

March 6, 2023

Secretary Xavier Becerra
Office for Civil Rights, Office of the Secretary
U.S. Department of Health and Human Services
VIA REGULATIONS.GOV

RE: Safeguarding the Rights of Conscience as Protected by Federal Statutes RIN 0945-AA18 Docket ID HHS-OCR-2023-0001

Dear Secretary Becerra,

We write to encourage the U.S. Department of Health and Human Services (HHS) to protect conscience rights and religious freedom. These statutory protections enable all Americans to promote the common good, protect unborn life, and freely live out their conscientious and religious convictions.

Alliance Defending Freedom (ADF) submits these comments to HHS's Office for Civil Rights (OCR) in response to the invitation to comment on the proposed rule, Safeguarding the Rights of Conscience as Protected by Federal Statutes, 88 Fed. Reg. 820 (Jan. 5, 2023). ADF is an alliance-building legal organization that advocates for the right of all people to freely live out their faith. It pursues its mission through litigation, training, strategy, and funding. ADF has handled many legal matters involving Section 1557 of the Affordable Care Act; the Administrative Procedure Act (APA); the Religious Freedom Restoration Act (RFRA); the First Amendment; healthcare conscience rights; and other legal principles addressed by the proposed rule.

ADF has represented many clients whose lives have been thrown into turmoil by those who are either unaware of or willfully dismissive of federal conscience protections. Every year countless medical practitioners needlessly suffer threats to their livelihoods and affronts to their religious beliefs and practices just for asserting their rights to conscience and religious freedom. These ordeals are made worse when HHS provides little recourse. When HHS fails to enforce laws protecting conscience and religious freedom, patients suffer and lose access to care because many providers cannot practice medicine if it means violating their conscience or their religious beliefs.

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Through this proposed rule, the Biden administration seeks to address these issues, as well as to "increase access to care and prevent discrimination." ¹

In some ways, the proposed rule significantly improves upon past rules that address conscience and religious freedom, but in many other ways the proposed rule does not go far enough. ADF thus urges HHS to enact the conscience protections in the proposed rule as a baseline, and then to go beyond this floor and further strengthen conscience protections in the final rule.

I. The regulations should serve the statutes' objectives to broadly protect the consciences of medical professionals and institutions.

The right to conscience was central to the founding of the American Republic.² James Madison deemed it an "unalienable right," "the most sacred of all property," 4 and Thomas Jefferson concurred, noting that conscience "could not [be] submit[ted]" to governmental oversight or authority. This same right of conscience has also been essential to the practice of medicine for millennia, as evidenced by the Hippocratic Oath and medicine's status as an autonomous profession concerned with doing right and avoiding wrong. 6

Congress has given HHS an important role in fulfilling our nation's historical commitment to respecting the rights of conscience and religious freedom. Congress has charged HHS with enforcing over two dozen federal laws that protect conscience and religious freedom rights for individuals and organizations in healthcare.⁷

¹ 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.

² Lynn D. Wardle, "Conscience Exemptions," 14 Engage: J. Federalist Soc'y Prac. Groups 77, 78–79 (2013) (explaining that protecting "conscience was one of the essential purposes for the founding of the United States of America and one of the great motivations for the drafting of the Bill of Rights").

³ James Madison, Memorial and Remonstrance Against Religious Assessments (1785), in Selected Writings of James Madison 21–27 (Ralph Ketcham ed. 2006).

⁴ James Madison, Property (1792), in Madison supra, note 3, at 223.

⁵ Thomas Jefferson, Notes on the State of Virginia 265 (1782).

⁶ Edmund D. Pellegrino, Toward a Reconstruction of Medical Morality, The American Journal of Bioethics, 6(2): 65–71, 2006 (stating that "[m]edicine is a moral enterprise . . . conducted in accordance with a definite set of beliefs about what is right and wrong").

⁷ These conscience and religious freedom laws are summarized on HHS's website at HHS OCR, *Religious Freedom*, https://www.hhs.gov/conscience/religious-freedom/index.html and HHS OCR,

HHS's conscience protections sit in the middle of the most important life-ordeath issues in American healthcare. As one commenter has explained, most of the statutory conscience laws that HHS is charged with enforcing "focus on the most controversial medical interventions of 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."8 These conscience protection laws include the Church Amendments (which provide conscience protections for individuals and entities related to abortion, sterilization, and certain other health services); the Coats-Snowe Amendment (which 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; the Weldon Amendment (which provides conscience protections from discrimination for health-care entities that do not provide, pay for, provide coverage of, or refer for abortions); the Affordable Care Act (which provides conscience protections for health-care providers related to abortion and assisted suicide, euthanasia, or mercy killing); and Medicare and Medicaid (which provide conscience protections for Medicare Advantage organizations and Medicaid managed care organizations with moral or religious objections to counseling or referral for certain services).9

HHS's enforcement role is critical for giving meaning to all of these conscience protections. In many cases, only HHS can enforce these laws. Because courts have held that some conscience protection laws do not contain an implied private right of action, often only HHS can bring litigation on behalf of an individual or entity whose rights have been violated. ¹⁰ That means that if HHS does not act to protect conscience and religious freedom, no one will.

II. ADF clients' experiences show that HHS urgently needs to enforce conscience and religious freedom protections.

Many of our ADF clients know what it is like to face professional consequences for following their consciences, despite the federal laws that should

Conscience and Religious Nondiscrimination, <a href="https://www.hhs.gov/conscience/cons

⁸ Rachel Morrison, *HHS Proposes Rule Modifying Healthcare Conscience Regulations*, FedSoc Blog (Feb. 16, 2023), https://fedsoc.org/commentary/fedsoc-blog/hhs-proposes-rule-modifying-healthcare-conscience-regulations.

⁹ *Id*.

 $^{^{10}}$ E.g., Cenzon-DeCarlo v. Mount Sinai Hosp., 626 F.3d 695 (2d Cir. 2010) (holding that the Church Amendments, 42 U.S.C. § 300a-7(c), do not create private right of action).

protect them. Their stories show the importance of creating a workable system of enforcement for healthcare conscience and religious freedom statutes.

HHS has requested information and examples addressing the scope and nature of the problems giving rise to the need for rulemaking, including specific problems arising under many of these conscience and religious freedom statutes. 88 Fed. Reg. at 826. These stories provide HHS the information it requested. And these cases underscore the urgent need for HHS rulemaking to promote HHS enforcement of conscience and religious freedom laws.

Danquah v. University of Medicine & Dentistry of New Jersey. 11 Nurses in the Same Day Surgery Unit at the University of Medicine and Dentistry of New Jersey were told they would have to assist with abortions or be fired or transferred out of the unit. Fe Danquah contacted Alliance Defending Freedom. ADF attorneys informed hospital officials that the new policy transgressed both state and federal laws that make it illegal to compel medical professionals to violate their conscience by forcing them to help with a non-emergency abortion.

Hospital administrators stubbornly contended that all abortions in the Same Day Surgery Unit—each scheduled weeks in advance—were "emergencies," and the nurses were required to assist in emergencies. So Fe, along with 11 other nurses, filed suit. Three nurses had been forced to go through hands-on abortion training. But ADF obtained a court order preventing the hospital from forcing any more nurses to participate while the case went forward. On the day of the preliminary-injunction hearing, the judge announced that a settlement had been reached. In a victory for the nurses and ADF, the hospital agreed not to force the women to participate in abortions, or to retaliate against them by replacing them.

