ALLIANCE DEFENDING FREEDOM
FOR FAITH. FOR JUSTICE.

October 3, 2022

Secretary Xavier Becerra
U.S. Department of Health and Human Services
VIA REGULATIONS.GOV

RE: Nondiscrimination in Health Programs and Activities
RIN Number 0945-AA17
Docket ID HHS-OS-2022-0012

Dear Secretary Becerra,

Through this proposed rule, Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47,824 (Aug. 4, 2022), the Biden administration seeks to impose unlawful and unsound healthcare mandates. The proposed rule disregards the sanctity of human life; harms children and adults who struggle with their sex; and threatens to force doctors to act against their medical judgment, religious beliefs, and conscience.

Alliance Defending Freedom (ADF) submits these comments to the Department of Health and Human Services (HHS) on the Notice of Proposed Rulemaking on Nondiscrimination in Health Programs and Activities, Docket ID HHS-OS-2022-0012. 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. Since its launch in 1994, ADF has handled many legal matters involving Section 1557 of the Affordable Care Act; Title IX; 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 strongly opposes any effort to redefine sex in federal regulations inconsistent with the text of Section 1557 or Title IX itself, or otherwise to impair the rights to life, free speech, religious exercise, and freedom of conscience. ADF thus urges the Department to withdraw and abandon the proposed rule.

COMMENTS

I. The proposed abortion mandate unlawfully disregards the sanctity of unborn human life.

All persons, including children in the womb, deserve respect for their human dignity. Babies deserve a chance to be born. Women deserve better options than taking their child's life and better care than suffering from the devastating physical, psychological, and emotional consequences of abortion.

Abortion on demand has led to millions of lives lost or ruined. Since 1973, when *Roe v. Wade* was decided, over 63 million babies have been denied the right to life. This injustice leaves a devastating mark upon our culture, including an entire industry profiting from each child killed in the womb.

In 2022, the overturning of *Roe v. Wade* by the Supreme Court in *Dobbs v. Jackson Women's Health*[1] returned the decision of how to regulate abortion to the people's elected representatives. Unborn babies now may be—and should be—universally recognized as human beings worthy of legal protection.

The federal government now has an important opportunity to protect women and children. It thus should promote life-affirming laws and build a culture that recognizes that life is a human right and that women and their unborn children must be supported across the country.

Instead, the proposed rule threatens to impose abortion mandates across healthcare. The proposed rule proposes to prohibit discrimination on the basis of "termination of pregnancy" by reference to the Department's Title IX rule, but the proposed rule fails to incorporate the explicit statutory prohibition on using Title IX to require any person to provide or pay for any service related to abortion.[2] The resulting mandate prohibiting any discrimination on the basis of abortion is thus staggering in its express scope and its potential implications.

The proposed rule's abortion mandate thus poses several issues of concern that the Department must address.

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[1] *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022).

[2] 87 Fed. Reg. at 47,878–79.

A. The proposed abortion mandate lacks authority.

Rather than narrowly tailoring its regulations to its actual legal authority, the Department proposes to promote abortion beyond the bounds of its legal authority. The Department lacks any authority to impose abortion mandates under Title IX, Section 1557, and myriad other federal laws. But the Department refuses to codify any of these restrictions in the proposed rule. If the proposed rule were drafted in a way that acknowledged statutory limits on its reach and disclaimed any intent to step beyond the very narrowly defined circumstances in which the Department has a role in abortion policy, the proposed rule might be limited, narrow, and (possibly) lawful. But the proposed rule lacks any such limits, in line with recent Department policy seeking to promote abortion by any means possible. Its exceedingly vague language is thus no accident.

As written, the proposed abortion mandate lacks any authority for three key reasons: (i) it improperly fails to incorporate and abide by Title IX's abortion neutrality provision and Title IX's religious exemption, which violates the statute and expands the rule's requirements; (ii) it adds a "termination of pregnancy" ground that expands the statutory text yet again; and (iii) the resulting abortion mandate is fatally unclear—its language is so vague and ambiguous that an official would be empowered to read the proposed rule as a virtually limitless source of authority for abortion mandates.

1. The proposed rule improperly fails to incorporate and abide by Title IX's abortion neutrality provision and Title IX's religious exemption.

First, the proposed abortion mandate is unlawful because it fails to incorporate and abide by Title IX's abortion neutrality provision and Title IX's religious exemption.

Section 1557 of the Affordable Care Act incorporates the provisions of Title IX. Section 1557 prohibits discrimination "on the ground prohibited under . . . [T]itle IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) . . . ." 42 U.S.C. § 18116(a). As the court in *Franciscan Alliance v. Burwell* correctly held, "Congress specifically included in the text of Section 1557 '20 U.S.C. 1681 et seq.' That Congress included the signal 'et seq.,' which means 'and the following,' after the

citation to Title IX can only mean Congress intended to incorporate the entire statutory structure, including the abortion and religious exemptions."[3]

Interpreted properly, Section 1557 thus includes Title IX's abortion neutrality clause, 20 U.S.C. § 1688: "Nothing in this chapter shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion." Title IX also "categorically exempts any application that would require a covered entity to provide abortion or abortion-related services."[4]

Section 1557 also includes Title IX's religious exemption, which states that Title IX does not apply to covered entities controlled by a religious organization if its application would be inconsistent with the religious tenets of such organization. 20 U.S.C. § 1681(a)(3).[5] Under this exemption, "a religious organization refusing to act inconsistent with its religious tenets on the basis of sex does not discriminate on the ground prohibited by Title IX."[6]

The proposed regulation, however, ignores Title IX's abortion neutrality clause and its religious exemption, and instead purports to create an abortion mandate with no exemptions. The proposed Section 1557 rule is thus unlawful on its face. Just as in the prior Section 1557 rule adopted in 2016 by the Obama Administration, "By not including these exemptions, HHS expanded the 'ground prohibited under' Title IX that Section 1557 explicitly incorporated."[7]

2. The proposed rule unlawfully includes "termination of pregnancy" as a prohibited ground of discrimination.

Second, the proposed rule is unlawful because it adds a "termination of pregnancy" ground that expands the statutory text and redefines sex discrimination to include abortion.

The Department seeks to create an abortion mandate by prohibiting discrimination on any of the "grounds" prohibited under Title IX. The "grounds" listed in the text of Title IX, however, include no mention of abortion. The

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[3] *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 690 (N.D. Tex. 2016). This case was affirmed on appeal. *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 376 (5th Cir. 2022).

[4] 20 U.S.C. § 1688; *Franciscan All.*, 227 F. Supp. 3d at 690.

[5] *Franciscan All.*, 227 F. Supp. 3d at 689–90.

[6] *Id.* at 690.

[7] *Franciscan All.*, 227 F. Supp. 3d at 691.

Department seeks to escape that fact by incorporating a new "ground" prohibited under its Title IX regulations–discrimination on the basis of pregnancy-related conditions, including childbirth, false pregnancy, termination of pregnancy, and recovery therefrom.[8] A new and textually nonexistent abortion mandate therefore arises from a textually nonexistent ground for nondiscrimination based on "termination of pregnancy." This abortion mandate is thus unlawful because it has no textual authority. And, of course, it is doubly unlawful because this abortion mandate in the Section 1557 rule or in the Title IX rule conflicts with Title IX's abortion neutrality clause, and the lack of exemptions conflicts with Title IX's required religious exemption.

