenge to the requirement-—not made with public notice and comment—that insurance coverage must include the preventative services identified by HHS's Health Resources & Services Administration (HRSA). *Cf. Kelley v Becerra*, No. 4:20-cv-00283-O (N.D. Tex.) (raising APA challenge to ACA requirement to cover HRSA's list of preventative services)

5. The agencies must conduct a regulatory flexibility analysis and properly consider the benefits and costs.

- *Regulatory Flexibility Analysis Required.* The summary of the rule states that it is undetermined whether the regulatory flexibility analysis is required but acknowledges that the rule is economically and other significant, which 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."
- *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 under the proposed rule.
- *Costs.* The agencies should consider the cost of any loss of free exercise of religion rights which results in irreparable harm.

6. **The 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 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 the agencies 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 the agencies have 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.