Christian Medical & Dental Associations v. Bonta. ¹² The Christian Medical & Dental Associations (CMDA) is a national organization of 19,000 conscientious Christian health-care professionals whose personal religious convictions and professional ethics oppose practices like physician-assisted suicide (PAS). Dr. Leslee Cochrane is a CMDA member and full-time hospice physician in California.

¹¹ See generally Danquah v. University of Medicine & Dentistry of New Jersey, https://adflegal.org/case/danquah-v-university-medicine-and-dentistry-new-jersey (last updated Feb. 15, 2023).

 $^{^{12}}$ See generally Christian Medical & Dental Associations v. Bonta, https://adflegal.org/case/christian-medical-dental-associations-v-bonta (last updated Feb. 20, 2023).

CMDA and its members like Dr. Cochrane seek to live out their Christian beliefs in their practice of health care, including their belief in the sanctity of human life. It would violate their consciences to participate in assisted suicide in any way. But California law now forces these health-care professionals to actively facilitate the PAS process. CMDA members' rights of conscience and religious freedom must be protected because the state lacks any authority to order them to act contrary to those sincere convictions.

In October 2021, California passed a law that weakened the already-permissive rules regulating the state's physician-assisted suicide law. The original law, passed in 2015, required a 15-day waiting period after a patient's request for assisted suicide, giving patients opportunity to reconsider their choice, discuss with family, and get further input from medical professionals. That timeline was sharply reduced by the new law and now requires just 48 hours between requests.

The law demands that even if a physician like Dr. Cochrane obeys his conscience by refusing to participate directly in a patient's suicide, he must still participate in the process, for example, by documenting a patient's suicide request, moving the patient closer to death.

But if health-care professionals continue to stand on their deeply held beliefs and focus on helping and healing instead of killing, they could be subject to civil or criminal penalties and could even lose their license. So, in February 2022, ADF filed a lawsuit. In September 2022, a federal court granted our motion for preliminary injunction, saying that the California law violates the First Amendment rights of medical professionals by requiring them to participate in physician-assisted suicide against their religious convictions and professional ethics.

But HHS should be leading the charge against this law through its enforcement arm in OCR. Section 1553 provides that the federal government, any state or local government, and any health-care provider that receives federal funding under the ACA, or any health plan created under the ACA, may not subject an individual or health-care entity to discrimination because the individual or entity does not provide services to cause or assist in the death of any individual, including through assisted suicide, euthanasia, and mercy killing. ¹³ Section 1553 provides that OCR will receive complaints of discrimination related to that section. ¹⁴ ADF filed a complaint with OCR over this violation.

¹³ 42 U.S.C. §§18023(b)(4),18113(a).

¹⁴ Id. § 18113(d).

Lacy v. Torrez.¹⁵ New Mexico also requires physicians who are to facilitate suicide by informing patients about assisted suicide and referring patients to physicians and organizations who will participate in ending their lives. If physicians decline to participate based on their religious beliefs or professional ethics, they can face substantial criminal, civil, administrative, and professional liability, including risking losing their medical licenses. Dr. Mark Lacy and the CMDA filed suit against this law in December 2022 and have moved for a preliminary injunction.

Vermont Alliance Ethical Healthcare v. Hoser. ¹⁶ In 2016, the Vermont Board of Medical Practice and Office of Professional Regulation read the state's assisted suicide law to require health-care professionals, regardless of their conscience or oath, to counsel patients on doctor-prescribed death as an option. Although Act 39, Vermont's assisted suicide bill, passed with a protection for attending physicians who don't wish to dispense death-inducing drugs themselves, state medical licensing authorities construed a separate, existing mandate to counsel and refer for "all options" for palliative care to include a mandate that all patients hear about the "option" of assisted suicide.

Two groups of Christian health-care professionals filed suit. These doctors and health-care workers believe that suffering patients need understanding and sound medical treatment, not encouragement to kill themselves. The state lacks any authority to order them to act contrary to that sincere and time-honored conviction.

A federal district court ruled for the plaintiffs, and they entered a consent agreement with the state attorney general.

Hellwege v. Tampa Family Health Centers.¹⁷ In the spring of 2014, nurse midwifery student Sara Hellwege, sought employment as a nurse midwife at Tampa Family Health Centers (TFHC). She was quizzed about her membership with American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) and her pro-life religious objection to certain hormonal abortifacients and birth control. She was then informed that, because she was a member of AAPLOG and held her religious convictions, she would not be allowed to proceed in the hiring process. Alliance Defending Freedom filed suit in federal district court in Florida,

¹⁵ See generally Lacy v. Torrez, https://adflegal.org/case/lacy-v-balderas (last updated Feb. 20, 2023).

¹⁶ See generally Vermont Alliance for Ethical Healthcare v. Hoser, https://adflegal.org/case/vermont-alliance-ethical-healthcare-v-hoser (last updated Mar. 3, 2023).

¹⁷ See generally Hellwege v. Tampa Family Health Centers, https://adflegal.org/case/hellwege-v-tampa-family-health-centers (last updated Feb. 20, 2023).

and filed administrative claims with HHS as well as the EEOC, claiming that the actions of TFHC violated Mrs. Hellwege's rights of conscience and were unlawful. The case ended in a settlement.

National Institute of Family and Life Advocates v. Becerra. In 2015, pro-life pregnancy centers filed suit in federal court in California, challenging a California law that required licensed medical centers that offer free, pro-life help to pregnant women to post or distribute a disclosure saying that California provides free or low-cost abortion and contraception services. The disclosure was also required to include a phone number for a county office that refers women to Planned Parenthood and others in the abortion industry. Additionally, the law forced unlicensed pregnancy centers to add large disclosures in multiple languages about their non-medical status in advertisements, which obscured and crowded out their pro-life speech. Failure to comply carried civil fines up to \$1,000 per violation. Among other constitutional problems with the law, the law violated the Coats-Snowe Amendment, 42 U.S.C. § 238n, which protects licensed health-care entities from being required to refer for abortion or make arrangements for such referrals. The U.S. Supreme Court ruled for the pro-life pregnancy centers to protect their free speech. Nat'l Inst. of Fam. & Life Advocs. v. Becerra, 138 S. Ct. 2361 (2018).

Caring Families v. City of Hartford. ¹⁹ The city of Hartford enacted an ordinance that forced a life-affirming, faith-based pregnancy care center to make compelled statements using signs inside and outside the facility, on its website, and in telephone conversations with clients. The ordinance is similar to portions of a California law that the U.S. Supreme Court struck down in NIFLA v. Becerra. Caring Families and its affiliated mobile care ministry challenged the local ordinance in federal court, arguing that the city's compelled statements are a violation of the First Amendment and incorrectly imply that the nonprofit is unqualified to provide the range of free services it offers to clients. The city of Hartford then settled the lawsuit.

ADF also filed a complaint with OCR.²⁰ Hartford is subject to the Chm-ch Amendments (42 U.S.C. § 300a-7), the Public Health Service Act(§ 245 (42 U.S.C. § 238n)), the Coats-Snowe Amendment (42 U.S.C. § 238n), and/or the Weldon

¹⁸ See generally NIFLA v. Becerra, https://adflegal.org/case/national-institute-family-and-life-advocates-v-becerra (last updated Feb. 27, 2023).