Termination of pregnancy is not and should not be a prohibited discrimination category under Title IX and its derivatives. Rather, terms like "pregnancy related conditions" should include miscarriage, not intentional abortions. Any use of the term "termination of pregnancy" should be expressly defined not to include elective abortions or any abortions prohibited by federal or state law. Any broader language threatens to require the provision of abortion throughout healthcare.

Whether Title IX addresses this ground is moreover a major question not clearly addressed in the statute and thus is not included in the law. If termination of pregnancy, i.e., abortion, is given equal status to pregnancy and childbearing, it necessarily requires acceptance of abortion as morally equivalent to pregnancy and childbirth. This would have negative ramifications for pro-life states, healthcare providers, and patients across the country, in conduct and speech. Congress never addressed this issue, let alone buried it in Title IX only to have it lie dormant for 50 years, and so this issue is thus reserved for Congress and the people's representatives to decide.

It is no defense to claim, as the proposed rule does,[9] that past regulations under Section 1557 may have also incorporated the same provisions involving "termination of pregnancy" or may have also omitted Title IX's abortion neutrality clause and religious exemptions. "Failure to incorporate Title IX's religious and abortion exemptions nullifies Congress's specific direction to prohibit only the ground proscribed by Title IX. That is not permitted."[10] And because the proposed rule revisits these matters, readopts this flawed reading of Section 1557, and seeks

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[8] 87 Fed. Reg. at 47,878–79.

[9] 87 Fed. Reg. at 47,878–79.

[10] *Franciscan All.*, 227 F. Supp. 3d at 690–91.

comment on the resulting mandates, the Department has reopened the propriety of reading Section 1557 in this way. That reading is unlawful, and so the Department must abandon this view of Section 1557.

3. The proposed rule's abortion mandate is fatally unclear—a virtually limitless source of authority for mandating abortion.

Third, the resulting abortion mandate is fatally unclear—its language is so vague and ambiguous that an official would be empowered to read the proposed rule as a virtually limitless source of authority for abortion mandates.

Simply put, discrimination based on "termination of pregnancy" is not adequately defined in HHS regulations. It is clear that the Department will read it to require abortion in some way. But the proposed rule does not explain all the many ways that this mandate could require changes in the regulated community. ADF is thus concerned that the federal government will, as HHS has indicated, give this vague provision an expansive understanding, with many far-reaching effects not addressed in the proposed rule or considered in their costs and benefits. And given the Department's maximalist position on abortion, its vagueness is likely to be an opportunity for department staff to impose broad abortion mandates on healthcare providers and insurers across the country.

This vagueness is fatal to the proposed rule. It gives no notice, let alone the clear notice required by Title IX or Section 1557, of what kinds of discrimination are prohibited. And, under constitutional principles of due process, a fatally vague law is no law at all.

The Department thus should consider disavowing "termination of pregnancy" discrimination from the scope of this rulemaking and should repeal it from the Department's Title IX rule. This approach would track the statute. At minimum, the Department's rule should codify the fact that 20 U.S.C. § 1688 restricts any application of this rule.[11] The vague definition in the proposed rule, however, leaves far too much discretion in the hands of officials.

Additionally, to address the vagueness of the proposed abortion mandate, the Department should provide examples of how this rule could require access to abortion. It should then put its reasoning and these situations up for a

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[11] The Department lacks any grounds to fear that a healthcare provider would refuse routine healthcare to a woman because she previously had an abortion. *Franciscan All., Inc. v. Burwell*, No. 7:16-CV-00108-O, 2017 WL 2964088, at *5 (N.D. Tex. Jan. 24, 2017).

supplemental comment period. Any failure to do so renders the proposed rule vague and procedurally improper.

Specifically, to properly engage in reasoned decision making on this vague new abortion mandate, the Department must explain the types of circumstances that constitute termination of pregnancy in its view, and examine and quantify the impact on pro-life healthcare providers, pro-life speech, pro-life medical organizations, and others who promote, adopt, and administer pro-life policies. Will the proposed rule require insurance coverage of abortions, including by private employer-sponsored plans? Will it require healthcare providers to offer, refer for, perform, or assist with abortions? Will all or just some doctors be forced to provide abortions, and will that depend on their geographic location or place of practice? Will all or just some insurers and employer health plans be forced to cover abortion? If not all, why not? Will the proposed rule restrict patient choices by preventing them from receiving any healthcare in a pro-life setting? How will this proposed rule affect medical schools and teaching hospitals? Would the proposed rule restrict pro-life education or instruction on abortion? Must medical schools prohibit pro-life activities? Is it discrimination to object to abortions or to notify parents about their minor child receiving abortion as a termination of pregnancy? What is the effect of laws allowing minors to make medical decisions? Would pro-life activities be considered harassment based on termination of pregnancy? How will the Department ensure that there is no chilling effect of this rule on free speech between doctors and patients? What are the costs of requiring that entities subject to Section 1557 provide abortions?

The Department needs to take a position on each of these questions and quantify those costs at a granular level, something the proposed rule fails to consider or attempt.[12] If the Department declines to take a position, it must quantify costs hypothetically for each particular possible application of the proposed rule. If the Department fails to do so, its abortion mandate will be fatally vague and procedurally improper.

B. The proposed rule conflicts with other federal and state provisions of law.

Not only does the proposed rule's abortion mandate lack any authority under Section 1557 or Title IX: it also conflicts with many other federal and state laws.

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[12] These costs of the new proposed rule are addressed in detail in the comments by ADF to the Department in its pre-publication meeting about this proposed rule (comments that are attached and reincorporated herein).

HHS does not have the power to ignore or displace these other laws. As a result, the abortion mandate is unlawful under each of these other provisions as well.

First and foremost, the abortion mandate will create conflicts with State pro-life laws. Under the Department's redefinition of "sex" to mean "termination of pregnancy" in Section 1557 and Title IX, the likelihood of conflict with pro-life laws is high. As shown in ADF's Title IX comments submitted to the Department of Education, and attached and incorporated to this comment, the federal government purports to place all healthcare providers in pro-life states in the crosshairs of its new rule.[13]

But the Department does not have any Spending Clause power to preempt state pro-life laws. By admission, all the Department can do to enforce this rule is decline to provide federal funds if conditions are not met. Conditions attached to federal financial assistance cannot preempt incompatible state laws—instead, federal funds could be disallowed from entities unable to comply. What is more, attempting to coerce States to abandon their pro-life laws as a condition of federal healthcare funding is itself impermissible coercive and unconstitutional.

Second, as discussed below in connection with the proposed rule's other new mandates on healthcare providers, the proposed new abortion mandate conflicts with many statutory and constitutional protections for sound medicine, conscience, free speech, and religious exercise, such as state laws protecting minors from sterilizing and irreversible interventions. If an enforcement official deems failure to provide access to abortion as discriminatory, then healthcare providers nationwide could have to provide abortions, despite state law protections for the unborn and for conscience rights.

Because the Department lacks any authority to ignore or preempt these laws, it must instead consider that its proposed rule conflicts with these laws, which would impermissibly exclude wide swathes of the country from participation in federal programs.

