ALLIANCE DEFENDING FREEDOM
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E.O. 12866 Meeting
Rescission of the Regulation entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority"
RIN: 0945-AA18
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Thank you for the chance to provide comments on OIRA's review of the proposed rule for Rescission of the Regulation entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (RIN 0945-AA18).

A. No Need for Federal Regulatory Action

- There is no need for this regulatory action.
- In fact, rescinding the current regulation will harm to healthcare providers and patients across the country by driving providers out of healthcare. Rescinding enforcement of conscience protections will exacerbate lack of access to care, especially after the pandemic has reduced healthcare staffing. This regulatory action will thus increase existing health disparities in rural and underserved communities.
- No evidence shows that the 2019 conscience regulation has caused or would cause any harms or inappropriate burdens requiring this regulatory action. To the contrary, ensuring compliance with conscience protections and religious freedom is an important goal. The agency should identify specific reasons why this 2019 regulation is causing harms or burdens and needs to be rescinded.
- HHS lacks a justification for rescinding the rule other than a desire not to defend the rule in litigation and a desire not to follow its statutory duties.
- Nor should HHS consider this regulatory action now. Many protections such as the Church Amendments depend on the definition of a "lawful abortion," and so HHS should delay this action until after the Supreme Court's forthcoming decision in *Dobbs*, which will define the scope of a lawful abortion.[1]

[1] *Dobbs v. Jackson Women's Health Organization*, No. 19-1392 (U.S.).

- HHS should consider and follow the recommendations of the career professionals in the Office for Civil Rights Conscience and Religious Freedom Division.

B. Alternative Regulatory Approaches

- The agency should consider the alternative of leaving this regulation in place, in whole or in part, and it should specify why each alternative approach cannot be maintained.
    - The current regulation helps eliminate religious discrimination and intolerance in healthcare.
    - In a pluralistic society, we should respect many religious perspectives.
- The agency needs to consider each of a host of alternative approaches that could be applied instead of the one chosen, including retaining the Obama-era 2013 conscience rule. If any of those approaches better protect conscience and religious freedom, it should be chosen, and full rescission without immediate replacement would not be appropriate.
- One alternative the agency should consider is leaving in place the portions of the rule that simply establish internal processes for investigating, handling, and resolving complaints, to the extent the agency believes other portions of the rule such as its definitions are non-procedural.
- The agency should also consider whether to leave the rule's internal processes in place for some of the 25 conscience and religious freedom laws set forth in the rule, rather than conclusively deciding that no portions of the rule creating enforcement mechanisms for any of those laws will be maintained.
- HHS's enforcement of the 25 conscience and religious freedom laws is required, not discretionary.[2] Rescinding the means for enforcing these laws, without replacement, puts HHS in violation of its mandatory duties.[3] HHS

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[2] As HHS explained, the rule ensures that "healthcare professionals will not feel compelled to leave the practice of medicine because they decline to participate in actions that violate their conscience such as abortion, sterilization, or assisted suicide. It also protects the right of diverse faith-based health care institutions to retain their religious beliefs and identity as part of their mission of serving others." HHS, Factsheet, Final Conscience Regulation (May 2, 2019), https://www.hhs.gov/sites/default/files/final-conscience-rule-factsheet.pdf.

[3] "The 2011 rule provided inadequate enforcement of conscience rights by only providing for handling complaints based on three federal conscience protection laws. This final rule implements approximately 25 federal conscience protection provisions, and provides significant tools and mechanisms appropriate for enforcing the conscience protections passed by Congress. These tools are needed in light of the substantial growth in conscience complaints received by the HHS Office for Civil Rights (OCR)." *Id.*

enforcement is important because many statutes lack a private cause of action, and so HHS's present course of non-enforcement leaves wronged people without recourse, such as when HHS recently refused to enforce protections for a nurse compelled to participate in an abortion against her conscience.[4]

- Simply put, HHS unlawfully refuses to perform its duties. This concern is particularly acute because HHS is simultaneously enacting many new mandates that conflict with conscience and religious freedom, without any specific conscience protections, and instead simply claiming in each new mandate that it will follow governing conscience and religious freedom laws. That is not enough. To comply with its duties, HHS must have an avenue for compliance with and enforcement of conscience and religious freedom protections.[5] Any contrary view of the law is incorrect and insufficient.
- Rescission of the 2019 regulation would also violate Section 1554 of the Affordable Care Act:
  - parts (1)–(2) and (6) because it pressures providers out of federally funded health programs and the practice of healthcare;
  - parts (3)–(4) because it requires 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;
  - part (5) because it requires providers to deprive patients of informed consent by preventing them from warning patients of the dangers of abortion or gender transition interventions; and
  - also part (5) because it forces providers to violate their ethical and conscientious standards as healthcare professionals.
- No court order prevents HHS from appealing the injunctions against the conscience rule, and no court order prevents HHS from reenacting the same or similar ways to enforce its duties. HHS's duty to defend its laws and regulations requires HHS to pursue the full range of litigation options.
- Failure to appeal would result (at best) from an incorrect view of the law, but an incorrect view of the law is not enough to justify rescinding

