ETHICS AND PUBLIC POLICY CENTER

March 6, 2023

Via Federal eRulemaking Portal

The Honorable Xavier Becerra
U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945–AA18
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: EPPC Scholars Comment Opposing HHS's Proposed Rule "Safeguarding the Rights of Conscience as Protected by Federal Statutes," RIN 0945–AA18

Dear Secretary Becerra:

We are scholars at the Ethics and Public Policy Center (EPPC), and we write in response to the Department of Health and Human Services (HHS) proposed rule "Safeguarding the Rights of Conscience as Protected by Federal Statutes"[1] and to the repeal of the majority of the 2019 Rule.

Rachel N. Morrison is an EPPC Fellow, director of EPPC's HHS Accountability Project, and former attorney at the Equal Employment Opportunity Commission. Eric Kniffin is an EPPC Fellow, member of the HHS Accountability Project, and a former attorney in the U.S. Department of Justice's Civil Rights Division. Mary Rice Hasson is the Kate O'Beirne Senior Fellow at EPPC, an attorney, and co-founder of EPPC's Person and Identity Project, an initiative that equips parents and faith-based institutions to counter gender ideology and promote the truth of the human person. Natalie Dodson is a Legislative and Regulatory Affairs Associate and a member of the HHS Accountability Project.

HHS claims that the proposed rule will "safeguard[] rights of conscience," "strengthen[] conscience and religious nondiscrimination," and "prevent discrimination." Yet, its proposed regulations tell a very different story. HHS's proposed rule would eliminate the robust enforcement mechanisms in the 2019 Rule, including its assurance, certification, and compliance requirements. HHS claims its proposal will reduce confusion and provide clarity. But it would delete definitions of key terms, explanations of applicable requirements and prohibitions for each conscience protection law, and the detailed enforcement scheme, making its proposal arbitrary and capricious. HHS also claims the authority to balance conscience rights against other interests, even though the conscience protection laws passed by Congress provide for no such balancing. In short, HHS's proposed rule—coupled with the Biden-Becerra HHS's abysmal track

[1] 88 Fed. Reg. 820.

record on protecting conscience and religious freedom rights—undercuts the Department's assertions that it takes these rights seriously. HHS should defend the 2019 Rule in court, or, at a minimum, adopt the same or better regulations as those found in the 2019 Rule.

1. HHS has failed to establish a need for the proposed rule.

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

HHS proposes to rescind the majority of the 2019 Rule and maintain "the framework" from the 2011 Rule with some modifications. HHS proposes to retain three aspects of the 2019 Final Rule: (i) the application to all the federal conscience law provisions identified in the 2019 Rule, (ii) several provisions related to complaint handling and investigations, and (iii) a voluntary notice provision. "Informed by the three district court decisions" that enjoined the 2019 Rule, HHS is proposing to rescind large portions of the 2019 Rule "because those portions are redundant, unlawful, confusing or undermine the balance Congress struck between safeguarding conscience rights and protecting access to health care, or because significant questions have been raised as to their legal authorization." We address these proposals in more detail below.

2. HHS rightly recognizes all conscience protection laws HHS is charged with enforcing.

We strongly support the Department's proposal to apply any updated regulations to all the conscience protection laws identified in the 2019 Rule. HHS is charged with enforcing over two dozen federal laws that protect conscience and religious freedom rights of individuals and organizations in health care. Many of these laws focus on the most controversial medical interventions such as abortion, sterilization, and assisted suicide, and provide protections for those who do not want to participate in or pay for such interventions based on their conscience—whether religious beliefs or moral convictions.

Of the three major iterations of HHS regulations on federal health care conscience protection laws in 2008, 2011, and 2019, only the 2019 Rule applied to the 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. In contrast, despite HHS's duty to enforce all federal constitutional and statutory protections for conscience and religious freedom rights, the 2008 and 2011 rules only applied to three laws—the Church Amendments,[2] the Weldon Amendment,[3] and the Coats-Snowe

[2] The Church Amendments provide conscience protections for individuals and entities related to abortion, sterilization, and certain other health services. 42 U.S.C. § 300a-7.

[3] The Coats-Snowe Amendment provides conscience protections for health care entities related to abortion provision or training, referral for such abortion or training, or accreditation standards related to abortion. 42 U.S.C. § 238n.

Amendment.[4] Other conscience protection laws include provisions of the Affordable Care Act[5] and Medicare and Medicaid programs.[6]

It would be arbitrary and capricious for HHS to propose regulations on conscience protection laws, but not apply those regulations to all conscience protection laws HHS is charged with enforcing.

3. HHS's proposed rule weakens—not safeguards or strengthens—conscience rights.

In accord with prior rules, the proposed regulations would delegate to OCR authority to enforce the conscience protection laws. Under the proposed rule, OCR would have the authority to: "(1) Receive and handle complaints; (2) Conduct investigations; (3) Consult on compliance within the Department; (4) Seek voluntary resolutions of complaints; and (5) Consult and coordinate with the relevant Departmental funding component, and utilize existing regulations enforcement, such as those that apply to grants, contracts, or other programs and services." We support this delegation of authority to OCR, but we oppose the Department's proposal to eliminate additional provisions from the 2019 Rule that elaborate on OCR's enforcement authority to ensure compliance and "vigorous enforcement."

The proposed rule states:

> The Department proposes to rescind the other portions of the 2019 Final Rule because those portions are redundant, unlawful, confusing or undermine the balance Congress struck between safeguarding conscience rights and protecting access to health care, or because significant questions have been raised as to their legal authorization. This includes the purpose provision at § 88.1, the definitions that appeared at § 88.2, the applicable requirements and prohibitions that appeared at § 88.3, the assurance and certification requirements at § 88.4, compliance requirements at § 88.6, the relationship to other laws provision at § 88.8, and the rule of construction and severability provisions at § 88.9 and § 88.10. Those portions of the 2019 Rule were either: (1) redundant and unnecessary, because they simply repeated the language of the underlying statute; (2) have been deemed unlawful in district court decisions that raise significant questions as to whether they exceed the scope of the Department's housekeeping authority; or (3) created

[4] The Weldon Amendment provides protections from discrimination for health care entities that do not provide, pay for, provide coverage of, or refer for abortions. *See* Consolidated Appropriations Act, 2022, Public Law 117–103, div. H, title V General Provisions, § 507(d)(1) (Mar.15, 2022).

[5] Affordable Care Act provides conscience protections for health care providers related to abortion and assisted suicide, euthanasia, or mercy killing. 42 USC § 18113 (Section 1553); 42 U.S.C. § 18023 (Section 1303); 42 U.S.C. § 18081 (Section 1411).