ADF is thus concerned that the federal government will, as HHS has indicated, threaten pro-life speech and intrude into doctor-patient relationships, with many far-reaching effects not addressed in the proposed rule or considered in their costs and benefits. To remedy these problems, the Department must explain

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[13] *See* ADF, *ADF to Biden: Hands off Title IX: ADF submits formal comments to U.S. Dept. of Education opposing proposed changes, defending women, parental rights, free speech*, https://adflegal.org/press-release/adf-biden-hands-title-ix.

whether its rule requires doctors to speak favorably about or in favor of abortions to patients. The Department must discuss whether it will make it illegal for healthcare providers to take the position in their patient-speech that abortions are harmful and that they will not promote them. The Department must explain if it will characterize anti-abortion speech by healthcare providers as "misinformation," or as speech that creates a "hostile environment" giving rise to "termination of pregnancy discrimination." The Department must explain such mandates could comply with *NIFLA v. Becerra* which held unconstitutional a California law that forced pro-life healthcare providers to speak about the availability of abortion.[14] And the Department must quantify and justify all of these effects on pro-life speech.

Third and finally, the ACA expressly prevents Section 1557 from being used to preempt state pro-life laws. Section 1303 of the ACA declares "Nothing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor."[15] It also states, "Nothing in this Act shall be construed to have any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion."[16] It therefore violates the ACA for this proposed rule to impose a termination of pregnancy discrimination prohibition that in any way purports to preempt state pro-life laws or federal conscience laws.

C. The Department should state its legal rationale for its abortion mandate and allow supplemental comment on this reasoning.

The Department has also not discussed many other important legal considerations, considerations which require the Department to abandon its proposed rule.

Perhaps the greatest omission from the Department's analysis concerning its proposed abortion mandate is any discussion of the new legal landscape on abortion. In its landmark *Dobbs* decision, the Supreme Court overruled *Roe v. Wade* and *Planned Parenthood of Southeastern Pennsylvania v. Casey*.[17] The Supreme Court

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[14] 138 S. Ct. 2361 (2018).

[15] 42 U.S.C. § 18023(c)(1).

[16] *Id.* at § 18023(c)(2).

[17] *Dobbs*, 142 S. Ct. 2228.

expressly returned the right to prohibit elective abortion to the people and their elected representatives. Since the decision was released on June 24, 2022, several states have passed or invigorated laws offering partial or nearly total protection to unborn children. Many of those laws currently are in effect. As discussed above, the Department must address this rule's allegedly preemptive effect upon pro-life state laws. The Department must explain how purportedly preemptive regulations will be applied in light of this new legal context—explanations that are intentionally lacking in the proposed rule. In particular, many protections such as the Church Amendments also depend on the definition of a "lawful abortion," making it critical for the government to explain what it learned from the ruling in *Dobbs* before analyzing or defining the scope of any exemptions.

The Department seeks comment on the intervening U.S. Supreme Court decision in *Dobbs*, but has the Department itself considered the effect of this decision? It is not enough for the Department to seek comment. The Department must analyze this decision itself, and then subject its analysis to public comment.

The Department must also consider the major questions doctrine from *West Virginia v. Environmental Protection Agency*.[18] Although the Department does not engage this decision, it is relevant to the proposed rule because it highlights the Department's lack of authority. Transforming the Section 1557 rule into an abortion mandate is a matter of vast political and economic significance that Congress did not clearly authorize HHS to impose. Indeed, Congress prohibited HHS from imposing an abortion mandate in multiple statutes, including Title IX's abortion neutrality clause, Section 1303 of the ACA, and healthcare conscience laws such as the Church, Coats-Snowe, and Weldon Amendments.

Dobbs teaches that abortion is a matter to be addressed by the legislative branches of government. And the major questions doctrine says that Congress cannot bury an unspoken abortion mandate in Title IX or the ACA, to be pulled out by officials years later just because *Roe v. Wade* was overruled. This is particularly true under Title IX's abortion neutrality clause. Under the major questions doctrine—as well as the clear-notice federalism canon—Congress must speak clearly as to these important matters, and since it has not, this rule cannot require any participation in abortion.

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[18] 142 S. Ct. 2587 (2022).

Simply put, *Dobbs* and *West Virginia* show that the Congress and state legislatures are empowered to address these issues, and that the Department lacks any legal authority for its unilateral abortion mandate.

The Department must consider these Supreme Court decisions, provide its rationales about these decisions, and then allow comment on these decisions in its notice before finalizing any rule. The Department must do this not only in the final rule but at the proposed rule stage. But the Department has omitted this crucial process, instead short-circuiting the issue by declining to subject its reasoning and rationales about these cases to public comment. The Department has not considered these questions in a way that gives a rationale subject to public comment. The Department has thus deprived the public of an opportunity to comment on its rationale in light of *Dobbs* and *West Virginia*. This is fatal to the validity of the final rule and requires that the Department articulate its rationales and republish the proposed rule to give the public an opportunity to comment on those rationales.

D. The proposed rule disregards the harms to children and mothers from promoting abortion.

Creating any abortion mandate will, of course, deeply victimize and target mothers by harming their unborn child and by subjecting them to dangerous procedures. A truly pro-woman and pro-healthcare rule would respect and care for both the mother and the child.

The proposed rule however impermissibly glosses over the serious harms of abortion, including its dangers to unborn children and to women. Abortion kills babies in the womb, and it can lead to injury or death for the mother.[19] Abortion puts a woman's body at risk. And legalizing or mandating abortion does not protect women. In particular, abortion can lead to premature birth in later pregnancies. According to a report by the Charlotte Lozier Institute, "a growing body of worldwide evidence suggests that the association between preterm birth and history of induced abortion is indeed credible."[20] What is more, abortion can result in the

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[19] The Department must quantify and consider the value of the many lives lost to abortion. Information on the methods and data to quantify this cost are available. One example is attached. *See* Joint Economic Committee, The Economic Cost of Abortion, June 15, 2022, https://www.jec.senate.gov/public/index.cfm/republicans/2022/6/the-economic-cost-of-abortion.

[20] https://s27589.pcdn.co/wp-content/uploads/2012/12/On-Point-Johnson-and-Calvin.pdf

mother's death. ADF's booklet, Investigate Their Plan, tells the stories of women who died from abortion complications.[21]

The Department must consider that the abortion industry drives down the standards for women's healthcare. The proposed rule thus should consider and quantify the medical dangers of many abortion facilities, including those who have received citations. In some abortion centers, abortions are performed without an actual doctor in the room. The abortion industry opposes requiring licensed doctors to perform abortions because it means fewer abortions and less profit. But lowering standards and credentials for abortionists creates more risk for women. The abortion industry also would like to exempt itself from basic outpatient surgery requirements such as doctors having local hospital admitting privileges and regular facility inspections. Avoiding such standards means lower costs for the abortion center but puts women at risk.

The proposed rule should also consider the harms of online abortion, especially because it proposes to extend its abortion nondiscrimination mandate to telemedicine. "Webcam Abortions" are a callous, cost-cutting measure invented by the abortion industry to facilitate more abortions by eliminating in-person consultations. Via webcam, an abortionist would have a brief online "chat" with the mother and then authorize her to receive the drugs that cause an abortion. The physician need not ever be in the room with her. Often, women can even obtain these drugs by mail just by filling out a form, and thus they need never see any health professional by video, by phone, or in person, not even a nurse or a pharmacist. If a woman has complications after taking the drugs, the woman has no doctor to turn to for help.

E. The proposed rule's abortion mandate will harm healthcare and imperil conscience rights.

The Department must consider the myriad conscience protection laws and religious freedom laws that apply in the abortion context, something that the proposed rule fails to adequately consider.