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[4] Roger Severino, *Becerra and Biden Betray Medical Professionals Being Forced to Assist in Abortions*, National Review, https://www.nationalreview.com/corner/becerra-and-biden-betray-medical-professionals-being-forced-to-assist-in-abortions/.

[5] 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/.

enforcement of statutory protections.[6]

C. Analytical Approaches

- Both a benefit-cost analysis and a cost-effectiveness analysis must be provided for this rule because it is a major rulemaking with a significant economic impact for which the primary benefits or costs bear on public health and safety as well as protections of conscience, religious freedom, and life.
- A valid effectiveness measure can and must be identified to represent expected health outcomes. The agency needs to identify what the measure of its goals are in terms of overall nationwide access to all kinds of care.
- The cost-effectiveness analysis needs to explain how the public health goals will be achieved based on likely behavior in response to the regulation. In particular, if failure to enforce conscience protection requirements causes professionals remain out of or to vacate the field, rather than to stay in the workplace, the agency needs to explain how the rule still meets its public health effectiveness measure.
- These cost-benefit analyses must occur with present 2022 data about shortages in healthcare staffing post-pandemic, not outdated data from beforehand.
- The analyses should also occur in light of OCR's record-high receipt of complaints between 2017–2020 identifying violations of conscience laws in comparison to the much smaller number of complaints filed before OCR announced in 2017 that is was "open for business" in enforcing these laws.
    - It would not be accurate or justified for the agency to dismissively characterize most of those complaints as objections concerning vaccines, for four reasons: (1) there are conscience and religious freedom laws enforced by the rule that concern vaccines explicitly or are broad enough to encompass vaccine-related objections, like 42 U.S.C. § 300a-7(c)(2) & (d); (2) dismissing the significance of objections concerning vaccines would ignore without justification the recent history of the COVID-19 pandemic where vaccine concerns have generated numerous cases that were litigated all the way to the U.S. Supreme Court, including significant cases ruling against this administration; (3) OCR cannot and

[6] The agency must consider significant issues in reasoned decision making even where it has statutory authority. *Biden v. Texas*, No. 21A21, 2021 WL 3732667, at *1 (U.S. Aug. 24, 2021) (citing *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909–15 (2020)). Plus, a decision involving denying or providing affirmative government protections is far "more than a non-enforcement policy" left to unreviewable agency discretion. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020).

by policy does not pre-judge the merits of a complaint simply based on characterizing it as concerning vaccines; and (4) even apart from the complaints concerning vaccines, the other complaints received concerning conscience and religious freedom laws from 2017–2020 far outpaced the number of similar complaints received between 2009–2016 during an administration that, like this one plans to do, rescinded a regulation enforcing conscience and religious freedom laws.

D. Identifying and Measuring Benefits and Costs

- The agency should assess the baseline properly. The proper baseline is *full enforcement of conscience and religious freedom laws*. The baseline is *not* a lack of enforcement or limited enforcement based on the 2013 Obama-era conscience rule. Put another way: the agency should consider the past, present, and future costs of the failure to enforce or to fully enforce conscience laws.
    - As evidenced by OCR's receipt of many more conscience complaints between 2017–2020 when it announced it was open for business to enforce these laws, mentioned above, the baseline economic estimate for rescinding this rule must assume that violations of conscience and religious freedom laws encompassed by this rule are occurring, and that rescinding this rule would not lead to fewer violations but to fewer complaints to, awareness by, and enforcement by HHS of those violations. Therefore the economic and non-economic impacts resulting from those violations need to be estimated in this rule even if it is anticipated that complaints would go down or have gone down since 2020.
- Because the current regulation protects conscience, religious freedom, diversity, and pro-life nondiscrimination, the agency should calculate the cost of losing those benefits if the current regulation is fully rescinded.
- The agency should assess the degree to which rescinding this regulation would lead to further discrimination, intolerance, and marginalization of religious people in healthcare, particularly those who are members of minority religions.
- The agency should consider the burdens and costs resulting from loss of diversity in healthcare from non-enforcement of statutory protections and from rescission of the regulation, and should assess the number of religious people and organizations out of practice or likely to be expelled from healthcare that currently should have protection under this regulation.
- The agency should also calculate the following specific costs on covered entities for the rule's full or partial failure to enforce any conscience

protections or to redefine down the nature of those requirements, including, but not limited to, quantifying the following specific components:

- The agency must calculate the stresses that will be placed on the nation's infrastructure of healthcare as a whole, and the detrimental public health consequences resulting from the inability of conscientious providers to participate in healthcare practice on equal terms.
- Costs must be assessed for patients who have lost or lose the ability to find any provider or the provider of their choice, and who thus are less likely to seek or receive timely care. The loss of a provider because of government coercion creates a lack of trust for patients, who will not easily trust new providers who do not share their values.
- Costs must be considered that result from companies that choose to ignore conscience protections, and thus lose employees and patients as a result, as a foreseeable result that would not occur except for HHS non-enforcement.
- Costs must be assessed for employees who lose their jobs or cannot practice medicine, including not only their economic losses, but greater payments in unemployment benefits, and decreased productivity among companies that lose employees. These combined factors will contribute to an increase in the national debt.
- The cost of the rule in exacerbating existing labor shortages, and the negative effects on the economy overall, should also be calculated.[7] The rule will contribute to a shortage in labor because many employees will quit or accept termination rather than participate in objectionable practices. Economic and health costs also result to consumers from exacerbating labor shortages. Shortages in nursing have led to increased travel and medical costs for patients, for example.
- Costs need to be calculated for time spent reading and understanding how to comply with the rule and for costs spent availing themselves of rights that HHS will not defend, respect, or enforce, including through litigation, in terms of time, expenses, and uncertainties.

- Consistent evidence before HHS for over a decade has put the agency on notice of high costs and significant reliance interests in this area, alerting the agency that *access to care will decrease—not increase—if federal regulations are not paired with enforcement of conscience and religious freedom protections.*

[7] *See, e.g.*, https://conference-board.org/topics/labor-shortages.

- Scientific polls of religious medical professionals show that religious doctors will leave the profession rather than violate their consciences, with disproportionate effects on poor and underserved communities.
- HHS has been on notice of these reliance interests from similar consistent polling presented to the agency since comments on 2009 conscience regulations.[8]
- For example, in comments submitted on HHS's 2019 Notice of Non-Enforcement for its Section 1557 rule, these polls informed HHS that:
  - More than "nine in ten (91%) faith-based health professionals and students say they 'would rather stop practicing medicine altogether than be forced to violate my conscience.'"
  - "Virtually all (97%) say it is necessary to have "conscience protection for medical professionals who decline to participate in healthcare procedures, like abortion, assisted suicide and transgender procedures and prescriptions, to which they object on moral or religious grounds."
  - "Three in five (62%) of the health professionals surveyed are 'currently involved in serving poor and medically-underserved populations, either domestically or overseas,'" and for "nearly three in ten (28%)" of all surveyed professionals, "between half and all of their patients 'qualify for low-income healthcare programs provided by the government.'"[9]
  - As these comments warned, "That means that if faith-based professionals are forced out of medicine by a lack of the conscience

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[8] *See, e.g.*, Jonathan Imbody, Christian Medical Association, *Comments Re: Data and analysis of two national surveys on conscience rights regulation and laws, as related to HHS requested information on rescission proposal*, Comment No. HHS-OPHS-2009-0001-5125 at 5–10 (April 9, 2009), available at https://www.regulations.gov/comment/HHS-OCR-2018-0002-64461 (reporting the key findings of scientific polls of religious providers: "In overwhelming numbers, faith-based healthcare professionals and students will quit medicine before compromising religious convictions": "Patient access—especially in medically underserved areas--will suffer if faith-based healthcare professionals are forced to violate their moral and ethical codes."; "Respondents have witnessed growing hostility toward medical professionals with strong moral and religious beliefs."; "High percentages of faith-based professionals report experiencing discrimination in education"; "Significant numbers are eschewing careers in obstetrics because of discrimination and coercion.").