[6] Medicare and Medicaid provide conscience protections for Medicare Advantage organizations and Medicaid managed care organizations with moral or religious objections to counseling or referral for certain services. 42 U.S.C. § 1395w–22(j)(3)(A)) (Medicare Advantage); 42 U.S.C. § 1396u– 2(b)(3)(A)) (Medicaid managed care).

confusion or harm by undermining the balance struck by Congress in the statutes themselves.[7]

The proposed rule fails to provide a "reasoned explanation" to justify its large-scale departures from the 2019 Rule. The three rationales identified by HHS are brought against portions of the 2019 Rule generally, but HHS fails to specify which rationale applies to which provision specifically.[8] Indeed, rationales (1) and (3) are at odds with each other and no particular provision is ever identified as redundant or confusing. HHS's failure to explain which of the three rationales justify rescinding each of the specific provisions in the 2019 Rule alone makes its proposal arbitrary and capricious. These provisions added much needed clarity as the 2019 Rule and remedied issues with the 2011 Rule by addressing the lack of knowledge and rights and obligations under HHS-funded or administrated health programs and correcting misunderstandings about conscience protections. HHS's claim that its proposal safeguards conscience rights falls flat.

Below we address the need and clarity these provisions provide, demonstrating how the Department's proposal is arbitrary and capricious. Later, we separately address the district court decisions and the assertion that the conscience protection laws provide a balancing of interests.

A. HHS's proposed removal of various provisions of the 2019 Rule that provided needed clarity is arbitrary and capricious.

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

HHS also proposes deleting the statement of broad interpretation in the purpose provision: "Consistent with their objective to protect the conscience and associated anti-discrimination rights of individuals, entities, and health care entities, the statutory provisions and the regulatory provisions contained in this part are to be interpreted and implemented broadly to effectuate their protective purposes." This provision, likewise, does not repeat language of the underlying statute and does not cause confusion or harm; rather, it provides clarity to inform all of how HHS intends to interpret and implement the conscience protection and nondiscrimination

[7] 88 Fed. Reg. 825-26; *see also id.* at 820 (proposing to set aside parts of 2019 Rule "because they are redundant or confusing, because they undermine the balance Congress struck between safeguarding conscience rights and protecting access to health care access, or because significant questions have been raised as to their legal authorization").
[8] 88 Fed. Reg. 825, 825-826.

laws. HHS claims that its proposal is "safeguarding the rights of conscience," "strengthen[ing] conscience and religious nondiscrimination," and "prevent[ing] discrimination."[9] Yet, its proposal to cut the statement of broad interpretation belies the Department's claim, making its purported rationale arbitrary and capricious.

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

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

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

Compliance Requirements. HHS proposes deleting the compliance requirements at § 88.6, including requirement to maintain records, cooperate with OCR enforcement, and refrain from intimidation or retaliatory acts. These requirements are not in the text of the statutes and are necessary means to ensure compliance. No specific reasons are given why these basic requirements are to be removed, and their removal undercuts the Department's purported commitment, as stated in the proposed rule, "to ensuring compliance." It is general practice for all civil rights laws that records be maintained, entities and individuals must cooperate with

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

government enforcement, and intimidation or retaliation are strictly prohibited and antithetical to promoting civil rights. It should be no different when it comes to conscience protection laws. For all these reasons, the proposed rescission of the compliance requirements is arbitrary and capricious; the requirements should be retained. In the alternative, HHS should adopt modified means of ensuring compliance.

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

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

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

Informal Resolution. Regarding resolution, the proposed regulation would state that if there is a violation, OCR will resolve the matter "by informal means whenever possible." It is unclear what "means" HHS considers "informal." "Informal means" alone is insufficient to guarantee compliance with conscience protection laws. It is also unclear what will happen if resolution is not met through informal means. Will HHS initiate formal means? What formal means will the Department consider on the table? Will those means include withholding of federal funds or referral to DOJ for lawsuit? We ask that HHS provide a clarifying definition of "informal means" and answers to these questions so that offending entities and complainants will be on notice as to the means HHS will employ to deter future violations, ensure compliance, enforce conscience protection laws, and vindicate those whose rights have been violated. HHS

should clarify that it will also consider formal means of resolution if a violating entity refuses to comply.

Voluntary Notice. Like the 2019 Rule, HHS encourages, but does not require, employers to provide their employees with notice of their rights under federal conscience protection laws. HHS solicited comments regarding whether the notice should be mandatory. We think it should be. Generally, employers and entities are required to publish notices of civil rights protections, and health care conscience protection laws should be no different. This is the easiest and most efficient way to inform both entities and individuals of their obligations and rights under the conscience protection laws.

At the very least, HHS should actively encourage notice by ensuring that such a notice will be non-dispositive evidence of compliance during an investigation. HHS explains that it deleted the provision "to avoid implying that covered entities can substantively comply with the underlying statute by simply posting a notice." We agree with the Department that "such an implication could undermine the conscience and nondiscrimination protections provided by the underlying statutes themselves, and therefore the goal of this rule." We disagree, however, that stating presence of the notice is "non-dispositive" evidence creates such an implication. Regardless, HHS could adopt an alternative approach of retaining the "non-dispositive evidence" provision but adding a provision clarifying that notice alone is not sufficient compliance with obligations under law. As proposed, HHS eliminates any incentive for entities to post a voluntary notice because it fears entities may conclude that simply posting a notice is enough to comply with their obligations. It is difficult to believe any entity would be so naïve. Surely no employer has ever defended a sex discrimination claim on the basis that it had hung a laminated poster in the break room. If the notice is not mandatory, HHS should provide an incentive to encourage posting of the notice, whether that is viewing the notice as "non-dispositive" evidence or something else.

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

Snowe Amendment—are insufficiently description to convey the important protections they provide.

In the alternative or in addition, HHS should explore alternative ways to inform and educate entities and individuals of their obligations and rights under the various conscience protection laws. This should be a top priority for the newly constituted OCR Enforcement Division and Strategic Planning Division. We ask HHS to explain how it plans to conduct education and outreach on conscience rights, especially in light of its proposals to remove the assurance of compliance and only voluntarily require notifications.

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

As mentioned above, the proposed rule references the three district court decisions that each enjoined the 2019 Rule in November 2019 but does little to describe each court's rationale or identify what HHS agrees or disagrees with in each.

This stands in sharp contrast to what HHS has done in other recent proposed rules. For example, in proposed rules issued February 2, 2023, HHS proposes to maintain a religious exemption to its "contraceptive services" mandate but eliminate the exemption for non-religious moral exemptions.[10] HHS acknowledges that a district court "reasoned that there was no rational basis" for "distinguishing between religious and moral exemptions."[11] But HHS summarily said there that it "respectfully disagree[d]" with the court's decision. Yet it completely and without explanation defers to court decisions here. This fails to meet HHS's obligation to provide a "reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy."[12]

HHS's categorical deference to the decisions vacating the 2019 Rule fails to explore and account for the important shortcomings in these decisions.