¹⁹ See generally Caring Families v. City of Hartford, https://adflegal.org/case/caring-families-v-city-hartford (last updated Feb. 13, 2023).

²⁰ ADF, Letter to OCR (May 21, 2019), https://adfmedialegalfiles.blob.core.windows.net/files/CaringFamiliesHHS-OCR-Letter.pdf.

Amendment (Continuing Appropriations Resolution, Pub. L. No. 113-164, Sec. 101(a) (Sept. 19, 2015)) by virtue of its status as a recipient of federal funding.

National Institute of Family and Life Advocates v. Schneider.²¹ Alliance Defending Freedom attorneys representing multiple pregnancy care centers, a pregnancy care center network, and a doctor and her medical practice filed suit in federal court against Illinois Gov. Bruce Rauner after he signed a bill into law that forces them to promote abortion regardless of their ethical or moral views. The lawsuit also named Bryan Schneider, secretary of the Illinois Department of Financial and Professional Regulation.²²

The Illinois law forces pregnancy care centers, medical facilities, and physicians who conscientiously object to involvement in abortions to adopt policies that provide women who ask for abortions with a list of providers "they reasonably believe may offer" them. Both federal and state law prohibit the government from placing burdens on religious conscience without a compelling interest for doing so. Additionally, the Illinois Constitution protects "liberty of conscience," saying that "no person shall be denied any civil or political right, privilege or capacity, on account of his religious opinions." Both the Illinois Constitution and the U.S. Constitution protect free speech, which includes the right not to be compelled by government to speak a message contrary to one's own conscience.

Medical professionals and pregnancy care centers shouldn't be forced to speak a message completely at odds with their missions and ethics. The centers offer women free information and services and do so at no cost to the government. They empower women who are or think they may be pregnant to give birth in circumstances where they may want to but don't feel they have the necessary resources or social support. All SB 1564 accomplishes is to eliminate this choice for the women who need it most.

ADF filed a complaint with OCR over these problematic Illinois provisions.²³ ADF explained that its clients have been subjected to unlawful discrimination by the Illinois Department of Financial & Professional Regulation, a state agency

²¹ See generally National Institute of Family and Life Advocates v. Schneider, https://adflegal.org/case/national-institute-family-and-life-advocates-v-schneider (last updated Feb. 27, 2023).

²² ADF also filed a similar lawsuit in state court. *See generally The Pregnancy Care Center of Rockford v. Rauner*, https://adflegal.org/case/pregnancy-care-center-rockford-v-rauner (last updated Mar. 1, 2023).

²³ Letter to HHS (September 11, 2017), https://adfmedialegalfiles.blob.core.windows.net/files/HHScomplaintGingrich.pdf.

subject to the Church Amendments (42 U.S.C. § 300a-7), the Public Health Service (PHS) Act (§ 245 (42 U.S.C. § 238n)), and/or the Weldon Amendment (Continuing Appropriations Resolution, Pub. L. No. 113-164, Sec. 101(a) (Sept. 19, 2015)) by virtue of its status as a recipient of federal funding.

Cedar Park Assembly of God of Kirkland v. Kreidler. ²⁴ A Washington state law, SB 6219, forces churches to cover elective abortions in their health insurance plans. The law requires Cedar Park to provide coverage for abortion if the church also offers maternity care coverage to its employees or face fines and criminal penalties, including imprisonment. As a result of the state's mandate, Cedar Park Church's insurance carrier inserted abortion coverage, including surgical abortion coverage, directly into the church's health plan. The insurer indicated that it would remove the offensive coverage if a court were to hold the law cannot constitutionally be applied to churches.

ADF filed a federal lawsuit in March 2019 in the U.S. District Court for the Western District of Washington. But in May 2020, the district court dismissed Cedar Park's lawsuit against the state. Alliance Defending Freedom attorneys then represented Cedar Park at the Ninth Circuit Court of Appeals to challenge Washington's law. On July 22, 2021, the Ninth Circuit sided with Cedar Park and ruled that the church has sufficient cause to sue the State of Washington and that the church properly alleged a free-exercise injury due to the government's proabortion law.

Washington state has no legal authority to force places of worship to fund abortions and violate their constitutional rights, as well as their religious beliefs. No church should be forced to cover abortions, and certainly not a church like Cedar Park that dedicates its ministry to protecting and celebrating life. ADF thus filed a complaint with OCR citing the Weldon Amendment.

Abortion Insurance. The federal Weldon Amendment prohibits states that receive federal funding from compelling healthcare plans to fund abortion.

But the California Department of Managed Health Care (DMHC) is requiring the church's health insurance policy to provide coverage for elective abortions. In August 2014, the DMHC sent letters to all insurance providers in California mandating that the insurance policies they provide cover elective abortions. In those letters, DMHC rescinded existing religious accommodations and mandated

 $^{^{24}}$ See generally Cedar Park Assembly of God of Kirkland v. Kreidler, https://adflegal.org/case/cedar-park-assembly-god-kirkland-v-kreidler (last updated Feb. 20, 2023).

immediate coverage of all legal abortions, regardless of existing plan language. DMHC went about this quietly without passing a new regulation or allowing for public input.

ADF filed complaints with OCR against California's DMHC regarding its abortion insurance mandate and its violation of federal conscience law. ²⁵ When the previous administration failed to address the concerns raised in those complaints, ADF filed lawsuits on behalf of California churches forced to fund elective abortions.

Initially, OCR issued its determination that the mandate violates federal law. ²⁶ OCR made the decision to disallow \$200 million in federal Medicaid funds going to California in an upcoming quarter due to the California Department of Managed Health Care's decision to illegally mandate that all healthcare plans cover elective abortions. But then, for intervening political reasons presenting an open-and-shut conflict of interest, OCR reversed course. ²⁷

ADF filed suit over this mandate in two cases.

• Skyline Wesleyan Church v. California Department of Managed Health Care. 28 Skyline Wesleyan Church in the San Diego area, is very strongly opposed to abortion. Skyline Church believes it has a religious obligation to care for its employees, and, because of that belief, it offers them a generous health insurance plan. Skyline also believes that all life is valuable and deserving of protection and that abortion is incompatible with that belief. The church only employs people who share its beliefs.

Skyline's health insurance policy was changed as a result of the mandate, and it is now unable to offer its employees a health insurance policy that is consistent with its views on protecting human life. In order to retain its

 $^{^{25}}$ Letter to OCR (Oct. 9, 2014), https://adfmedialegalfiles.blob.core.windows.net/files/CalifChurchesComplaint.pdf.

²⁶ ADF applauds HHS action to enforce federal conscience laws, hold CA agency accountable (Dec. 16, 2020), https://adflegal.org/press-release/adf-applauds-hhs-action-enforce-federal-conscience-laws-hold-ca-agency-accountable.

²⁷ See generally Roger Severino, The Biden-Becerra Budget: Equity Is In, Religious Freedom Is Out, National Review, (June 11, 2021), https://www.nationalreview.com/2021/06/the-biden-becerra-budget-equity-is-in-religious-freedom-is-out/; HHS, State of California Letter, https://www.hhs.gov/conscience-protections/ca-letter/index.html.