Americans cherish the freedom to live according to their faith and conscience, free from government coercion. Unfortunately, nurses, doctors, and healthcare providers have faced discrimination and even have lost their jobs because of their

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[21] ADF, Investigate Their Plan, https://adflegal.blob.core.windows.net/mainsite-new/docs/default-source/documents/resources/campaign-resources/life/investigate-their-plan/investigatetheirplan_booklet_textpages2.pdf

commitment to saving life. The government has a duty to respect and enforce federal conscience and religious freedom protections for pro-life healthcare providers, not to enact new abortion mandates that trample these rights.

ADF defends the rights of pro-life healthcare professionals in court. Forcing doctors and nurses to end life is the opposite of good healthcare or good government. When the government has not protected conscience right and religious freedom, ADF has gone to court to do so. Avoiding coerced participation in abortion is vital, as many doctors and nurses told HHS in formal comments in 2018 on the HHS conscience rule.

> "After 28 years of working as a critical care and emergency room nurse, I never imagined my employer would force me to choose between taking the life of an unborn child and losing my job. But 11 other nurses and I were ordered to assist in abortion even though it violated our religious convictions and contradicted our calling as a medical professional to protect life. Both New Jersey and federal law prohibited this discrimination. But those laws are only as effective as the willingness of government officials to enforce them." — *Fe Esperanza Racpan Vinoya, Danquah v. University of Medicine and Dentistry of New Jersey*

> "My faith in God and the Catholic Church's teachings about the value of all human life inspired my career in nursing and encouraged me to never harm or intentionally take the life of an innocent person. I'll never forget the day my supervisor ignored the law and forced me to participate in an abortion. I still have nightmares about that day." — *Cathy DeCarlo, Cenzon-DeCarlo v. The Mount Sinai Hospital*

> "I never dreamed that my desire to serve women and their families would prevent me from joining the medical profession, but it almost did. I applied for a nurse-midwife position at a federally-funded center that provides health care to poor, underserved women in Florida. But I was shocked when the center refused to consider my application because I was a member of a pro-life medical association and was committed to saving lives not ending them. . . . Diversity among health providers, including religious and moral diversity, helps ensure women have more options available to them in finding a medical professional who shares and supports their values." — *Sara Hellwege, Hellwege v. Tampa Family Health Centers*

> "The pregnancy care center I help lead informs pregnant moms about all their options—parenting, placing a child for adoption, and abortion.

> We offer hope, encouragement, and practical support. But the state of California tried to force us to speak a message we didn't believe, refer for free abortions, and turn our walls into a billboard for the abortion industry. Thankfully, the Supreme Court ruled that the government can't force us to speak a message that contradicts the very core of who we are and why we exist . . . ."— *Heidi Matzke, National Institute of Family and Life Advocates v. Becerra*

As this shows, many individuals in the medical community are finding themselves censored or punished for their pro-life views. Alliance Defending Freedom stands with those who stand for life. So should the federal government. Unfortunately, pro-life doctors and healthcare providers, including crisis pregnancy centers, are subject to campaigns of ongoing government coercion and private harassment and violence.

Virginia nurse practitioner Paige Casey, for example, is suing MinuteClinic, a division of the CVS drugstore chain, after the health clinic illegally fired her for declining to provide abortion-inducing drugs to customers in keeping with her religious beliefs.[22] Paige Casey, who has been a licensed nurse practitioner in northern Virginia since 2018, follows the teaching of her Catholic faith, which prohibits her from providing, prescribing, or facilitating the use of any drug, device, or surgical procedure that can cause an abortion, including drugs like certain hormonal contraceptives, Plan B, and Ella. Casey's religious objection never posed an issue to coworkers, patients, or supervisors, and just two days before she was fired, she received a merit-based pay increase. For three and a half years, CVS respected Casey's religious beliefs by allowing her to decline to provide or facilitate the use of abortion-inducing drugs. But in January, CVS informed her that they would no longer accommodate her faith and fired her a few months later—directly violating Virginia's Conscience Clause. Virginia's Conscience Clause prohibits employers from discriminating against their employees who decline to participate in providing abortifacients because of their religious or ethical beliefs. ADF attorneys are suing CVS on Casey's behalf to prevent the company from forcing healthcare professionals to violate their faith in order to keep their jobs. The proposed rule would take this problematic situation in Virginia and nationalize it, making providers across the country participate in abortion in all sorts of settings.

Rather than impose further unlawful and unsound abortion mandates that harm unborn children, mothers, and healthcare providers, the federal government

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[22] ADF, *Casey v. MinuteClinic Diagnostic of Va.*, https://adflegal.org/case/casey-v-minuteclinic-diagnostic-virginia.

should respect the intrinsic value of all human life. It should take steps to limit abortion and protect conscience rights, rather than push for more abortions and trample conscience rights.

And, at the very least, the Department must calculate the economic cost to the taxpayers of all the lawsuits the Department will defend against and lose as the result of this rule.

F. The Department should select pro-life alternative policies.

The Department should consider and adopt one of several pro-life alternative policies. The Department should consider the alternative of codifying and complying with Title IX's abortion neutrality clause, as well as Section 1303 of the ACA. The Department should also consider codifying broad exemptions on the face of the rule for scientific, medical, conscientious, or religious objections to its abortion mandates. This alternative includes grandfathering existing categories of healthcare; exempting religious institutions; and crafting privacy exemptions for facilities and programs.

The rule should state that it does not preempt state or local laws including state heath laws, malpractice suits, child abuse law, parental rights laws, and abortion laws. In particular, the Department should clarify that the rule does not preempt any state or local laws restricting abortion or other medical interventions, especially in light of Section 1303's prohibition on preemption, and especially following *Dobbs*.

So that regulated entities and individuals have recourse short of litigation, the Department should consider creating an explicit exemption for conscience and religious objections that operates on the face of the rule without an entity needing to request the exemption. The Department should say that any investigation launched under the rule's prohibition on termination of pregnancy discrimination will immediately and automatically be closed if a complainant has a religious or moral objection to taking the action or omission the complaint alleges. The Department should also ensure that no system of records tracks religious and moral objectors.

The Department should also consider specifying that the rule cannot mandate coverage for abortion or situationally for any related reproductive services (like infertility treatments, IVF, gestational surrogacy, or contraceptives) contrary to a provider's belief that sexuality and marriage is reserved for the union of one man and one woman and to the belief that each child deserves a mother and a father.

The Department likewise should expressly make clear that its mandates do not require health care professionals to perform any procedures, such as abortions, on children under 18, even if requested. It should expressly state that parental notification and consent is required for any abortion. And it should allow parents and patients to opt out of providing coverage for abortion in any health insurance plans.

The Department should also consider the alternative of adopting pro-life rules expressly stating that forcing or pressuring a pregnant person to have an abortion is prohibited sex discrimination. The federal government should be concerned that in healthcare and education mothers are often pressured to abort their children and are not given important societal support. This problem of coerced abortion often can arise in the context of female students in competitive medical school programs or on competitive college athletic teams, where pregnant female students are pressured to abort their children. In athletic settings, healthcare entities regulated by HHS provide care to female athletes who are often pressured to abort to maintain their athletic positions and scholarships.[23] HHS OCR has jurisdiction over healthcare provided to Olympic athletes from universities receiving HHS funds.[24]

Pregnancy discrimination in the form of pressure to abort can also occur in the context of human trafficking, where traffickers bring their victims to healthcare facilities that perform abortions to evade accountability and to perpetrate additional abuse. It can arise in the context of healthcare employment, where corporate employers would rather pressure employees to abort and even pay for abortions than provide meaningful maternity leave and childcare support for working mothers. The Department should adopt a rule that requires covered entities to take the same affirmative steps to end coerced abortion as end other forms of sex discrimination.