For example, the first of the three decisions, *New York v. HHS*, improperly relied on a provision in the Affordable Care Act, 42 U.S.C. § 18023, in support of its finding that the 2019 Rule acted "contrary to law" by overriding Title VII's religious accommodation framework and EMTALA's requirement that hospitals provide emergency care.[13]

The *New York* decision claimed that "the ACA's Conscience Provision does not alter any Title VII rights and responsibilities," citing 42 U.S.C. § 18023(c)(3).[14] But § 18023(c)(3) only applies to "this subsection." The ACA's conscience protections on assisted suicide, euthanasia, and mercy killing (§ 18113(a)) and on abortion (§ 8023(a)) are all located *outside* subsection 18023(c). It would have been easy for Congress to make the application of § 18023(c)(3)

[10] 88 Fed. Reg. 7236, 7249 (Feb. 2, 2023).
[11] *Id*. (citing *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015)).
[12] *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009).
[13] 413 F. Supp. 3d 475, 529, 536-38 (S.D.N.Y 2019).
[14] *Id*. at 529.

broader, so that it applied to the conscience provisions noted above. But Congress chose not to, and the *New York* court was legally wrong to indicate otherwise.

Congress' decision to limit the application of § 18023(c)(3) is even clearer in light of § 18023(d), regarding EMTALA. There, Congress said that "[n]othing *in this Act* shall be construed to relieve any health care provider from providing emergency services as required by [EMTALA]" (emphasis added). Unlike the Title VII provision, this EMTALA provision was written broadly to cover the ACA's conscience protections in Sections 18113(a) and 18023(a).

Section 18023(d) does limit "HHS's latitude to rule-make in this area," but this part of the ACA has no bearing on HHS's authority with regard to the other federal statutes on which it relied in the 2019 Rule.[15] For some of those statutes, the *New York* court relies on legislative history from "the sponsors of each of the Church, Coats-Snowe, and Weldon Amendments."[16] But selected quotations from individual legislators is scant evidence of Congressional intent and violates Supreme Court direction on statutory interpretation. "The only thread" supporting the district court's interpretation of the Church, Coats-Snowe, and Weldon Amendments "is legislative history, and the problems of legislative history are well rehearsed."[17] These snippets do not support the district court's holding in *New York* and HHS is wrong to rely on or defer to that decision in its proposed rule.

The second district court decision HHS relies on, *Washington v. Azar*, found the *New York* decision described above "well-reasoned and thorough" and "adopt[ed] the reasoning set forth" in that decision without reservation.[18] The *Washington* decision therefore adds no further weight to HHS's arguments in favor of the proposed rule.

The last of these three district court decisions, *City & County of San Francisco v. Azar* is likewise flawed.[19] The court's decision to vacate the 2019 Rule rests in large part on its holding that "the new rule sets forth new definitions that conflict with the statutes themselves."[20] But this holding relies excessively on legislative history and factual errors.

The *San Francisco* court begins, correctly, by stating that "[t]he statute itself is what has the force of law, not the interpretation."[21] But in the pages that follow, the court repeatedly relies on legislative history—selective statements of various persons' "interpretation" of the "statute"—as definitive evidence of what the Church Amendments and Weldon Amendment mean.[22] The court's excessive reliance on legislative history should be read as a concession that the text of these conscience provisions do not support the court's conclusions. The *San Francisco* court had it right the first time: it is the "statute itself" that "has the force of law, not the interpretation." If HHS does not find that federal law itself supports vacating the 2019 Rule, pointing to the *San Francisco* court's weak reasoning does not strengthen HHS's proposed rule.

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[15] *Id*. at 538.
[16] *Id.* at 538.
[17] *Wooden v. United States*, 142 S. Ct. 1063, 1077 (2022).
[18] 426 F.Supp.3d 704, 719-20.
[19] 411 F. Supp. 3d 1001 (N.D. Cal. 2019).
[20] *Id*. at 1011.
[21] *Id*.
[22] *Id*. at 1013-22.

The *San Francisco* decision also faulted the 2019 Rule's inclusion of pharmacies and pharmacists as health care entities, based on an inaccurate understanding of the role that pharmacists play in controversial medical procedures. The Court claims that Congress did not intend pharmacists to be covered by the Coats-Snowe Amendment, because a pharmacist does not dispense medication that could cause "an abortion or sterilization procedure."[23] "A pharmacist's only role" in such procedures "would be dispensing advance medicine to facilitate the procedure or post-procedure medication to stabilize or heal the patient, such as pain medication. Dispensing such medication, however, is not specific to the performance of the procedure itself."[24]

Though the district court judge in *San Francisco* may believe this statement to be true, HHS knows it to be false. Last July, HHS warned pharmacies that they had a legal obligation to fill prescriptions for "methotrexate to halt [a] pregnancy."[25] Last September, HHS issued a statement defending women's access to "abortion medication."[26] In January of this year, the Food and Drug Administration (FDA), which is part of HHS, loosed safety restrictions on abortion drugs, permitting certified pharmacies to dispense the drugs directly.[27]

Similarly, the growing field of "fertility preservation for transgender individuals" exists because cross-sex hormone therapy generally results in infertility.[28] (Below, we provide additional evidence that pharmaceuticals prescribed as part of so-called "gender transition services" cause sterilization.)

It is indisputable that pharmacists may be asked to fill prescriptions that can be used for assisted suicide, for a chemical abortion, and that can result in sterilization. A key factual premise in the *San Francisco* court's decision is plainly wrong. HHS knows this premise to be wrong, and HHS failed to take this flaw into account when citing the decision in support of its proposed rule, making its reliance on the district court decision arbitrary and capricious.

For all these reasons, HHS should not summarily accept the flawed reasoning of the three district court decisions that vacated the 2019 Rule. HHS should not rely on these suspect decisions in its rulemaking and should instead robustly defend the 2019 Rule in court.

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[23] *Id*. at 1016.
[24] *Id*.
[25] Dep't of HHS, *Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services*, July 14, 2022, https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html.
[26] Dep't of HHS, *Statement by HHS Secretary Xavier Becerra on House Republicans Introducing Legislation to Rip Away Women's Access to Contraception and Abortion Medication*, Sept. 14, 2022, https://www.hhs.gov/about/news/2022/09/14/statement-by-hhs-secretary-xavier-becerra-house-republicans-introducing-legislation-to-rip-away-womens-access-contraception-abortion-medication.html.
[27] *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Jan. 24, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation ("Under the Mifepristone REMS Program, mifepristone must be dispensed by or under the supervision of a certified prescriber or by certified pharmacies for prescriptions issued by certified prescribers.").
[28] Mayo Clinic, *Mayo Clinic offers fertility preservation for transgender individuals*, March 15, 2022, https://www.mayoclinic.org/medical-professionals/obstetrics-gynecology/news/mayo-clinic-offers-fertility-preservation-for-transgender-individuals/mac-20529346.

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

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

> The Federal health conscience protection and nondiscrimination statutes represent Congress' attempt to strike a careful ***balance***. Some doctors, nurses, and hospitals, for example, object for religious or moral reasons to providing or referring for abortions or assisted suicide, among other procedures. Respecting such objections honors liberty and human dignity. It also redounds to the benefit of the medical profession.
>
> Patients also have autonomy, rights, and moral and religious convictions. And they have health needs, sometime urgent ones. Our health care systems must effectively deliver services—including safe legal abortions—to all who need them in order to protect patients' health and dignity.
>
> Congress sought to ***balance*** these considerations through a variety of statutes. The Department will respect that ***balance***.[29]

To the contrary, Congress said that the federal government must respect the conscience rights of health care professionals and entities, full stop. For example, nothing in the Church Amendments describes any conditions under which a public official or entity can require an individual to perform an abortion or sterilization procedure in violation of his or her religious beliefs or moral convictions.[30] More to the point, nowhere did Congress grant HHS rulemaking authority to "balance" other interests with the government interest spelled out in the text of the Church Amendments.