²⁸ See generally Skyline Wesleyan Church v. California Department of Managed Health Care, https://adflegal.org/case/skyline-wesleyan-church-v-california-department-managed-health-care (last updated Feb. 28, 2023).

right to not pay for abortions, Skyline Church had no choice but to sue.

ADF represents Skyline Church, which could be faced with the decision to pay for abortions or forego health insurance for its employees, subjecting it to crippling penalties and fines. ADF is seeking to protect Skyline Church and all churches from government mandates that violate their sincerely held religious beliefs, in particular when they are forced to pay for ending human life. On May 13, 2020, the U.S. Court of Appeals for the 9th Circuit ruled that the church properly challenged the state's abortion-coverage mandate and that a lower district court was wrong to dismiss the church's claims.

Foothill Church v. Watanabe. 29 The same legal issues are also present in Foothill Church v. Watanabe, another ADF lawsuit challenging the California Department of Managed Health Care's mandate that forces churches to pay for elective abortions in their health plans. As revealed in e-mails that Alliance Defending Freedom attorneys who represent the churches discovered, the agency issued its mandate in response to specific demands from Planned Parenthood. Those demands asked agency officials to implement a "fix" requiring the health plans of religious organizations to include coverage for abortion, regardless of moral or conscientious objections and despite state recognition up to that point that religious groups shouldn't be subject to such requirements. The abortion giant threatened to promote its own legislative "solution" if the administrative agency didn't act, so DMHC issued its mandate in 2014. A federal district court ruled that this California mandate that forces churches to pay for elective abortions in their health insurance plans is unconstitutional.³⁰ Final judgment has now issued for the church.

Contraceptive/abortifacient mandate. The contraceptive mandate instituted through HHS by President Obama's administration also infringed on Americans' conscience rights, in violation of the Weldon Amendment and Church Amendments, among other laws. The administration's mandate forced employers, regardless of their religious or moral convictions, to facilitate access to abortifacient drugs, sterilization, and contraception under threat of heavy penalties. ADF, along

²⁹ See generally Foothill Church v. Watanabe, https://adflegal.org/case/foothill-church-v-rouillard (last updated Feb. 16, 2023).

³⁰ ADF, Court: CA mandate that forced churches to cover abortions is unconstitutional, https://adfmedia.org/case/foothill-church-v-watanabe,

with its allied attorneys, has represented many individuals and organizations to challenge this illegal provision.

- Conestoga Wood Specialties v. Burwell.³¹ The Hahns are a practicing Mennonite Christian family who have sought to run their company, Conestoga Wood Specialties, which manufactures custom wood products, in a manner that reflects their sincerely held religious beliefs, including their belief in the sanctity of human life. Their ability to do so was challenged when HHS issued a mandate requiring businesses to pay for insurance coverage for abortion-inducing drugs and devices. Businesses that refused would face crippling fines. Conestoga Woods Specialties and the Hahn family filed a lawsuit challenging the abortion pill mandate. The U.S. Supreme Court issued a landmark ruling under the Religious Freedom Restoration Act (RFRA) and said that families do not have to surrender their religious freedom to be in business. (The case was litigated in parallel with Hobby Lobby Stores v. Burwell, which had similar facts.)
- Newland v. Burwell.³² The Newland family, which owns and operates private HVAC manufacturer Hercules Industries, filed a federal lawsuit against HHS over its mandate that forces the family-owned business to violate its religious beliefs by requiring it to offer insurance coverage for abortion-inducing drugs, sterilization, and contraception. The family business was the first in the nation to obtain a preliminary court order against the Obama administration's mandate. A federal district court later issued a permanent injunction in favor of Hercules Industries and its owners.
- **Dobson v. Azar.** ³³ Dr. James Dobson and his religious radio show filed suit in federal court in Colorado. In 2014, the court issued a preliminary injunction against the enforcement of the mandate against Dr. Dobson, and a permanent injunction followed in 2019.

³¹ See generally Conestoga Wood Specialties v. Burwell, https://adflegal.org/case/conestoga-wood-specialties-v-burwell (last updated Feb. 20, 2023).

³² See generally Newland v. Burwell, https://adflegal.org/case/newland-v-burwell (last updated Feb. 27, 2023.

³³ See generally Dobson v. Azar, https://adflegal.org/case/dobson-v-azar (last updated Feb. 15, 2023).

- Association of Christian Schools International v. Azar. ³⁴ Six Christian nonprofit organizations filed suit in federal court in Colorado, and in 2018, the court issued an order to permanently prevent the enforcement of the abortion-pill mandate against the six organizations.
- March for Life v. Azar.³⁵ The pro-life organization March for Life exists to protect human life at every stage, and to cover the destruction of human life through abortifacients would contradict that core value. The organization filed suit in the federal district court in the District of Columbia in 2014, and the court entered a permanent injunction in favor of the organization in 2018.

American College of Pediatricians v. Becerra.³⁶ The American College of Pediatricians (ACPeds) and the Catholic Medical Association (CMA) filed suit in federal court to challenge a Biden administration mandate requiring doctors to perform gender transition procedures on any patient, including a child, if the procedure violates a doctor's medical judgment or religious beliefs. Under this mandate, HHS requires doctors to perform, refer for, and affirm many life-altering medical procedures, such as mastectomies, testosterone suppression, and hormone administration, to remove or impair the healthy organs of persons who identify as the opposite sex.³⁷

HHS made no provision for a doctor's medical judgment, religious beliefs, or conscientious objection. HHS's new mandate thus violates a multitude of statutory and constitutional protections.

Because gender treatments often result in sterilizations, the Section 1557 gender identity mandate violates 42 U.S.C. § 300a-7(d) because it compels ACPeds and CMA members, within health service programs funded by HHS, to provide gender identity procedures, interventions, and

³⁴ See generally Association of Christian Schools International v. Azar, https://adflegal.org/case/association-christian-schools-international-v-azar (last updated Feb. 6, 2023).

 $^{^{35}}$ See generally March for Life v. Azar, https://adflegal.org/case/march-life-v-azar (last updated Feb. 24, 2023).

³⁶ See generally American College of Pediatricians v. Becerra, https://adflegal.org/case/american-college-pediatricians-v-becerra (last updated Feb. 20, 2023).

³⁷ Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375 (May 18, 2016) (codified at 45 C.F.R. pt. 92); Notice of Interpretation and Enforcement of Section 1557, 86 Fed. Reg. 27,984, 27,985 (May 25, 2021); see also Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47,824 (Aug. 4, 2022) (proposed rule reinstating 2016 provisions).

information, including sterilizations, in violation of their religious beliefs and moral convictions.

- The Section 1557 gender identity mandate contradicts the ACA's provision that "[n]othing in this Act shall be construed to have any effect on Federal laws regarding (i) conscience protection." 42 U.S.C. § 18023(c)(2); see Executive Order 13535, Enforcement and Implementation of Abortion Restrictions in [ACA], 75 Fed. Reg. 15599 (Mar. 29, 2010).
- The Section 1557 gender identity mandate also contradicts Section 1554 of the ACA, 42 U.S.C. § 18114; specifically: parts (1)–(2) and (6) because it pressures ACPeds and CMA members out of federally funded health programs and the practice of healthcare; parts (3)–(4) because it requires ACPeds and CMA members to speak in affirmance of gender identity and refrain from speaking in accordance with a patient's biological sex and related medical needs; part (5) because it requires ACPeds and CMA members to deprive patients of informed consent by preventing them from warning patients of the dangers of gender transition interventions; and also part (5) because it forces ACPeds and CMA members to violate their ethical and conscientious standards as health-care professionals.
- The Section 1557 gender identity mandate is also contrary to RFRA, because it substantially burdens the exercise of religion by CMA's members, and the religious members of ACPeds, and is not the least restrictive means of advancing a compelling government interest.
- It also violates constitutional protections for free speech, association, and assembly, free exercise of religion, structural protections of federalism, the Spending Clause, the clear notice canon, and the Tenth Amendment.