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[23] *See, e.g.*, https://www.nytimes.com/2019/05/12/opinion/nike-maternity-leave.html; https://www.nytimes.com/2019/05/22/opinion/allyson-felix-pregnancy-nike.html; https://www.si.com/olympics/2017/06/06/sanya-richards-ross-opens-about-abortion; https://time.com/6077124/allyson-felix-tokyo-olympics/; https://verilymag.com/2021/07/olympics-brianna-mcneal-abortion-pressure-2021; https://www.espn.com/college-sports/news/story?id=2865230.

[24] https://www.hhs.gov/sites/default/files/vra-between-msu-and-ocr.pdf

II. The proposed rule's redefinition of sex to address gender identity and sexual orientation harms patients and healthcare providers.

By changing the meaning of "sex" discrimination to address "sexual orientation" and "gender identity," the proposed rule threatens to impose an additional nationwide standard of care that harms patients and coerces the performance of dangerous and life-altering medical procedures.

Not only does the proposed rule coerce the provision of abortion (as discussed above), the proposed rule also seeks to coerce providers to alter a person's appearance as a male or as a female in order to resemble a person of the opposite sex. The proposed rule thus seeks to coerce providers to perform on-demand surgeries, such as mastectomy or sterilization, and to coerce many other procedures on-demand, such as administration of puberty blockers or testosterone suppression.

But a nondiscrimination provision cannot establish what is medically necessary, let alone decide what is good or bad medicine. This mandate harms the interests of patients and providers by ignoring the best evidence about good medicine, by crushing free speech, and by ignoring conscience protections for medical providers.

These negative impacts should cause the Department to reconsider and withdraw the proposed rule. This section of ADF's comment thus discusses the many harms of this aspect of the proposed rule—harms to patients, parents, providers, counselors, women, children, and the freedoms of speech, religion, and conscience. (The following section of ADF's comment will discuss the significant legal infirmities and procedural defects in this aspect of the proposed rule.)

A. The proposed rule requires the performance of harmful, life-altering procedures.

The proposed rule seeks to coerce many life-altering, serious procedures. The Department's "gender identity" mandate in healthcare apparently requires providers to participate in, at a minimum, the following problematic practices:

a. Prescribing puberty blockers off-label from the FDA-approved indication to treat gender dysphoria and start or further interventions in adults and children;

b. Prescribing hormone therapies off-label from the FDA-approved indication to treat gender dysphoria in all adults and children, including testosterone injections and suppression, which are often lifelong practices;

c. Providing other continuing interventions to further interventions ongoing in both adults and minors;

d. Performing hysterectomies or mastectomies on healthy women who believe themselves to be men;

e. Removing the non-diseased ovaries of healthy women who believe themselves to be men;

f. Removing the testicles of healthy men who believe themselves to be women;

g. Performing a process called "de-gloving" to remove the skin of a man's penis and use it to create a faux vaginal opening;

h. Removing vaginal tissue from women to facilitate the creation of a faux or cosmetic penis;

i. Performing similar surgeries, such as orchiectomy and penectomy (removal of testicles and penis); clitoroplasty, labiaplasty, and vaginoplasty (creation of a clitoris, labia, and vagina); vulvectomy and vaginectomy (removal of vulva and vagina); and metoidioplasty and phalloplasty (creation of penis);

j. Performing other cosmetic procedures to make a person appear like the opposite sex, such as blepharoplasty (eye and lid modification); face/forehead or neck tightening; facial bone remodeling for facial feminization; genioplasty (chin width reduction); rhytidectomy (cheek, chin, and neck); cheek, chin, and nose implants; lip lift/augmentation; mandibular angle augmentation/creation/reduction (jaw); orbital recontouring; rhinoplasty (nose reshaping); laser or electrolysis hair removal; and breast/chest augmentation, reduction, construction;

k. Performing or participating in any combination of the above mutilating cosmetic procedures, or similar surgeries;

l. Offering to perform, provide, or prescribe any such interventions, procedures, services, or drugs;

m. Referring patients for any such interventions, procedures, services, or drugs;

n. Ending or modifying existing policies, procedures, and practices of healthcare providers to not offer to perform or prescribe these procedures, drugs, and interventions;

o. Saying, against the medical and moral judgment of healthcare providers, that these intervention procedures are the standard of care, are safe, are beneficial, are not experimental, or should otherwise be recommended;

p. Treating patients according to "gender identity" and not sex;

q. Expressing views on interventions contrary to a medical provider's professional and moral beliefs;

r. Counseling patients to accept their biological sex, to be comfortable with sexual relations between a man and a woman;

s. Saying that sex or "gender" is nonbinary or on a spectrum;

t. Using language affirming any self-professed "gender identity";

u. Using patients' preferred pronouns according to "gender identity," rather than using no pronouns or using pronouns based on biological sex;

v. Creating medical records and coding patients and services according to "gender identity" and not biological sex;

w. Providing the government assurances of compliance, providing compliance reports, and posting notices of compliance in prominent physical locations, if the 2016 ACA Rule's interpretation of the term "sex" governs these documents;

x. Refraining from expressing medical, ethical, or religious views, options, and opinions to patients when those views disagree with "gender identity" theory or procedures;

y. Allowing patients to access single-sex programs and facilities, such as mental health therapy groups, breastfeeding support groups, post-partum support groups, educational sessions, changing areas, restrooms, communal showers, and other single-sex programs and spaces, by "gender identity" and not by biological sex; and

z. Denying patients the right for provider choice or chaperone selection by sex, in favor of a provider or chaperone's "gender identity."

Of course, these procedures may have appropriate medical purposes to address disease or injury. They are harmful when performed not to correct a true disease or injury, but to alter a person's appearance as a man or as a woman, in order to make the person appear to be the opposite sex.

The Department admitted in the 2016 rule that it required these interventions to be provided even if they were not medically necessary, including serious surgeries, such as a mastectomy or sterilization, and life-altering procedures, such as puberty blockers or testosterone suppression.[25]

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[25] 81 Fed. Reg. at 31,429, 31,455.

The proposed rule requires the same. In sweeping terms, it provides that all these procedures must be provided on-demand. Indeed, the proposed rule does not even require a confirmed diagnosis of gender dysphoria to obtain these procedures: "not all individuals for whom such care is clinically appropriate will specifically identify as transgender, nor will all gender-affirming care specifically be related to transition from one binary gender to another. . . . A person's use of particular identity terminology is not determinative of whether the care in question is appropriate."[26] Nor does the proposed rule state what event or diagnosis requires insurers or providers to provide or cover a certain procedure.

Given the sheer scope of what the Department proposes to mandate across health care, the final rule should speak with specificity to each of these procedures, and, for each, directly state what it proposes to mandate and state under what circumstances it is required. It should also identify the source of its standard of care, including the medical associations or activist groups setting that standard of care. It should also identify who may make a determination of medical necessity and what happens when providers disagree about medical necessity. It should also identify whether each procedure is required even if it is not considered medically necessary by the provider, or the Department should state under what circumstances a provider must certify that a procedure is medically necessary. If the Department's standard is not one of medical necessity, but is a standard of promoting comfort or alleviating distress,[27] the Department should identify the basis for this standard and explain what its limits are in practice. This task requires identifying when other considerations may be taken into account, such as cost containment, alternative treatments, provider judgment, evolving scientific knowledge, and moral or religious considerations.