But even if it were permissible to balance federal conscience rights against other interests, surely HHS could only put on the other side of the scale those interests that Congress has affirmed. Here, it is critical that HHS recognize that there is no federal right to abortion. As the Supreme Court recognized last summer, "the Constitution does not confer a right to abortion."[31] "The inescapable conclusion is that a right to abortion is not deeply rooted in the Nation's history and traditions. On the contrary, an unbroken tradition of prohibiting abortion on pain of criminal punishment persisted from the earliest days of the common law until 1973," when the Supreme Court improperly removed that question from the democratic process.[32] Laws regulating abortion are entitled to a "strong presumption of validity," and "must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate

[29] 88 Fed. Reg. at 826 (emphases added).
[30] *See* 42 U.S.C. § 300a-7(b).
[31] *Dobbs v. Jackson Women's Health Or*g., 142 S. Ct. 2228, 2279 (2022).
[32] *Id*. at 2253-54.

state interests."[33] Such "legitimate interests include respect for and preservation of prenatal life at all stages of development; the protection of maternal health and safety; the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability.[34] Nothing in the Constitution and nothing in federal law established a federal right to abortion, let alone as a right that is to be balanced against the compelling governmental interest in protecting rights of conscience described explicitly in the federal conscience protection laws that Congress has charged this Department with enforcing.

HHS claim that the proposed rule is justified because the 2019 Rule "exceeded the Department's authority." And yet nothing in the 2019 Rule is half as bold as HHS's declaration here that it will balance rights set out in federal law against rights it wishes were set out in federal law.

Congress has unambiguously established federal laws to protect the rights of health care professionals and entities that have religious or moral based opposition to certain medical procedures and drugs. Congress has unambiguously passed on every opportunity it has had to establish a federal right to abortion. Moreover, nothing in federal conscience protection laws gives HHS the authority to balance those rights against anything—let alone policy objectives Congress has rejected again and again. HHS's efforts in the proposed rule are therefore "incompatible with the expressed or implied will of Congress," where the executive branch's "power is at its lowest ebb."[35] To suggest otherwise, makes HHS's proposal contrary to law.

4. HHS should acknowledge conscience protection laws apply to sterilizing gender transition interventions.

A. Under the Church Amendments, conscience protections regarding "sterilization procedures" apply to various "gender-affirming" medical or surgical interventions.

The Church Amendments protect individuals and institutions from coercion or forced participation not only regarding abortion procedures but also in relation to sterilization or sterilizing procedures. The language of the Church Amendments provides this protection in language that specifically refers to "sterilization" and "sterilization procedures," as well as under language that provides conscience protections regarding unspecified health services.

"Gender-affirming" interventions or "gender transition" procedures "include puberty suppression, hormone therapy, and gender-affirming surgeries among others," according to the World Professional Association of Transgender Health (WPATH), an advocacy group that supports "gender-affirming" protocols.[36] Many "gender-affirming" directly disable or destroy the function of the reproductive system, significantly impairing or eliminating the individual's fertility. The fertility-compromising nature of these interventions has been discussed in medical

[33] *Id*. at 2284.
[34] *Id*. (cleaned up).
[35] *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 637-38 (1952).
[36] WPATH SOC 8, p. S7 According to the World Professional Association of Transgender Health (WPATH), "Standards of Care 8" (2022).

literature for more than a decade but has garnered widespread public attention only in recent years.[37] The most recent guidelines of WPATH repeatedly emphasizes that "[g]ender-affirming hormone treatments have been shown to impact reproductive functions and fertility …. It is considered an essential part of the informed consent process to discuss fertility and fertility preservation options 'prior to the initiation of gender-affirming treatments.'"[38]

The number of persons seeking gender transition treatments has increased at a dramatic scale. Driven by demand, the market "is expected to expand at a compound annual growth rate (CAGR) of 11.23% from 2022 to 2030.[39] At the same time, the fact that specific "gender-affirming" medical and surgical interventions *sterilize* gender-dysphoric individuals, including minors, has generated significant controversy.

Physicians have voiced strong objections to the reckless sterilization of minors under current "gender-affirming" practices. Clinicians and medical institutions have spoken out publicly, given evidence in court, and testified before state legislatures (Arkansas and Alabama, among others), and state medical boards (FL) to object to "gender transition" procedures that lead to "permanently sterilizing surgical mutilation."[40] Religiously-affiliated medical associations and individual clinicians have turned to the courts to seek injunctions against regulations and laws that seek to mandate their participation in or referrals for sterilizing gender transition procedures.[41] The threat to conscience rights—specifically, efforts to coerce medical professionals or institutions to participate in or refer for sterilizing gender transition procedures, in spite of their religious or moral objections, is very real.[42] Consequently, it is critically important for the Department to uphold, and any final rule recognize, the legal rights of

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[37] *See, e.g.*, Chen D, Simons L. *Ethical Considerations in Fertility Preservation for Transgender Youth: A Case Illustration*. Clin Pract Pediatr Psychol. 2018 Mar; 6(1):93-100. doi: 10.1037/cpp0000230. PMID: 29963344; PMCID: PMC6023412 ("The decision to transition with gender-affirming hormones (estrogen and testosterone) has long-term implications, including possible irreversible impairment to reproductive functioning (Ikeda et al., 2013; Schulze, 1988)."

[37] Michael Biggs (2022) *The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence*, Journal of Sex & Marital Therapy, DOI: 10.1080/0092623X.2022.2121238.

[38] WPATH, Standards of Care 8, at S39 (internal citations omitted).

[39] Dagi AF, Boskey ER, Nuzzi LC, Kang CO, Ganor O, Labow BI, Taghinia AH. *Legislation, Market Size, and Access to Gender-affirming Genital Surgery in the United States*, 9(2) Plast Reconstr Surg Glob Open. e3422 (Feb 16, 2021), doi: 10.1097/GOX.0000000000003422. PMID: 33680670; PMCID: PMC7929723. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7929723/. U.S. Sex Reassignment Surgery Market Size, Share & Trends Analysis Report By Gender Transition (Male To Female, Female To Male), And Segment Forecasts, 2022 – 2030, Grand View Research (2022), https://www.grandviewresearch.com/industry-analysis/us-sex-reassignment-surgery-market.

[40] Dr. Patrick Lappert, *Doctor: Time for Transgender Treatment Industry to Follow the Science*, Alabama.com (May 14, 2021), https://www.al.com/opinion/2021/05/doctor-time-for-transgender-treatment-industry-to-follow-the-science.html.

[41] *Court victories strengthen Catholic groups protections against 'gender transition' mandates*, Catholic News Agency (Jan. 22, 2021), https://www.catholicnewsagency.com/news/246215/court-victories-strengthen-catholic-groups-protections-against-gender-transition-mandates.