But HHS successfully persuaded a district court that it lacks the power to review this healthcare mandate—leaving these doctors with no recourse.³⁸

Christian Employers Alliance v. Equal Employment Opportunity Commission.³⁹ The same Section 1557 mandate is also at issue in another ADF case raising profound religious freedom concerns and serious questions about the best interests of patients. The Christian Employers Alliance (CEA) is challenging this mandates that forces religious nonprofit and for-profit health-care providers to

³⁸ Am. Coll. of Pediatricians v. Becerra, No. 1:21-cv-195, 2022 WL 17084365, at *18 (E.D. Tenn. Nov. 18, 2022), appeal filed.

³⁹ See generally Christian Employers Alliance v. Equal Employment Opportunity Commission, https://adflegal.org/case/christian-employers-alliance-v-equal-employment-opportunity-commission (last updated Feb. 13, 2023).

perform gender transition surgeries, procedures, counseling, and treatments in violation of their religious beliefs.

A federal court has already entered a preliminary injunction for CEA against this mandate, enjoining HHS under RFRA from interfering with health-care providers' best medical judgment, conscientious objections, and religious freedom. "No government agency ought to be in the business of evaluating the sincerity of another's religious beliefs," the court wrote in its order. But HHS "encourages a parent to file a complaint if a medical provider refuses to gender transition their child, of any age, including an infant. The thought that a newborn child could be surgically altered to change gender is the result of the Biden HHS Notification and HHS Guidance that brands a medical professional's refusal to do so as discrimination. Indeed, the HHS Guidance specifically invites the public to file complaints for acting in a manner the Alliance says is consistent with their sincerely held religious beliefs." 40

HHS's gender identity mandate harms children and adults who struggle with gender dysphoria. It coerces doctors to perform dangerous and life-altering medical procedures, even if doing so violates their medical judgment, their conscience, or their religious beliefs. It inhibits full and frank conversations between doctors and patients, driving Christian health-care professionals and counselors out of the healing professions entirely. And it precludes parents, children, and patients from seeking the medical treatment in their best interest. That is why the court went on: Beyond the religious implications, the Biden HHS Notification and resulting HHS Guidance frustrate the proper care of gender dysphoria, where even among adults who experience the condition, a diagnosis occurs following the considered involvement of medical professionals." The court added: "By branding the consideration as 'discrimination,' the HHS prohibits the medical profession from evaluating what is best for the patient in what is certainly a complex mental health question." ⁴²

State of Texas and Mayo Pharmacy v. Becerra.⁴³ Under the same purported Section 1557 authority, HHS also told the nation's pharmacies—all 60,000 of them—that because they serve patients covered by a federally funded

⁴⁰ Christian Emps. All. v. EEOC, No. 1:21-CV-195, 2022 WL 1573689 (D.N.D. May 16, 2022).

⁴¹ Tingley v. Ferguson, 47 F.4th 1055, 1077 (9th Cir. 2022).

⁴² See generally Christian Employers Alliance v. Equal Employment Opportunity Commission, https://adfmedia.org/case/christian-employers-alliance-v-equal-employment-opportunity-commission.

⁴³ See generally State of Texas and Mayo Pharmacy v. Becerra, https://adfmedia.org/case/state-texas-and-mayo-pharmacy-v-becerra.

plan, they must stock and dispense first-trimester chemical abortion drugs. ⁴⁴ This new pharmacy mandate requires pharmacies that serve patients with Medicare, Medicaid, or other federally funded coverage to stock and dispense elective abortion drugs. HHS threatens legal action against any pharmacy or pharmacist that does not comply, even if doing so violates their religious beliefs, as is the case of Mayo Pharmacy, Inc. (Mayo Pharmacy), an independent pharmacy in Bismarck, North Dakota, run by Catholic pharmacist Kevin Martian, PharmD.

In an effort to defend the legally protected rights of religious pharmacists to work in a manner consistent with their beliefs, ADF attorneys added their client, a North Dakota pharmacy, to a lawsuit challenging the Biden administration's attempt to require pharmacies that receive federal funding to dispense abortion-inducing drugs. ADF attorneys joined with the state of Texas to file an amended complaint in *State of Texas and Mayo Pharmacy v. Becerra* on behalf of Mayo Pharmacy. As a devout Catholic, Martian has operated his pharmacy in accordance with Catholic ethical and moral principles, including the teaching that human life begins at conception. As such, Mayo Pharmacy does not dispense drugs for abortion purposes; however, if the administration's pharmacy mandate takes effect, the pharmacy will be forced to either stop serving customers who receive federal assistance or violate its religious beliefs.

In the amended complaint, ADF's and Texas' attorneys explain that the administration's pharmacy mandate directly conflicts with multiple federal statues as well as Texas' pro-life laws. No federal regulation states that Sections 1557 require pharmacies to stock and dispense first-trimester abortion drugs, nor could it. That is because the Affordable Care Act explicitly states that nothing in it negates federal laws regarding "refusal to provide abortion" or state laws prohibiting abortion. 42 U.S.C. 18023(c). The pharmacy mandate also conflicts with another provision of the ACA, which prohibits the Secretary from issuing any regulations that "violate[]... the ethical standards of health care professionals." 42 U.S.C. § 18114. The mandate also conflicts with yet another provision of the ACA, which provides:

No Preemption of State Laws Regarding Abortion

Nothing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or

⁴⁴ HHS, Off. for Civ. Rts., Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services (July 13, 2022), https://perma.cc/KTQ5-M7FP.

requirement of) coverage, funding, or procedural requirements on abortions.

42 U.S.C. § 18023(c)(1). And where Section 1557 only bans sex discrimination by incorporation of that ban under Title IX of the Education Amendments of 1972, the pharmacy mandate contradicts Congress' explicit statement in Title IX that it does not require any entity to provide any service related to an abortion. 20 U.S.C. 1688. Moreover, Title IX does not protect against "termination of pregnancy" discrimination. 20 U.S.C. § 1681.

The pharmacy mandate also conflicts with the Hyde Amendment, which prohibits federal dollars from being used to fund abortions except when the pregnancy is the result of rape or incest, or if the woman's life is in danger. Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, Div. H., Tit. V, §§ 506–07. By conditioning pharmacies' receipt of federal funds on their dispensing abortion-inducing drugs, the administration's pharmacy mandate uses federal dollars to fund abortions outside the allowable scope of the Hyde Amendment. Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, Div. H., Tit. V, §§ 506–07.

Finally, the pharmacy mandate also conflicts with RFRA. RFRA prohibits the government from substantially burdening a person's exercise of religion unless the government can demonstrate that application of the burden to that person is in furtherance of a compelling governmental interest and is the least restrictive means of achieving it. 42 U.S.C. § 2000bb-1. Mayo Pharmacy wishes to exercise its religion by operating without stocking and/or dispensing drugs for abortion purposes except to the extent consistent with its religious beliefs.