B. The proposed rule harms patients and makes informed consent impossible.

The proposed rule's coercion of these serious procedures will harm children and adults. The best medicine suggests that procedures aimed at altering one's appearance as a man or a woman are dangerous and have unknown long-term effects. As a result, it is impossible for adults or parents to provide informed consent

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[26] 87 Fed. Reg. at 47,867.

[27] See WPATH's new guidelines (misnamed "Standards of Care") version 8: https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644.

for these procedures or treatments. Nor is it possible for patients to meaningfully consent to otherwise allow doctors to ignore a patient's biological sex.

Sex matters in medicine. Medicine relies on biology; and rewriting the definitions of "male" and "female" in the context of medicine is anti-science, unlawful, and dangerous. A few years ago, the *New England Journal of Medicine* reported that a patient who was rushed to the hospital with hours of abdominal pain was identified in medical records as male. Since the patient had been on high blood pressure medication and recently stopped, the nurse classified the patient as a non-emergency. Unfortunately, the patient was not a male, despite the medical records that identified the patient as a male, and in fact was pregnant and in labor. Tragically, because the nurse was operating from inaccurate information, the patient's baby did not survive.[28]

The medical profession has long respected the biological differences between men and women, as well as boys and girls. Women's and men's bodies are not the same; they react differently to different medications, they are at greater risks for different types of cancer, and, of course, only women are capable of being pregnant.

Making doctors act as if patients are a different sex creates inaccurate, dangerous, and potentially lethal situations for patients of all ages. Doctors should not be forced to perform experimental, often-dangerous procedures on anyone—especially on minors. Doctors should be free to diagnose and treat each person consistent with their expertise. In nearly all cases, gender dysphoria is resolved in children with no intervention. Doctors should not be forced to experiment unnecessarily on children.

In short, the government lacks any authority to interfere with what doctors, exercising sounds medical judgment, can and cannot say about and on the debated topic of sex and sexuality in the context of the patient-physician relationship. Families have a right to know certain facts about documented harms associated with these interventions as well as the permanence of a decision to follow through with a related procedure.

When it comes to the science, the Department is wrong to treat sex and biology as separate from gender.[29] Human sexuality is an objective biological binary

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[28] 85 Fed. Reg. at 37,188.

[29] The medical science supporting these facts is laid forth in medical declarations in a pending ADF case. *See* Declaration of Quentin Van Meter, M.D., *Am. Coll. of Pediatricians v. Becerra*, No. 1:21-cv-00195, ECF No. 15-1 (E.D. Tenn. Nov. 10, 2021). The complaint in this case, as well as the attached

trait: "XY" and "XX" are genetic markers of sex—not genetic markers of a disordered body. The norm for human design is to be conceived either male or female with the purpose being the reproduction and flourishing of our species. This principle is self-evident. Children who identify as "feeling like the opposite sex" or "somewhere in between" do not comprise a third sex. They remain biological boys or biological girls. Normalizing the myth of innate gender fluidity will cause psychological trauma to youth by inviting confusion about their sex.

Disorders of sex development (DSD), known as intersex conditions, do not show otherwise. Disorders of sex development are maladies in which normal sexual differentiation and function are disrupted. Some argue that disorders of sex development prove the existence of more than two sexes. But disorders of sex development do not represent additional reproductive organs, gonads, or gametes. Thus, by definition, disorders of sex development do not constitute additional sexes.

Human sex is binary, not a spectrum, and disorders of sex development are rare congenital disorders affecting 0.02% of the population in which either genitalia are ambiguous in appearance, or an individual's sexual appearance fails to match what would be expected given the person's sex chromosomes. Reflecting the unfortunate nature of these conditions, all disorders of sex development are linked to impaired fertility.

Young children and developing adolescents struggling with their sex characteristics should receive counseling, not medical experimentation. Up to 98% of children who struggle with their sex desist and will accept their sex by adulthood.[30]

Teaching children to question their biology and sex, in contrast, is untested and unscientific. The long-term effects of puberty blockers and cross-sex hormones have not been rigorously studied.[31] There is no solid foundation of evidence for any

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detailed medical declarations, are attached to this comment and incorporated herein. A brief summary follows.

[30] Michael K Laidlaw, et al., "Letter to the Editor: 'Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline'," The Journal of Clinical Endocrinology & Metabolism, 104, no. 3 (March, 2019): 686–687, https://academic.oup.com/jcem/article/104/3/686/5198654 ("Children with GD will outgrow this condition in 61-98% of cases by adulthood.").

[31] Paul W. Hruz, et al., "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," New Atlantis, Spring 2017, https://www.thenewatlantis.com/publications/growing-pains, ("Whether puberty suppression is safe and effective when used for gender dysphoria remains unclear and unsupported by rigorous scientific evidence."); See also: Johanna Olson-Kennedy, et al., "Health

of the interventions that the proposed rule seeks to coerce as a new standard of care. No drugs have been approved by the Food and Drug Administration (FDA) to treat gender dysphoria. But puberty blockers and cross-sex hormones combined will sterilize many youth and cause them to develop serious chronic illnesses such as diabetes, heart disease, stroke, and cancers that they otherwise would have never experienced. And, after sex-reassignment surgery, people who identify as the opposite sex are nearly 20 times more likely to die from suicide than the general population.[32]

In no other area of science would these types of surgeries, procedures, and interventions be promoted and even mandated by the federal government without the research to support them. There are serious deficits in understanding the cause of this condition or in understanding the reasons for the marked increase in people presenting for medical care. There is in particular a lack of high-quality scientific data for common interventions, such as the general lack of randomized prospective trial design, a small sample size, recruitment bias, short study duration, high subject dropout rates, and reliance on opinion. Under the established principles of evidence-based medicine, providers should exercise a high degree of caution before accepting interventions as a preferred treatment approach. It is thus recommended to give continued consideration and rigorous investigation of alternate approaches to alleviating suffering in people with gender dysphoria, especially further investigation of the phenomenon of adolescent girls with no prior expression of gender dysphoria presenting as having an opposite-sex identity in social networks (aka rapid onset gender dysphoria).[33]

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considerations for gender non-conforming children and transgender adolescents," UCSF Center of Excellence for Transgender Health, June 17, 2016, https://transcare.ucsf.edu/guidelines/youth [https://web.archive.org/web/20220916063817/https://transcare.ucsf.edu/guidelines/youth], ("While clinically becoming increasingly common, the impact of GnRH analogues administered to transgender youth in early puberty and <12 years of age has not been published.").

[32] A long-term study conducted in Sweden followed 324 transgender-identified people who had undergone sex reassignment surgery and found that after surgery, these adults were nearly 5 times more likely to attempt suicide and nearly 20 times more likely to commit suicide than the general population. As a result, "Persons with transsexualism, after sex reassignment, have considerably higher risks for mortality, suicidal behaviour, and psychiatric morbidity than the general population. Cecilia Dhejne, et al., "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," PLoS One 6, no. 2 (2011):e16885, https://doi.org/10.1371/journal.pone.0016885.

[33] Paul W. Hruz, Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria, 87 Linacre Quarterly 34, 34-42 (Sept. 20, 2019), https://doi.org/10.1177/0024363919873762.