[42] Press Release, Federal Appeals Court blocks controversial Biden Administration transgender mandate, Becket Law (Dec. 9, 2022), https://www.becketlaw.org/media/federal-appeals-court-blocks-controversial-biden-administration-transgender-mandate/; Pete Williams, *Supreme Court Won't Take up Catholic Hospital Appeal over Surgery for Transgender Man*, Nbcnews.com (Nov. 1, 2021), https://www.nbcnews.com/politics/supreme-court/supreme-court-won-t-take-catholic-hospital-appeal-over-surgery-n1282851.

individuals or institutions with religious or moral objections to performing, participating in, or assisting in sterilizing "gender transition" treatments.[43]

B. Conscience protections regarding "sterilization procedures" apply to "gender-affirming" puberty blockers, cross-sex hormones, and surgeries on gonads and reproductive organs.

"Gender-affirming" interventions that are "sterilizing procedures" fall into two general categories: the surgical removal or impairment of natal gonads or reproductive organs, and the provision of sterilizing medications, whether used alone, sequentially, or in combination (*e.g.*, puberty blockers and "gender-affirming hormone therapies" or "cross-sex hormones"). Each of these is discussed briefly below.

The Dutch protocol for medical transition of gender-dysphoric adolescents was introduced in the U.S. in 2007. Soon after, the ages at which pubertal suppression and cross-sex hormones were administered to adolescents dropped rapidly, with little recorded concern for the sterilizing effects of pubertal suppression followed by cross-sex hormones.[44] The mechanism of pubertal suppression is clear:

> Pubertal suppression with GnRH agonists will suspend pubertal progression at the point when treatment is initiated by suppressing the hypothalamic-pituitary-gonadal axis. This prevents production of gonadal sex hormones (i.e., testosterone and estrogen). If GnRH agonists are discontinued, the hypothalamic-pituitary-gonadal axis reactivates, and endogenous puberty progresses…Pubertal development, however, is necessary for sperm production and egg maturation (Finlayson et al., 2016). Mature gametes (i.e., sperm and eggs) are typically not present until the later stages of pubertal development. Thus, TGD [transgender and gender diverse] youth prescribed GnRH agonists in the early stages of puberty, as recommended by the current standards of care (Coleman et al., 2012; Hembree et al., 2017), will likely not have mature gametes at the time of GnRH agonist treatment initiation. Most TGD youth go on to initiate GAH without discontinuing GnRH agonists. For instance, in a recent report of 143 TGD adolescents treated with GnRH agonists, 87% started GAH after a median duration of 0.8 years (0.3–3.8 years) on GnRH agonists (Brik et al., 2020).[45]

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[43] The Department's 2019 Rule, which the proposed rule partially rescinds, supported a case-by-case determination regarding the rules application to gender dysphoria treatments. However, the rising demand for sterilizing gender transition procedures and the countervailing rise in conscience-based objections by medical providers reinforces the need for the Department to clarify that federal conscience protections apply in the context of sterilizing gender transition treatments.

[44] Michael Biggs *The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence*, J. of Sex & Marital Therapy (2022), DOI: 10.1080/0092623X.2022.2121238.

[45] Afiya Sajwani, Moira A. Kyweluk, Elisa J. Gordon, Emilie K. Johnson, Courtney Finlayson & Diane Chen, *Fertility Considerations in Parental Decision-Making about Pubertal Suppression Treatment for Their Transgender and Gender-Diverse Children*, LGBTQ+ Family: An Interdisciplinary J. (2022), DOI: 10.1080/27703371.2022.2113947.

As the study quoted above notes, nearly all gender-dysphoric children who begin pubertal suppression move directly to cross-sex hormones, without pausing to permit their gonads to mature. In some studies, 100% of children on puberty blockers continued on to cross-sex hormones.[46] The sequential process of using puberty blockers in a reproductively immature child, followed by "cross-sex" hormones (high-dose estrogen in a male, high-dose testosterone in a female) sterilizes the child permanently. (Gender clinicians admit, however, that "pre- and peri-pubertal children may not have the emotional maturity to think through their future fertility desires and weigh the benefits and risks of undergoing an elective invasive procedure for FP [fertility preservation]."[47])

Diane Ehrensaft, PhD, a leading clinician-advocate for "gender affirming" medical interventions for adolescents, describes in stark term the sterilizing nature of the one-two combination of pubertal suppression followed by cross-sex hormones: "[A] child who begins puberty blockers at Tanner Stage 2 and proceeds directly to cross-sex hormones will be rendered infertile."[48]

Dr. Johanna Olson-Kennedy, a gender clinician at Children's Hospital Los Angeles, acknowledges the sterilizing nature of puberty blockers and hormones in the "Informed Consent" document used for the Trans Youth study:

> Risk to Puberty Blockers:
> - The side effects and safety of these medicine are not completely understood. There may be long-term risks that are not yet known.
> - If your child starts puberty blockers in the earliest stages of pubert, and then goes on to gender affirming hormones, they will not develop sperm or eggs. This means that they will not be able to have biological children. *This is an important aspect of blocking puberty and progressing to hormones that you should understand prior to moving forwad with puberty suppression*.[49]

Less is known about the long-term, potentially sterilizing effects of cross-sex hormones in reproductively mature individuals. However, WPATH SOC 8 acknowledges the likelihood of impaired fertility: "Anti-androgens and estrogens [cross-sex hormones used by males] result in an impaired sperm production …. Spermatogenesis might resume after discontinuation of prolonged treatment with anti-androgens and estrogens, but data are limited …. Testicular

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[46] Carmichael, P., Butler, G., Masic, U., Cole, T. J., De Stavola, B. L., Davidson, S., Skageberg, E. M., Khadr, S., & Viner, R. *Short-term Outcomes of Pubertal Suppression in a Selected Cohort of 12 to 15 Year Old Young People with Persistent Gender Dysphoria in the UK*, 16 PLoS One (2021), e0243894, 10.1371/journal.pone.0243894; Michael Biggs, *The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence*, J. Sex & Marital Therapy (2022), DOI: 10.1080/0092623X.2022.2121238.

[47] Afiya Sajwani, Moira A. Kyweluk, Elisa J. Gordon, Emilie K. Johnson, Courtney Finlayson & Diane Chen *Fertility Considerations in Parental Decision-Making about Pubertal Suppression Treatment for Their Transgender and Gender-Diverse Children*, LGBTQ+ Family: An Interdisciplinary Journal (2022), DOI: 10.1080/27703371.2022.2113947.

[48] Ehrensaft D. *Gender nonconforming youth: current perspectives*, 8 Adolesc Health Med Ther. 57-67 (May 25, 2017), doi: 10.2147/AHMT.S110859. PMID: 28579848; PMCID: PMC5448699. https://pubmed.ncbi.nlm.nih.gov/28579848/.