State of Texas, AAPLOG, and CMDA v. Becerra. ⁴⁵ HHS also has created violations of conscience and religious-freedom laws with another abortion mandate: it has sought to turn practically all hospitals into on-demand abortion clinics. HHS told all hospitals receiving Medicare funds that have emergency rooms, that regardless of state laws protecting the unborn they must perform abortions under

 $^{^{45}}$ See generally State of Texas v. Becerra, https://adflegal.org/case/state-texas-v-becerra (last updated Feb. 28, 2023).

HHS's novel interpretation of the 1986 Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. 1395dd.⁴⁶

ADF attorneys representing AAPLOG and CMDA in *State of Texas v. Becerra* went to court to halt the administration from employing EMTALA to force doctors to provide elective abortions in the emergency room while their lawsuit proceeds. They obtained an injunction that applies in Texas and to the members of AAPLOG and CMDA. But, across the country where the injunction does not apply, HHS threatens to create serious conflicts with doctors' protections for conscience and religious freedom.

This abortion mandate conflicts with federal law's ban on the federal government discriminating against hospitals and health-care providers that do not provide, assist, or refer patients for abortions. Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, Div. H., Tit. V, §§ 506–07; 42 U.S.C. § 238n; 42 U.S.C. § 300a-7. HHS should be in the business of following this law, not violating it—and not forcing hospitals and providers nationwide to violate it.

As the federal district court held when it preliminary enjoined the mandate in Texas, and for members of certain pro-life medical organizations represented by ADF, the mandate lacked statutory authority for many reasons. ⁴⁷ HHS went "well beyond EMTALA's text, which protects *both* mothers and unborn children, is silent as to abortion, and preempts state law only when the two directly conflict." ⁴⁸ The court went on: "AAPLOG and CMDA's members face a substantial threat of enforcement and severe penalties for their inevitable violation of the Guidance's requirements with regards to abortion." ⁴⁹

* * *

Unfortunately, in our experience, HHS's existing federal conscience protections have proven incapable of preventing these violations because they lack meaningful enforcement mechanisms, whether HHS or private parties are the

⁴⁶ Memorandum from Ctrs. for Medicare & Medicaid Servs. on Reinforcement of EMTALA Obligations Specific to Patients Who Are Pregnant or Are Experiencing Pregnancy Loss (July 11, 2022) (revised Aug. 25, 2022), https://perma.cc/ND68-86SK.

⁴⁷ See Texas v. Becerra, No. 5:22-CV-185-H, 2022 WL 3639525, at *19–26 (N.D. Tex. Aug. 23, 2022).

⁴⁸ *Id.* at *1.

⁴⁹ *Id.* at *29.

violators. Each of these stories shows the urgent need for HHS to enforce (and abide by) statutory conscience and religious freedom protections.

In the end, there is no substitute for good-faith enforcement by HHS of its statutory duties to protect conscience rights and religious freedom. This administration has not sought to implement these duties in good faith.⁵⁰ It is thus far past time for HHS to reverse course, follow the law, and begin to fully protect conscience and religious freedom rights.

III. The proposed rule makes important improvements over past conscience rules, but ultimately does not go far enough.

The proposed rule makes a welcome contribution to increasing HHS's enforcement efforts in the area of conscience and religious freedom, but the proposed rule should be strengthened to provide for fuller and more robust enforcement.

In two ways, the proposed rule makes significant improvements over past rules. These two improvements should be part of the final rule.

First, the 2008 Final Rule and the 2011 Final Rule only applied to three statutes (the Church Amendments, the Weldon Amendment, and the Coats-Snowe Amendment). But the proposed rule correctly goes further than the 2011 Final Rule by applying to a wider array of statutes that HHS is charged with enforcing. It is correct and important that the proposed rule provides for enforcement of all of these conscience and religious freedom protections. These provisions should be retained in the final rule.

Second, the proposed rule delegates authority to OCR to investigate violations. The proposed rule empowers OCR with 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

⁵⁰ Rachel Morrison, In Its First Year, Biden's HHS Relentlessly Attacked Christians And Unborn Babies (Mar. 18, 2022), https://thefederalist.com/2022/03/18/in-its-first-year-bidens-hhs-relentlessly-attacked-christians-and-unborn-babies (cataloguing examples). Of particular serious concern is OCR's decision in July 2021, in coordination with Department of Justice, to dismiss an enforcement lawsuit and withdraw 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. Likewise, of grave concern, is OCR's reconsideration of two notices of violation against California (and then-Attorney General Becerra) for forcing nuns and others to provide insurance coverage of abortion in violation of the Weldon Amendment.

regulations enforcement, such as those that apply to grants, contracts, or other programs and services." 88 Fed. Reg. 829. Empowering this enforcement is critical, especially given the lack of private rights of action in some provisions. The lack of expressly delegated enforcement power to HHS OCR is a reason that HHS historically had underenforced protections for conscience and religious freedom. It is long past time to ensure that HHS OCR has the proper delegated authority. These provisions should be retained in the final rule.

IV. The agency should consider additional alternatives to strengthen conscience and religious freedom protections.

In other ways, however, the proposed rule stands to be strengthened further when compared to prior rules. Along with maintaining the two positive parts of the proposed rule, HHS should also consider the following specific alternatives—which would strengthen the final rule.

First, the 2019 Final Rule provided for "vigorous enforcement" and detailed a "robust enforcement" scheme. Whether provided for in the proposed rule's regulatory text or through other plans, HHS should stake steps to provide for vigorous and robust enforcement, too. HHS's failure to provide vigorous and robust enforcement leaves health-care professionals in serious jeopardy.

Second, HHS should also consider retaining or restoring the 2019 Final Rule in whole or in individual parts, especially as to the proper import of Title VII. The 2019 Final Rule took significant steps to expand enforcement of federal conscience protections. But several district courts vacated the rule on various rationales, and the agency chose not to defend the rule on appeal. Those district court decisions were wrongly decided. And given that those decisions relied in part on court precedents about Title VII's undue-hardship exception, the agency should wait to issue any final rule until the Supreme Court issues its decision in Groff v. DeJoy later this year, as that case will address the Title VII question.

⁵¹ See Washington v. Azar, 426 F. Supp. 3d 704 (E.D. Wash. 2019), appeal pending, No. 20-35044 (9th Cir.); City & Cnty. of San Francisco v. Azar, 411 F. Supp. 3d 1001 (N.D. Cal. 2019), appeal pending, Nos. 20-15398 et al. (9th Cir.); New York v. HHS, 414 F. Supp. 3d 475 (S.D.N.Y. 2019), appeal pending, Nos. 19-4254 et al. (2d Cir.).

 $^{{\}small 52~See~generally~https://adfmedialegalfiles.blob.core.windows.net/files/HHS-ConscienceRightsRule-AmicusBrief-2ndCircuit.pdf.}$

⁵³ Groff v. DeJoy, 35 F.4th 162 (3d Cir. 2022), cert. granted, 143 S. Ct. 646 (2023).

Third, the 2011 Final Rule was titled "Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws," and throughout the proposed rule, the agency uses the term "Federal health care provider conscience protection statutes." *E.g.*, 88 Fed. Reg. at 823. However, the statutes do not simply apply to "health care providers." So the agency should remove "provider" from the phrase, wherever used.