Because of this lack of any evidence supporting these interventions, the United Kingdom, Sweden, and Finland have sought to limit these interventions in youth. Sweden's Karolinska University Hospital restricted its use of the Dutch Protocol (medical interventions to alter appearance) with children under 16 years old stating it is "potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis."[34] World-renowned child psychiatrist Dr. Christopher Gillberg has referred to this as "possibly one of the greatest scandals in medical history." His neuropsychiatry research group at Gothenburg University has called for "an immediate moratorium on the use of puberty blocker drugs because of their unknown long-term effects."[35]

In short, these procedures are experimental, controversial, and life-altering. Given the unknown state of science, the lack of proven benefits, and the uncertain long-term effects, it is impossible for adults or parents, let alone children, to consent to these procedures or practices.

The proposed rule fails to grapple with these serious medical questions—even though the proposed rule purports to set a new medical standard of care by virtue of its effects on medicine in federally funded settings.

But, on all these issues, there is thus no standard of care requiring what the Department purports to mandate in the proposed rule. No consensus of practitioners backs up these mandates. Indeed, the Hippocratic Oath forbids abortions and procedures that suppress healthy and normal biological processes associated with normal human sexual development—or that destroy healthy organs

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[34] Cummings DM, Swedish Hospital No Longer Gives Puberty Blockers or Sex Hormones to Children," Lifesite News (May 6, 2021), https://www.lifesitenews.com/news/swedish-hospital-no-longer-gives-puberty-blockers-sex-hormones-to-children; Karolinska University Hospital Dutch Protocol Policy, https://segm.org/sites/default/files/Karolinska%20_Policy_Statement_English.pdf (last accessed Sept. 22, 2022) (concluding that from April 1, 2021 onwards, "hormonal treatments (i.e., puberty blocking and cross-sex hormones) will not be initiated in gender dysphoric patients under the age of 16").

[35] Jonathan Van Maren, World-renowned child psychiatrist calls trans treatments "possibly one of the greatest scandals in medical history," The Bridgehead (Sept. 25, 2019), https://thebridgehead.ca/2019/09/25/world-renowned-child-psychiatrist-calls-trans-treatments-possibly-one-of-the-greatest-scandals-in-medical-history/ ("Professor Gillberg's neuropsychiatry group at Sweden's Gothenburg University—which has research hubs in Britain, France, and Japan—has called for an immediate moratorium on the use of puberty blocker drugs because of their unknown long-term effects.") (citing The Australian, https://www.theaustralian.com.au/nation/doctors-back-inquiry-on-kids-trans-care/news-story/6f352bc99da430b194620a2605e8a50d).

and tissue. The best evidence suggests that a few non-representative activist groups seek to impose an ideology on other providers—contrary to a patients' best interests—and to drive out of medicine providers who are not on board with their ideology.

C. The proposed rule threatens to coerce healthcare providers to perform harmful medical procedures, such as sterilizations and surgeries to remove healthy sexual organs.

The proposed rule wrongly seeks to coerce healthcare providers to harm their patients and to implement the Department's misguided new standard of care.

The government should promote the common good and dignity of all people, while upholding the constitutional freedoms of all Americans. Doctors, patients, and families deserve no less. The government should not force doctors to offer or participate in procedures that go against doctors' deeply held medical and ethical convictions—especially when it involves children and adolescents—and especially life-altering surgeries, such as a mastectomy or sterilization, or life-altering procedures, such as puberty blockers or testosterone suppression.

Under the government's overreaching interpretation, doctors now face an untenable choice: either act against their medical judgment and deeply held convictions by performing controversial and often medically dangerous interventions, or succumb to huge financial penalties, lose participation in Medicaid and other federal funding, and, as a practical matter, lose the ability to practice medicine in virtually any setting.

Many providers have medical, ethical, or religious objections to these activities. Yet all of these objectionable practices are coerced by the Department under the proposed rule, as well as under its current enforcement practices. The proposed rule suggests that any refusal to treat will be considered more than *de minimis* harm. But there is no sound policy reason to coerce providers to act against their best medical judgment, their consciences, and their religious beliefs to provide these serious, life-altering procedures, especially on children. Nor should physicians be forced to prescribe treatments which are not approved by the FDA.

As a result, if the proposed rule is adopted, doctors and hospitals will have to provide harmful services, including for children, if they provide the same services for other purposes. Even though the proposed rule gives lip service to the idea that it is permissible under the proposed regulations for a health care professional to refuse to provide services such as sterilizations or testosterone suppression to a particular patient based on medical judgment, the proposed rule also states that "a

provider's view that no gender transition or other gender-affirming care can ever be beneficial for such individuals (or its compliance with a state or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not clinically appropriate."[36] This means that many healthcare professionals, who view these interventions as controversial, harmful, and irreversible, and contrary to their conscience and best medical judgment, will be coerced to provide harmful procedures and treatments.[37]

That the proposed rule will impose this coercion is all the more clear because the proposed rule will apply to doctors that are technically proficient in the procedure of interest. Of course, procedures like mastectomies and sterilization procedures are performed by many doctors for sound medical reasons, often by oncologists or OBGYNs. Indeed, the same technical skill is required for abortions as for miscarriage management. So, for all these harmful procedures, the purpose of the proposed rule is to strip these providers of their medical judgment and coerce them into implementing the Department's radical ideology.

Even if a provider may be able to obtain occasion exemptions in individual cases, there is no across-the-board exemption for philosophical, moral, or religious objections, or for across-the-board categorical disagreements as matters of medical judgment.

This coercion also applies at the organizational level for covered entities. Under the proposed rule, a covered entity like a hospital or insurance company would be prohibited from "having or implementing a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care."[38] An exclusion on the basis that such interventions are "experimental" would be considered discriminatory. While all services would not have to be covered, insurers may not limit or deny services based on "gender identity," and to the extent that a service is covered for standard healthcare purposes, it would have to be covered for the purpose of altering a person's appearance as a man or as a woman. For instance, if a hospital will perform and an insurer will cover a hysterectomy to save a woman from cancer, the hospital must perform and the insurer must pay for the same procedure if a woman wishes to

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[36] 87 Fed. Reg. at 47,867.

[37] Rachel Morrison, *HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate in Health Care*, https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-in-health-care-1.

[38] 87 Fed. Reg. at 47,871.

remove her uterus because she identifies as man. And the same is true for every other procedure or practice listed above. This will coerce everyone across healthcare into ignoring sound medicine in favor of the Department's agenda.

The Department thus must explain why the federal government should compel medical doctors to perform surgeries, prescribe drugs, and speak and write about patients according to "gender identity," rather than biological reality—regardless of doctors' medical judgment or conscientious objections, and regardless of a patient's age or the parent's informed consent.

D. The proposed rule will restrict free speech by restricting talk therapy.

The proposed rule will also impose burdens on free speech by providers because it purports to prohibit many forms of talk therapy.

One of the most problematic applications of the proposed rule is that it threatens a prohibition on talk therapy and counseling. Talking therapy seeks to help patients achieve their own goals of becoming comfortable in their bodies. But the proposed rule prohibits talk therapy (and deny insurance coverage for it), unless the therapist expresses the government's viewpoint.

The proposed rule prohibits talk therapy if the therapist seeks to counsel the client to become comfortable in the client's own body—and even if the client's personal goal is to become more comfortable in his or her own body. The proposed rule states that "needed services" include "gender-affirming care," and it defines "gender-affirming care" to "include. . . *counseling*, hormone therapy, surgery, and other services designed to treat gender dysphoria or support gender affirmation or transition.[39] The proposed rule then cites to another document, which takes a position on what forms of counseling are acceptable. This document states that "gender-affirming care" is acceptable": "Psychotherapy should focus on reducing a child's or adolescent's distress related to the gender dysphoria and on ameliorating any other psychosocial difficulties. For youth pursuing sex reassignment, psychotherapy may focus on supporting them before, during, and after reassignment." [40] But it states that any other forms of counseling or treatment are

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[39] 87 Fed. Reg. at 47,834 (emphasis added).