[49] *Assent to participate in a research study, Trans Youth Care*, Children's Hospital Los Angeles, https://drive.google.com/file/d/1Q-zJCivH-QW7hL25idXT_jITfJZUUm1w/view.

volumes diminish under the influence of gender-affirming hormone treatment."[50] The Mayo Clinic cautions, "The risk of permanent infertility increases with long-term use of hormones. That is particularly true for those who start hormone therapy before puberty begins. Even after stopping hormone therapy, your testicles might not recover enough to ensure conception without infertility treatment."[51]

Gender clinicians observe that "the impact of long term GAHT [gender-affirming hormone therapy] on future reproductive function is still unknown," but the likelihood of sterilization is significant enough that WPATH, the "Endocrine Society, and the American Society for Reproductive Medicine (ASRM) all recommend counseling on the potential risk for fertility impairment and options for fertility preservation (FP) prior to initiating GAHT."[52] Given the lack of research on long-term effects of GAHT and the indications that it may lead, in some unknown number of cases, to permanent sterility, WPATH's SOC 8 guidelines repeatedly emphasize the importance of "fertility preservation" ahead of any hormonal and surgical "gender-affirming" interventions."[53]

C. "Gender-affirming" surgery that removes or alters natal gonads or reproductive organs is a sterilization procedure.

Human fertility, unassisted by reproductive technology, depends on the presence of mature, functioning gonads and reproductive organs (penis, vagina, and uterus). Not surprisingly, "[s]urgical treatment that includes gonadectomy unquestioningly results in sterilization…."[54]

Fertility-destroying surgeries that remove or alter genital or reproductive organs include: vaginoplasty, metoidioplasty, phalloplasty, ovariohysterectomy/colpectomy, oophorectomy, and orchiectomy.[55] WPATH SOC 8 acknowledges in multiple sections the sterilizing nature of "gender transition" surgery: "surgery that removes gonads is an irreversible procedure that leads to loss of fertility and loss of the effects of endogenous sex steroids"; "[s]urgical interventions

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[50] WPATH SOC 8, S158.

[51] *Feminizing Hormone Therapy*, Mayo Clinic, https://www.mayoclinic.org/tests-procedures/feminizing-hormone-therapy/about/pac-20385096.

[52] Kelley CE, Davidge-Pitts CJ, Breaking down barriers to reproductive care for transgender people., AACE Clinical Case Reports (2021), doi: https://doi.org/10.1016/ j.aace.2021.08.001.

[53] WPATH SOC 8, S118. "We recommend health care professionals inform and counsel all individuals seeking gender-affirming medical treatment about the options available for fertility preservation prior to initiating puberty suppression and prior to treating with hormone therapy." See also: "Consequently, "health care providers should discuss fertility goals and fertility preservation procedures prior to initiating GAHT." WPATH SOC 8 S110.

[54] Kelley CE, Davidge-Pitts CJ, Breaking down barriers to reproductive care for transgender people., AACE Clinical Case Reports (2021), doi: https://doi.org/10.1016/ j.aace.2021.08.001.

[55] "The removal of internal reproductive organs is often performed before genitoplasty. Individuals may request hysterectomy and/or oophorectomy due to discomfort in having 'female' internal reproductive organs, to obviate the need to survey these organs, and/ or to decrease the risk of developing gynecological cancers. Some individuals may retain their reproductive organs for a variety of reasons, including fertility preservation, childbearing, and/or sexual gratification. Colpectomy, removal of the vaginal epithelium with colpocleisis, closure of the vaginal canal, is usually performed in conjunction with metoidioplasty or phalloplasty." Oles N, Darrach H, Landford W, Garza M, Twose C, Park CS, Tran P, Schechter LS, Lau B, Coon D., *Gender Affirming Surgery: A Comprehensive, Systematic Review of All Peer-reviewed Literature and Methods of Assessing Patient-centered Outcomes (Part 2: Genital Reconstruction)*, 275(1) Ann Surg. e67-e74, e68 (Jan 1, 2022), doi: 10.1097/SLA.0000000000004717. PMID: 34914663. https://pubmed.ncbi.nlm.nih.gov/34914663/.

that alter reproductive anatomy or function may limit future reproductive options to varying degrees"; "Infertility is often a consequence of both gender-affirming hormone therapy (temporary) and GAS (permanent)…."[56]

Gender clinicians and activists alike clearly view "gender-affirming" surgeries as "sterilizing procedures." WPATH cites to international human rights agreements as well as medical ethics norms in highlighting the ethical obligation of clinicians to discuss the sterilizing consequences of "gender-affirming" hormonal and surgical interventions and promoting "fertility preservation" procedures to harvest gametes or even immature reproductive tissue.[57] Human Rights Watch has long advocated against legal requirements that trans-identified persons must undergo sterilizing gender transition procedures in order to obtain legal recognition documents that recognize their asserted identity. "Making hormones and surgery leading to infertility a mandatory requirement for recognizing trans people's gender identity ignores [their] individual circumstances.…"[58] Trans-activist Samantha Allen railed in a similar vein in an opinion piece for the *Daily Beast* against California's then-law that required, as a condition for "sex reassignment surgery," that Allen sign California's 'Consent to Sterilization' form [PDF]."[59]

When gender medicine and trans-activist communities recognize the sterilizing nature of specific gender-affirming interventions, it should not be controversial that medical professionals or institutions also recognize them as such. And when some medical professionals and institutions object, on religious or moral grounds, to participating in or referring for these sterilizing procedures, it should be similarly uncontroversial to recognize their right not to be coerced or forced into doing so. Clinicians and institutions should never face the prospect of being coerced into providing sterilizing puberty blockers, cross-sex hormones, or surgeries to gender-dysphoric youth, or paying the price of defending an anti-discrimination lawsuit or professional losses.

In sum, we urge the Department to acknowledge the application of conscience protections under conscience protection laws to individual and institutional religious and moral objections related to the performance, participation, or assistance in sterilizing gender transition procedures.

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[56] WPATH S132; S 41. See also: "[T]here are major gaps in knowledge, and findings regarding the fertility of trans feminine people who take estrogen and antiandrogens are inconsistent (Cheng et al., 2019)." WPATH S118; S156.
[57] WPATH SOC 8, 156: "Medically necessary gender-affirming hormonal treatments (GAHTs) and surgical interventions … that alter reproductive anatomy or function may limit future reproductive options to varying degrees [citations omitted]. It is thus critical to discuss infertility risk and fertility preservation (FP) options with transgender individuals and their families prior to initiating any of these treatments and to continue these conversations on an ongoing basis thereafter."
[58] *Controlling Bodies, Denying Identities*, Human Rights Watch (Sept. 13, 2011), https://www.hrw.org/report/2011/09/13/controlling-bodies-denying-identities/human-rights-violations-against-trans-people.
[59] *It's Not Just Japan. Many U.S. States Require Transgender People Get Sterilized*, Daily Beast (Mar. 22, 2019) https://www.thedailybeast.com/its-not-just-japan-many-us-states-require-transgender-people-get-sterilized (linking to PDF: https://files.medi-cal.ca.gov/pubsdoco/forms/PM-330_Eng-SP.pdf).