Fourth, Secretary Becerra removed OCR's authority to enforce conscience and religious projections under RFRA and the First Amendment—at the request of OCR. ⁵⁴ But OCR should be tasked with enforcing civil rights protections in health and human services, not removing them. This action removed the only internal entity that would hold HHS accountable to following RFRA and the First Amendment. HHS should reverse course and restore OCR's ability to fully enforce RFRA and the First Amendment on all HHS entities and programs. In addition, given HHS's 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 HHS or its programs will comply with RFRA, but OCR must indicate how that is possible under this OCR rule when OCR's delegation has been withdrawn.

Fifth, the agency should consider providing definitions for material terms in the regulations. For example, the proposed section 88.2(d)(2) says OCR will prioritize "informal means" of resolution. 88 Fed. Reg. at 830. It is unclear what this provision means, and it is unclear how informal resolutions will deter future violations.

Relatedly, HHS should not prioritize informal resolution at the cost of achieving final resolution for the maximum number of complaints. Presumably, the proposed rule's "informal means" of resolution means that the agency will prioritize non-binding results. Not only does this regulation lack clarity, but it lacks the necessary enforcement teeth to make the conscience protections meaningful. The agency should prioritize formal resolution of OCR complaints instead.

When OCR permits resolution through informal means, OCR does not require any meaningful resolution. Formal resolution involves the withdrawal of funds or a lawsuit. Informal resolution, in contrast, results only in technical assistance (essentially, a suggestion). There is no guarantee of any resolution or change with informal means. As a result, OCR must pursue a binding resolution at all times and so the proposed rule should restore the formal means. What is more,

⁵⁴ HHS, Delegation of Authority, 86 Fed. Reg. 67067 (Nov. 24, 2021).

OCR should also specify all its remedies, such as termination of funds, and include requirements that OCR must listen to complainants and do something in response to each complaint.

Sixth, the voluntary notice provisions in the proposed rule should be strengthened. Notice provisions help provide widespread information about the rights of those who work in health-care facilities or are otherwise subject to HHS protections. This information is a helpful tool to ensure that Americans can know and timely assert their rights. The agency should consider making the notice requirement stronger or mandatory. In addition, the agency should modify the Model Text in the proposed Appendix A to Part 88. 88 Fed. Reg. at 830. The Model Text should identify specific rights that individuals have under the conscience protection statutes, rather than simply listing the names of the statutes. The best way to inform people of their rights is not simply by listing the names of laws, but by informing people of what their rights mean—in plain English.

Seventh, HHS should consider restoring the prior structure of OCR, including restoring the Conscience and Religious Freedom Division. Just days before this comment period closed, HHS announced without warning that it had eliminated its OCR division focused exclusively on protecting conscience and religious freedom. This remarkable action occurred even though HHS acknowledged that "OCR's caseload has multiplied in recent years, increasing to over 51,000 complaints in 2022—an increase of 69 percent between 2017 and 2022" with "7 percent alleged violations of conscience/religious freedom." With around 3570 complaints of conscience and religious freedom complaints filed annually—and growing—HHS should abide by its statutory duties and dedicate the enforcement resources necessary to process these complaints.

It is no consolation for HHS to simply have one "enforcement" division—particularly when HHS simultaneously maintained a separate substantive division for information privacy. Conscience and religious freedom laws require substantive expertise just as much as information privacy laws. Worse, in the same document, HHS expressly added sexual orientation and gender identity categories to OCR's mission, setting the stage for conflicts. This action impairs HHS's ability to recruit

⁵⁵ HHS, Notice, Statement of Organization, 88 Fed. Reg. 12,954 (March 1, 2023). This reorganization was approved by the Secretary of HHS on February 10, 2023, and it took effect on February 25, 2023.

⁵⁶ 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.

and hire career professionals with experience and substantive expertise on conscience laws and religious freedom. By dismantling the conscience and religious freedom division, and by instead setting up other divisions with the dedicated expertise necessary to enforce other rights, HHS suggests that HHS does not seriously intend to enforce conscience and religious freedom rights and that HHS instead intends to give them a second-class status.

Eighth, HHS should consider assigning career professionals from the former Conscience and Religious Freedom Division to review and process complaints on conscience and religious freedom issues in the first instance. This approach will help preserve institutional memory, apply the needed expertise, and ensure continuity of processing. In addition, HHS should prioritize educational outreach and ensure that the public is informed of these laws. What is more, HHS should explain how the restructuring will not affect the processing of comments on the proposed rule, the timely processing of complaints, and the promotion of educational outreach.

Ninth, the agency should consider the alternative of including the compliance requirements set forth in the 2019 Final Rule, including its definitions.⁵⁷ HHS should consider whether some or all of these approaches could be included, rather than viewing it through an all-or-nothing lens. For example, HHS should include mechanisms for referring complaints to the Department of Justice. HHS should also consider whether the judicial decisions on the past rule would have been likely to be reversed on appeal, if vigorously defended. HHS thus should also consider whether, if similar provisions were enacted in a new rule, they would in fact survive judicial review. If so, HHS could provide for a more robust enforcement approach similar to the prior rule.

Many terms benefit from clear definitions, and so removing these definitions will only case further uncertainty in the regulated healthcare sectors. Rather than remedying confusion, HHS is adding confusion by removing these definitions. HHS should explain how equity or clarity is promoted by singling out protections for religious minorities and removing clear language protecting minority practitioners, rather than by retaining clear and robust protections. For example, it is important to have a definition of the key term "discrimination." By removing or omitting a definition of a key term such as that, HHS is not promoting clarity or predictability for protected classes.

⁵⁷ HHS, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84 Fed. Reg. 23,170, 23,270 (May 21, 2019).

In sum, although the proposed rule significantly improves upon past rules, in many other ways the proposed rule does not go far enough. ADF thus urges the Department to enact the conscience protections in the proposed rule as a baseline, and then to go beyond this floor and enact further strengthened conscience protections in the final rule—so that HHS enforcement is mandatory.

V. The proposed rule mistakenly frames conscience rights as in conflict with health-care access.

On top of these shortcomings in the proposed rule's new operative provisions, HHS's analysis of the proposed rule in its preamble and commentary also suffers from a serious error: a basic misunderstanding of the mandatory and unequivocal nature of statutory conscience protections. The proposed rule often suggests that new rules are necessary to reflect the "balance" Congress allegedly struck in the conscience protection laws between competing interests—but such a balance is not mentioned in the text of the laws. For example, in the preamble, HHS states that statutory conscience protections reflect a "balance Congress struck between safeguarding conscience rights and protecting access to health care." 88 Fed. Reg. at 825.

But statutory conscience protections do not reflect a "balance Congress struck between safeguarding conscience rights and protecting access to health care." *Id.* In fact, the proposed rule does not identify any federal law or conscience law that supports making this point. HHS may not fail to fully enforce the law. The law provides that organizations and personnel may not be forced to perform procedures that violate their conscience. There is no provision for weak or partial enforcement, and certainly not in the name of "balancing" patient care and access with conscience rights.