[9] Jonathan Imbody, Christian Medical Association, *Comments RE: RIN 0991-AC16, Docket Number: HHS-OS-2019-0014 Notification of Nonenforcement of Health and Human Service Grants Regulation*, Comment No. HHS-OS-2019-0014-109029 at 4–6 (Dec. 19, 2019), available at https://www.regulations.gov/comment/HHS-OS-2019-0014-109029 (reporting the key findings of scientific polls of religious providers: "Faith-based health professionals need conscience protections to ensure their continued medical practice"; "Religious health professionals face rampant discrimination"; "Access for poor and medically underserved patient populations depends on conscience protections.").

protections that allow them to practice according to ethical norms, *the poor and medically underserved populations served by these professionals stand to suffer a devastating loss of healthcare access*."[10]

- Comments on the 2020 ACA Section 1557 Rule confirmed this evidence, including for providers with purely scientific or medical objections, with "one in four survey respondents (25%) experienced pressure, coercion or punishment for declining to 'refer a patient for a procedure to which you had *medical* or *scientific* objections.'"[11]
  - "Virtually all (97%) say it is necessary to have 'conscience protection for medical professionals who decline to participate in healthcare procedures, like abortion, assisted suicide and transgender procedures and prescriptions, to which they object on moral or religious grounds.'"[12] At the same time, virtually all surveyed professionals reported that they still care for all patients even if they cannot validate all of their life choices.[13]
  - The survey thus concluded that "without conscience protections to protect faith-based professionals and institutions from being pressured, penalized and forced out of medicine, American patients would suffer a *catastrophic loss of healthcare access*."[14]
- Comments on another rulemaking in 2020 again warned that tying grants to HHS's mandates, without robust conscience protections, "threatens to decrease care for needy individuals—by narrowing the field of potential grantees and thus decreasing the likelihood that federal grants will expand the effective reach of the nation's best programs."[15]

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[10] *Id.* at 6.

[11] Jonathan Imbody, Christian Medical Association & Freedom2Care, *Comments RE: Section 1557 NPRM, RIN 0945–AA11, ID: HHS-OCR-2019-0007-0001*, Comment No. HHS-OCR-2019-0007-127215 at 4–7 (Aug. 12, 2021), available at https://www.regulations.gov/comment/HHS-OCR-2019-0007-127215.

[12] *Id.* at 4.

[13] *Id.* ("Virtually all faith-based respondents (97%) attest that they 'care for all patients in need, regardless of sexual orientation, gender identification, or family makeup, with sensitivity and compassion, even when I cannot validate their choices.'")

[14] *Id.* at 4.

[15] Jonathan Imbody, Christian Medical Association & Freedom2Care, *Comments RE: Ensuring Equal Treatment of Faith-Based Organizations RIN 0991–AC13 Docket Number: HHS–OS– 2019–0012*, Comment No. HHS-OS-2020-0001-15615 at 2–5 (Feb. 12, 2020), available at https://www.regulations.gov/comment/HHS-OS-2020-0001-15615. The same polling shows, "Virtually all faith-based respondents (97%) attest that they 'care for all patients in need, regardless of sexual orientation, gender identification, or family makeup, with sensitivity and compassion, even when I cannot validate their choices.' Clearly the issue at hand is not one of refusing to care for certain

- This evidence is why in the 2021 Grants Rule HHS expressed concern that the 2016 Grants Rule could deter participation and thus "undermine the effectiveness" of its grants programs by reducing the number of service providers.[16]

- HHS also analyzed the 2009 survey data in detail, as well as similar data, in the 2019 conscience rule, concluding that this data provided reason to increase (not decrease) HHS enforcement of conscience protections and reason to think that HHS enforcement of conscience protections would increase (not decrease) access to care.[17] The final rule also provided much other information about the need for enforcement that HHS must consider, including increased OCR complaints.
- HHS thus cannot in 2021 return to its earlier positions against robust conscience protection policies with no reasoned explanation of its change, let alone without considering this evidence that HHS so recently credited about the serious reliance interests of religious doctors and their patients in conscience and religious freedom protections.
- There is no harm to any purported contrary governmental interest, especially with so many other providers available.[18] Any improvement in access by attempts to coerce participation in objectionable practices will be greatly outweighed by transferring the costs to others.
- If anything, the government has a much stronger interest in strengthening relationships with faith-based providers and groups, so that the government promotes new providers and avoids reductions in care for poor and rural underserved communities.[19]

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individuals, but rather simply declining to participate in certain morally controversial procedures and prescriptions." *Id*.

[16] Health and Human Services Grants Regulation, 86 Fed. Reg. 2,257, 2,257, 2,259, 2,263, 2,269, 2,273 (Jan. 12, 2021).

[17] HHS, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority 84 Fed. Reg. 23,170, 23,175–76, 23,181–82 (May 21, 2019).

[18] Jonathan Imbody, Christian Medical Association & Freedom2Care, *Comments RE: Section 1557 NPRM,* RIN 0945–AA11, ID: HHS-OCR-2019-0007-0001, Comment No. HHS-OCR-2019-0007-127215, Att. 2 at 2 (Aug. 12, 2021), available at https://www.regulations.gov/comment/HHS-OCR-2019-0007-127215 (78% of survey respondents reporting that it was "not common" "that patients are ultimately unable to obtain an abortion, sterilization, assisted suicide or transgender related procedures and unable to obtain an abortion, sterilization, assisted suicide or transgender related procedures and prescriptions, or similar types of treatment because of moral, religious, or ethical objections of healthcare professionals").