5. Robustly enforcing conscience rights leads to important benefits, while lack of enforcement leads to harm.

The health care profession is full of entities and individuals that have conscience or religious objections to participating in medical interventions affecting life, such as abortion, sterilization, and assisted suicide. Faith-based hospitals make up 17% of the hospitals in the United States,[60] and there are countless medical professionals serving in various capacities throughout the nation. As one poll indicated, up to 91% of religious health care professionals would rather stop practicing medicine than violate their religious beliefs, and many commenters to the 2019 Rule indicated that they would leave the health care profession or have already left or limited their practice because of pressure to violate their beliefs.[61]

With the advent of new medical advances and technology, health care professionals face the daunting challenge of abiding by their conscience or religious beliefs, best medical judgment, and the law. For example, the FDA's relaxation of the safety requirements for the abortion drug, Mifepristone,[62] and green light by HHS for pharmacies to directly dispenses chemical abortion drugs imposes new difficulties for who oppose abortion based on conscience or religious beliefs.[63] Additionally, those with conscience objections to assisted suicide, sterilization (including sterilizing gender transition interventions), and vaccines are facing increased pressure to violate their consciences. These conflicts have and will force many health care professionals out of the medical profession as many will choose to leave rather than violate their consciences or religious beliefs.

HHS in these proposed rules presupposes that robust enforcement of federal conscience protections laws would be contrary to the public good, because it would negatively impact access to care. But HHS fails to consider that failing to enforce federal law would push doctors, nurses, and pharmacists out of their profession, which would itself hurt access to care.

While expert medical professionals retiring prematurely will always be a big loss, the harm would be compounded were a large-scale resignation to take place when the health care system is already suffering from a shortfall. And yet that is the situation our health care system finds itself in now. A report published by the Association of American Medical College projects physicians "shortages by 2034" that include "a shortfall of between 17,800 primary care physicians … a shortfall of between 21,000 and 77,100 non-primary care physicians, including 15,800 and 30,200 surgical specialists."[64] Instead of pushing health care professionals out of the medical field by undercutting conscience protections, HHS should focus on incentivizing retention and sustainability.

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[60] *Percentage of Faith-Based Hospitals as a Proportion of Total Hospitals in the U.S. from 1995 to 2016,* Statista (Mar. 2, 2018), https://www.statista.com/statistics/800807/percentage-of-faith-based-hospitals-in-the-us/.
[61] *See* 84 Fed. Reg. 23175–76, 23180–81 & nn.46–48.
[62] *Dangers of Relaxed Restrictions on Mifepristone*, Am. Ass'n of Pro-Life OB/GYNS (Oct. 2021, updated July 2022), https://aaplog.org/wp-content/uploads/2022/07/CO-9-Mifepristone-restrictions-update-Jul-22.pdf.
[63] *Abortion Pills Can Now Be Offered at Retail Pharmacies, F.D.A. Says*, N.Y. Times (Jan. 3, 2023) https://www.nytimes.com/2023/01/03/health/abortion-pill-cvs-walgreens-pharmacies.html.
[64] *Physician Supply and Demand—A 15-Year Outlook: Key Findings*, Ass'n of Am. Med. Colleges (May 2021), https://www.aamc.org/media/54686/download?attachment.

Because courts have held that certain conscience protection laws do not contain an implied private right of action, meaning that an individual or entity whose rights have been violated is unable to sue in federal court, it is incumbent on HHS to vindicate any violation of federal conscience rights. Further, there are not sufficient state-law equivalents to fill the gap if HHS refuses to robustly enforce federal conscience protection laws.

6. HHS should redeem its abysmal record on conscience and religious freedom protections.

The proposed rule claims "The Department remains committed to educating patients, providers, and other covered entities about their rights and obligations under the conscience statutes and remains committed to ensuring compliance." Yet the proposed rescission of the 2019 Rule follows a disturbing trend of HHS paying lip service to conscience and religious freedom rights, while blatantly disregarding and ignoring those rights.[65]

HHS has only made it more difficult across the board for the Department to enforce vital conscience and religious protections in health care. HHS crippled its Office for Civil Rights' ability to receive complaints and enforce religious protections under the Religious Freedom Restoration Act and the First Amendment by gratuitously removing the delegation of authority authorizing OCR to enforce those laws.[66]

In July 2021, in coordination with DOJ's dismissal of an enforcement lawsuit, OCR withdrew a notice of violation against the University of Vermont Medical Center for violating the Church Amendments by forcing a nurse to participate in an abortion despite her known religious objection.[67] The nurse received no compensation for the blatant violation of her rights. OCR under this administration also reconsidered two notices of violation against California (and then-Attorney General Xavier Becerra) for forcing nuns and others to provide insurance coverage of abortion in violation of the Weldon Amendment.[68]

Apart from the clear conflict of interest with Becerra, these actions do not bode well for HHS's alleged "commit[ment] to ensuring compliance."[69] These actions, coupled with the

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[65] *See, e.g.*, Rachel N. Morrison, *In Its First Year, Biden's HHS Relentlessly Attacked Christians and Unborn Babies*, The Federalist (Mar. 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).
[66] 86 Fed. Reg. 67,067 (Nov. 24, 2021) (Delegation of Authority); see also Letter from Lisa J. Pino, Director, Office for Civil Rights, U.S. Dep't of Health & Human Servs., to Xavier Becerra, Secretary, U.S. Dep't of Health & Human Servs., on DECISION—Sign Delegation of Authority on the Religious Freedom Restoration Act and the Religion Clause of the First Amendment to the U.S. Constitution (Nov. XX, 2021), https://www.lankford.senate.gov/imo/media/doc/HHS%20RFRA%20Memo.pdf (requesting Becerra rescind OCR's delegation of authority to enforce RFRA and the Religious Clauses of the First Amendment and recognizing that the Department will be criticized that it "does not take seriously its compliance with RFRA or the First Amendment").
[67] Letter, Robinsue Frohboese, Acting Direct and Principal Deputy, Office for Civil Rights, HHS, to David Quinn Gacioch, on OCR Transaction Number 18-306427 (July 30, 2021), https://www.hhs.gov/conscience/conscience-protections/uvmmc-letter/index.html.
[68] Letter, Robinsue Frohboese, Acting Direct and Principal Deputy, Office for Civil Rights, HHS, to Rob Bonta, Attorney General, State of California, on OCR Transaction Numbers 17-274771 and 17-283890 (Aug. 13, 2021), https://www.hhs.gov/conscience/conscience-protections/ca-letter/index.html.
[69] 88 Fed. Reg. 826.

weakened enforcement mechanism proposed by HHS, suggest that HHS under the Biden administration does not respect and will not enforce rights under conscience protection laws.

Based on HHS's record, many believe that HHS will not respect their conscience or religious freedom complaints, so there is no point in filing a complaint. Nevertheless, conscience and religious freedom complaints constitute a significant portion of HHS complaints. For example, in 2022, 7% of HHS OCR complaints allege violations of conscience/religious freedom![70] In comparison, just 27% of HHS OCR complaints allege violates of civil rights, which covers discrimination on the basis of race, color, national origin, disability, age, *and* sex, which puts conscience/religious freedom complaints at least on par with other civil rights violations. Of all civil rights complaints (excluding alleged privacy and HIPPA violations), conscience and religious freedom complaints were over 20% (7/34). With a robust commitment and enforcement of conscience and religious freedom rights by the Department, this number would likely only increase. As is, many likely do not file complaints under the impression HHS does not care or does not take such complaints seriously.