To the contrary, conscience protections promote access to health-care services by allowing religious medical professionals and institutions to practice and operate, reaching additional populations and communities. Access to care will decrease—not increase—if federal regulations are not paired with enforcement of conscience and religious freedom protections.⁵⁸

Scientific polls of religious medical professionals show that religious doctors will leave the profession rather than violate their consciences, with disproportionate

⁵⁸ HHS has requested "Information, including specific examples where feasible, supporting or refuting allegations that the 2019 Final Rule hindered, or would hinder, access to information and health-care services, particularly sexual and reproductive health care and other preventive services." 88 Fed. Reg. at 826.

effects on poor and underserved communities. HHS has been on notice of these reliance interests from similar consistent polling presented to the agency in several comment periods.⁵⁹ 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." 60

As these comments warned, "That means that if faith-based professionals are forced out of medicine by a lack of the conscience protections that allow them to

⁵⁹ 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), https://www.regulations.gov/comment/HHS-OPHS-2009-0001-5125 and https://downloads.regulations.gov/HHS-OPHS-2009-0001-5125/attachment_1.doc (reporting the key findings of scientific polls of religious providers: "In overwhelming numbers, faith-based health-care professionals and students will quit medicine before compromising religious convictions": "Patient access—especially in medically underserved areas—will suffer if faith-based health-care 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.").

⁶⁰ 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), 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.").

practice according to ethical norms, the poor and medically underserved populations served by these professionals stand to suffer a devastating loss of healthcare access." ⁶¹ 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%) experience[ing] pressure, coercion or punishment for declining to 'refer a patient for a procedure to which you had medical or scientific objections." ⁶²

These concerns extended to abortions and other interventions required by the proposed rule. "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." 63 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. 64

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.*" ⁶⁵

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." ⁶⁶ This evidence is why in the 2021 Grants Rule HHS

⁶¹ *Id.* at 6.

⁶² 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), https://www.regulations.gov/comment/HHS-OCR-2019-0007-127215.

⁶³ *Id*. at 4.

⁶⁴ *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.")

⁶⁵ Id. at 4.

⁶⁶ 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), 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

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.⁶⁷

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. 68 The final rule also provided much other information about the need for enforcement that HHS must consider, including increased OCR complaints.

Given these earlier positions, HHS must not change its view without reasoned explanation.

There is no harm to any purported contrary governmental interest, especially with so many other providers available. ⁶⁹ 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. ⁷⁰

Moreover, while health-care access is important, to be clear, abortion is not health care. The proposed rule states, "Our health care systems must effectively deliver services—including safe legal abortions—to all who need them in order to

validate their choices.' Clearly the issue at hand is not one of refusing to care for certain individuals, but rather simply declining to participate in certain morally controversial procedures and prescriptions." Id.

 $^{^{67}}$ Health and Human Services Grants Regulation, 86 Fed. Reg. 2,257, 2,257, 2,259, 2,263, 2,269, 2,273 (Jan. 12, 2021).

^{68 84} Fed. Reg. at 23,175-76, 23,181-82.

⁶⁹ Jonathan Imbody, *supra* note 62, Att. 2 at 2 (In response to the question, "In your experience, how common is it that patients are ultimately 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?" 78% of respondents said it was not common: "18% Not Too Common" or "60% Not At All Common").

⁷⁰ See, e.g., Lisa Cooper, Op-ed, Faith-based groups have a role to play in ending health care disparities, Baltimore (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.").

protect patients' health and dignity." But pregnancy is not an illness, and healthcare is not abortion. Abortion always takes an innocent life, and abortion often risks the health, safety, and welfare of women as well. These concerns are particularly important considering changing medical technology, including the new proliferation of unlawful chemical abortion drugs.

The proposed rule points to comments from professional medical organizations opposing the 2019 Final Rule. The comments raised concerns about access to medical care and professional obligations to treat patients. These comments highlight the need to bolster regulations to protect conscience rights. As we have discussed, professional medical associations have questioned the role of conscience in the provision of medical care. This means that without enforcement of the federal conscience healthcare provisions, hospitals may follow the conscience-undermining guidance of the professional medical organizations. In other words, many professional medical organizations have reached the exact opposite conclusion that Congress set forth in the covered conscience statutes.

HHS's regulatory impact analysis should seriously engage these issues, rather than focus only on compliance costs for regulated entities. The 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. First, 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. Second, 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

⁷¹ See Alliance Defending Freedom, Comment Letter on Proposed Rule on Protecting Statutory Conscience Rights in Health Care (Mar. 26, 2018), https://adfmedialegalfiles.blob.core.windows.net/files/ADFcommentHHSConscienceRule2018.pdf. This comment collects additional examples of the harms of HHS's lack of enforcement of conscience and religious freedom laws. Rather than repeat this information, ADF incorporates this prior comment by reference.

⁷² HHS also needs to assess and certify the impact on small businesses and all non-profits under the Regulatory Flexibility Act, using the above analysis on costs and explaining its reasoning. Notably, non-profit organizations count as small entities for this purpose, since most do not dominate their field, and this would include many religiously affiliated hospitals and health-care facilities, where the entities themselves and their employees are protected by many laws encompassed by this rule. Likewise, the agency must estimate the impact on small health-care practitioners based on the likelihood that religious and other conscientious health-care practitioners that would be protected by this rule are in small practices.

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.

In addition, the agency should assess the baseline properly, in a way that it takes seriously its enforcement duties. 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: HHS should consider the past, present, and future costs of the failure to enforce or to fully enforce conscience laws. 73 Because the current regulation protects conscience, religious freedom, diversity, and pro-life nondiscrimination, HHS should calculate the cost of losing those benefits if the current regulation is fully rescinded. HHS 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. HHS 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 final 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 health care as a whole, and the detrimental public health
consequences resulting from the inability of conscientious providers to
participate in healthcare practice on equal terms.

⁷³ As evidenced by OCR's receipt of many more conscience complaints between 2017 and 2020 when it announced it was open for business to enforce these laws, 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. As a result, 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.

- 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 nonenforcement.
- 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. The rule will contribute to a shortage in labor because many employees will quit or accept termination rather than participate in objectionable practices. These labor shortages will create economic and health costs for consumers. 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.

The analyses should also occur in light of OCR's record-high receipt of complaints between 2017 and 2020 identifying violations of conscience laws in comparison to the much smaller number of complaints filed before OCR announced in 2017 that it was "open for business" in enforcing these laws.⁷⁴

⁷⁴ 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 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 about vaccines, the other complaints

In particular, HHS should consider the rising number of conscience and religious freedom complaints, and it should devote the resources necessary to fully enforcing conscience and religious freedom laws. HHS is receiving a large and growing number of complaints about conscience and religious freedom violations. As HHS just announced, "OCR's caseload has multiplied in recent years, increasing to over 51,000 complaints in 2022—an increase of 69 percent between 2017 and 2022—with 27 percent alleged violations of civil rights, 7 percent alleged violations of conscience/religious freedom, and 66 percent alleged violations of health information privacy and security laws." This amounts to an estimated 3570 complaints of conscience and religious freedom violations annually—a number that HHS admits is growing.

These conscience and religious freedom complaints deserve serious responses, and HHS should allocate significant resources to the enforcement process. HHS should not give conscience and religious freedom rights second-class status among other civil rights.

Thank you for your attention to these important matters.

Respectfully Submitted,

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received about conscience and religious freedom laws from 2017 to 2020 far outpaced the number of similar complaints received between 2009 to 2016 during an administration that, like this one plans to do, rescinded a regulation enforcing conscience and religious freedom laws.

⁷⁵ 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.