[19] *See, e.g.,*, Lisa Cooper, Op-ed, *Faith-based groups have a role to play in ending health care disparities*, Baltimore Sun Nov. 22, 2021), https://www.baltimoresun.com/opinion/op-ed/bs-ed-op-1122-faith-health-inequity-20211122-skuql4uuvrgkpk53oyaasrah4q-story.html ("Now, more than ever, we need health organizations to forge alliances with faith groups, bringing their shared talents to the task of fostering healing and restoration in our most vulnerable communities.").

E. Specialized Analytical Requirements

Small Businesses and Non-Profits

- The agency needs to assess and certify the impact on small businesses and all non-profits under the Regulatory Flexibility Act ("RFA"), using the above analysis on costs and explaining its reasoning.[20]
    - Notably, non-profit organizations count as small entities for this purpose, since most do not dominate their field, and this would include numerous religiously affiliated hospitals and health care facilities, where the entities themselves and their employees are protected by many of the laws encompassed by this rule.
    - Likewise, the agency must estimate the impact on small healthcare practitioners based on the likelihood that religious and other conscientious health care practitioners that would be protected by this rule are in very small practices.
- Under the Small Business Regulatory Enforcement Fairness Act, HHS must convene a SBREFA panel before publishing the rule. The panel should arrange meetings with small businesses, distinctly including nonprofit entities and religious organizations, to give them an opportunity to provide advice and recommendations to minimize the rule's burdens.

Religious Freedom Restoration Act

- Religious businesses, non-profits, and individuals also have rights under the Religious Freedom Restoration Act ("RFRA") that must be considered. Any substantial burden on religious exercise cannot be imposed absent a compelling interest imposed by the least restrictive means of regulation. 42 U.S.C. § 2000bb-1.
- Failure to respect the religious rights of nonprofit religious entities as entities needs to be justified under RFRA specifically.[21] The agency thus

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[20] Under the RFA, 5 U.S.C. Section 605(b), Congress 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 effect 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."

[21] *See, e.g.*, *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367 (2020) ("If the Departments did not look to RFRA's requirements or discuss RFRA at all when formulating their solution, they would certainly be susceptible to claims that the rules were arbitrary and capricious for failing to consider an important aspect of the problem.").

must consider at this stage, *for each applicable conscience law*, whether removing enforcement mechanisms will lead to or avoid compliance with RFRA under present conditions in 2022.

- It also violates RFRA for this agency to single out a regulation that protects religious groups and target that regulation for elimination, since removal of the statutorily mandated protection afforded by that regulation would substantially burden the religious exercise of providers and patients.
- The RFRA and Title VII implications of imposing objectionable practices in healthcare in violation of employees' sincerely held religious beliefs also need to be considered. Both laws apply to employee objections. RFRA imposes a distinct standard from Title VII as applied to this mandate because the mandate is being imposed by the federal government; RFRA cannot be assumed to impose no greater standard than Title VII.[22]
- In light of HHS's recent announcement withdrawing the delegation for OCR to enforce RFRA within the agency, HHS's rescission of this rule cannot rely on mere hortatory language indicating that it will comply with RFRA, but must indicate how that is possible under this *OCR rule* when OCR's delegation has been withdrawn.

Federalism

- The rule has significant effects on federalism and preemption of state and local law. Nearly all of these conscience protections are connected to federal spending programs in which states participate or to other federal programs that displace state laws.
- This regulation also governs state-operated or state-funded medical facilities, raising issues about the rights of public healthcare employees and patients.

States and Tribal Consultation

- The agency should consult and coordinate with State and Tribal governments about the effects of this rule under Executive Orders 13,132 and 13,175.
- President Biden also required tribal consultation in his January 26, 2021, Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships.

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[22] *See Bostock v. Clayton Cnty., Georgia*, 140 S. Ct. 1731, 1754 (2020) ("RFRA operates as a kind of super statute, displacing the normal operation of other federal laws, it might supersede Title VII's commands in appropriate cases.").

Comment period

Because of the wide-ranging impacts of this rule on so many healthcare providers and patients, and because of the lack of negative impact of leaving the current rule in place while this rule is considered, and because there is no legal deadline to issue this rule, the agency should provide at least **60 days** for a public comment period so groups have a sufficient chance to obtain and submit helpful information.