7. HHS should consult with the career professional experts in the (former) Conscience and Religious Freedom Division.

Under the Biden administration, OCR's Conscience and Religious Freedom Division, which was dedicated to protecting conscience rights, was sidelined and the career professionals with expertise in conscience protection laws were prohibited from investigating complaints under those laws or from advising on the 2023 proposed rule and other conscience related matters. Indeed, HHS recently announced a restructuring of OCR, which officially cut the Conscience and Religious Freedom Division.[71] This move suggests that HHS does not take investigations and enforcement of conscience and religious freedom rights seriously and will relegate them to second-class status.

We ask the Department to clarify how OCR will handle complaints alleging violations of conscience and religious freedom. Specifically, which of the new offices will investigate conscience and religious freedom complaints? Will those staffed in those offices have particular expertise with conscience protection laws? We also ask for clarity over who is tasked with making enforcement decisions, such as a notice of violation and the appropriate remedy to be sought.

We urge HHS to utilize the expertise of the career professionals of the former Conscience and Religious Freedom Division in not just evaluating this proposal, but also in investigating complaints alleging violations of conscience and religious freedom.

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[70] Press Release, HHS, HHS Announces New Divisions Within the Office for Civil Rights to Better Address Growing Need of Enforcement in Recent Years (Feb. 27, 2023), https://www.hhs.gov/about/news/2023/02/27/hhs-announces-new-divisions-within-office-civil-rights-better-address-growing-need-enforcement-recent-years.html. For reference only approximately 3-4% of charges of employment discrimination filed with the Equal employment Opportunity Commission are based on religion. *See Charge Statistics (Charges filed with EEOC) FY 1997 Through FY 2021*, EEOC (last visited Mar. 6, 2023), https://www.eeoc.gov/data/charge-statistics-charges-filed-eeoc-fy-1997-through-fy-2021.

[71] 88 Fed. Reg. 12955 (Feb. 25, 2023) (Statement of Organization), https://www.federalregister.gov/documents/2023/03/01/2023-03892/statement-of-organization.

8. HHS must conduct a meaningful economic analysis and consider the proposed rule's costs and impacts.

Economic Analysis. In accord with EO 12866 and OMB Circular A–4,[72] HHS agrees the proposed rule is an "economically significant rule," that requires meaningful economic analysis.[73] The proposed rule increases confusion and decreases clarity, and suggests the Department is not serious about robustly enforcing conscience protection laws. In light of these concerns with the current proposal, HHS must take into consideration the following key inputs as part of its regulatory impact and economic analysis of the costs, benefits, and transfers:

- 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.
- 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.

[72] 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."

[73] 88 Fed. Reg. 827,

- 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 enabling 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 robustly enforce the laws, no one can).
- The compounding harms of not robustly enforcing conscience protections while at the same time mandating performance of procedures that violate the conscience of health care professionals.
- The government's lack of countervailing interest in coercing medical professionals to participate in procedures that violate their conscience or religious beliefs.
- The analysis must consider as the baseline, the 2022 reality of a post-COVID pandemic health care landscape. Pre-pandemic numbers won't accurately reflect the strain on the health care community from professionals to institutions.

All of these factors, 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.

Federalism Concerns. HHS's proposal will clearly have federalism implications as it will impact state hospitals, medical facilities, and insurance plans. In addition, there are state and local laws protecting conscience and religious freedom rights, which could be impacted. These impacts must be addressed in any final rulemaking.

Comment Period. We recognize that the Department gave the public 60 days to provide meaningful public comment on such a major and significant proposed rule. This has unfortunately not been the norm for HHS and other agencies under the current administration[74] and we applaud the Department for not following that trend for this proposed rule.

9. The proposed rule must be analyzed in conjunction with other laws and regulations.

There are several laws and regulations discussed below that HHS must consider in conjunction with this proposed rule.

RFRA. HHS must analyze its proposed 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

[74] 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.

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.

Further to the extent that HHS claims a competing interest in nondiscrimination, such as by requiring medical professionals provide abortion or sterilizing gender transition interventions, Congress provided the balance by providing unbalanced protections for conscience rights in the various conscience protection laws. As the Supreme Court made clear in *Fulton v. City of Philadelphia*[75] 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 formerly withdrew the delegation of authority from OCR to enforce RFRA,[76] and so any perfunctory statement that HHS will comply and follow relevant laws, including RFRA is suspect. Any final rule should explain *specifically* how HHS intends to uphold its duty to comply with RFRA when OCR's delegation has been withdrawn. We urge HHS to restore OCR's ability to enforce RFRA within the agency.

Title VII. HHS must also consider its proposed regulations 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.

Further, given that the district court decisions enjoining the 2019 Rule relied, in part, on court precedents about Title VII's religious accommodation exception, HHS should wait to issue any final rule until the Supreme Court issues its decision in *Groff v. DeJoy* this term as it will clarify the scope of an employer's undue hardship defense to a denial of a religious accommodation request.[77]

Section 1554. HHS must consider its proposal in light of 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;

[75] 141 S. Ct. 585 (2021).
[76] HHS, Delegation of Authority, 86 Fed. Reg. 67067 (Nov. 24, 2021).
[77] *See generally* Rachel Morrison, *No One Should Be Forced to Choose Between His Faith and His Paycheck*, The Federalist (Mar. 6, 2023), https://thefederalist.com/2023/03/06/no-one-should-be-forced-to-choose-between-his-faith-and-his-paycheck/ (summarizing legal issues in *Groff*).

(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."

There are many ways the proposed regulations could violate Section 1554. For example, not providing robust protections for conscience rights in health care could drive medical professionals out from a specific specialty or from the profession altogether. This would violate (1), (2), and (6) by creating a provider gap and thus a barrier to medical care and lack of timely access to health care services and limiting the availability of health care treatments for patients' medical needs. Requiring medical professionals to violate their consciences and refer for abortion or sterilizing gender transition interventions would violate (3) and (4). Not protecting medical professionals from forced participation in life-ending or life-altering medical interventions, such as abortion, euthanasia, or sterilizing gender transition drugs and surgeries, would encourage medical professionals to violate the ethical standards set out in the Hippocratic oath to "do no harm" and would violate (5).

Other regulations. HHS has proposed other rules that reference conscience protection laws, such as proposed rules on Section 1557 and Partnerships with Faith-Based and Neighborhood Organizations, so these regulations and the process HHS establishes to protect conscience rights is all the more important. This rule should be considered in conjunction with those rules that implicate conscience and religious freedom rights in health care.

Conclusion

HHS should defend the 2019 Rule in court. In the alternative, HHS should retain or improve on—not gut—the provisions in the 2019 Rule providing robust enforcement of the conscience protection laws HHS is charged with enforcing.

Sincerely,

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