[40] World Prof. Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, pp. 68-71 (7th Version 2012), https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English2012.pdf?_t=1613669341 (last visited Feb. 7, 2022).

not acceptable" "Treatment aimed at trying to change a person's gender identity and expression to become more congruent with sex assigned at birth has been attempted in the past without success . . . Such treatment is no longer considered ethical."[41] Because the proposed rule incorporated this document, the proposed rule appears to have adopted these positions as a nationwide standard of care. The result is to consider the standard of care to be the provision of "gender-affirming care," and to consider the standard of care to exclude any talk therapy that is not "gender-affirming." The effect is to prohibit talk therapy in which the therapist seeks to counsel the client to become comfortable in the client's own body.

Nor is this effect a surprise. Talk therapy in which the therapist seeks to counsel the client to become comfortable in the client's own body is exactly what the Biden administration seeks to prohibit, as the President said in an executive order.[42] This executive order considered many forms of talk therapy to be "conversion therapy." But every American is protected under the Constitution to freely live and work according to their religious beliefs, and the President cannot remove those fundamental rights with a stroke of his pen.

It is a gross overreach of presidential and HHS authority to mandate what counselors can say, or not say, in private conversations with their clients. Consider the case of our client, Brian Tingley.

Brian Tingley is a licensed counselor who has been practicing in Washington state for more than 20 years. During that time, he has helped adults, couples, teenagers, and children identify and achieve the goals that they set for themselves, consistent with their own moral values and religious beliefs. Under Brian's guidance, his clients have pursued meaningful and positive changes in their lives. Brian cares deeply about his clients and wishes to help them in any way he can. He carefully listens to and reasons with his clients, providing feedback and guidance. Brian engages in nothing but ordinary counseling methods—listening to each client, regardless of what they are facing, and supporting them as they work through these challenges to pursue their own life goals.

Like many of his clients, Brian is a Christian. And his Christian beliefs inform his understanding of human nature. But Brian never tries to force his own beliefs on his clients. Brian works with Christian and non-Christian clients, many

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[41] *Id.*

[42] Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals (June 15, 2022).

of his clients are referred to him by local churches, and the majority share his Christian faith.

But now, Brian's practice is in jeopardy. In 2018, Washington passed a law that allows government officials to censor private conversations between counselors and their clients. The law prohibits any conversation between individuals and their chosen counselor that seeks to help the client achieve comfort with his or her biological sex, or reduce unwanted same-sex attractions. This includes clients who desire this counseling to help them bring their hearts, minds, and conduct in line with the teachings of their faith. If Brian has such discussions with his clients, he faces fines of up to $5,000 per violation, suspension from practice, and even losing his license and livelihood.[43]

The government doesn't belong in a counselor's office. And this law violates both freedom of speech and religious freedom. In fact, just last year the United States Court of Appeals for the 11th Circuit ruled that an almost identical law is unconstitutional.[44]

Just like Washington State's mandate, the proposed rule improperly seeks to hurt counselors like Brian Tingley, as well as many other licensed marriage and family therapists, by prohibiting certain private client-counselor conversations and counseling goals that the government disfavors. For government officials to insert themselves into confidential counseling sessions—and determine what goals counselors and their clients can pursue and what topics they can discuss—violates both free speech and religious freedom.

The government has no right to instruct patients what goals they must pursue through private counseling. Similarly, it's up to counselors like Brian Tingley to determine how best to help their clients achieve their counseling goals during their sessions. The government has no business telling counselors what topics they can and cannot discuss during these sessions.

All people have the right to free speech, whether in a public environment or in a private counseling session. The government has no right to decide what people can discuss in their own private conversations, and it does not belong in a

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[43] ADF, Tingley v. Ferguson, https://adflegal.org/case/tingley-v-ferguson. More information about this case and about the legal infirmities with banning talk therapy are found in the attached case documents.

[44] *Otto v. City of Boca Raton*, 981 F.3d 854 (11th Cir. 2020).

counselor's office. The proposed rule thus will harm patients and counselors by prohibiting talk therapy and should not be finalized.

E. The proposed rule will drive healthcare providers out of medicine.

Consistent evidence before HHS for over a decade has put the agency on notice of these significant reliance interests for objecting healthcare providers, alerting the agency that its mandates will decrease—not increase—care.

Scientific polls of religious medical professionals show that religious doctors will leave the profession rather than violate their consciences, with disproportionate effects on poor and underserved communities. In fact, HHS was on notice of these reliance interests from similar consistent polling presented to the agency since comments on prior conscience regulations.[45] For example, in comments responding to HHS's 2019 Notice of Non-Enforcement, 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.' "
- "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.' "[46]

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

[46] 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

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 practice according to ethical norms, the *poor and medically underserved populations served by these professionals stand to suffer a devastating loss of healthcare access*."[47] Comments on the 2020 ACA 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.'"[48]

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.'"[49] At the same time, almost all surveyed professionals reported that they still care for transgender-identifying patients even if they cannot validate all of their life choices.[50] The survey thus concluded that, in this context, "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*."[51] Comments on another rulemaking in 2020 again warned, based on this data and in the context of "gender identity," that tying grants to HHS's mandates "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."[52]

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ensure their continued medical practice"; "Religious health professionals face rampant discrimination"; "Access for poor and medically underserved patient populations depends on conscience protections.").

[47] *Id.* at 6.

[48] 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.

[49] *Id.* at 4.

[50] *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.'")

[51] *Id.* at 4.

[52] 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/

This evidence is why in the 2021 grants rule HHS expressed concern that the 2016 grants rule could deter participation and thus "undermine the effectiveness" of its grants programs by reducing the number of service providers.[53] HHS also analyzed the 2009 survey data in detail, as well as similar facts, in a 2019 conscience rule, concluding that this data provided reason to increase (not decrease) HHS conscience protections and reason to think that conscience protections would increase (not decrease) access to care.[54] ADF clients' experience bears out these concerns.[55]

The Department assumes that anything short of a universal mandate would lead to denied care. But this assumption ignores actual evidence about the other side of the equation: the potentially reduced access to care for society as a whole, especially in poor and rural underserved communities, if the Department forces religious health care providers out of the health care profession entirely.

F. The proposed rule will disproportionately impact women and girls.

The Department also ignores that in practice many of its mandates have harsh, disproportionate effects on women and girls.

Unprecedented numbers of young girls are confused about their sex and identifying as the opposite sex, often with no history of gender dysphoria.[56] Imposing these dangerous medical practices on healthcare nationwide will harm these women and girls the most. The Department thus must conduct rigorous studies to identify the sources of this social contagion and ensure that girls do not suffer from rushed medical experiments. Women and girls should be affirmed in their biological sex and they should be supported in ways that help them be

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comment/HHS-OS-2020-0001-15615. The same polling shows, "Virtually all faith-based respondents (97%) attest that they 'care for all patients in need, regardless of sexual orientation, gender identification, or family makeup, with sensitivity and compassion, even when I cannot validate their choices.' Clearly the issue at hand is not one of refusing to care for certain individuals, but rather simply declining to participate in certain morally controversial procedures and prescriptions." *Id.*

[53] 86 Fed. Reg. at 2,259, 2,263, 2,269, 2,273.

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

[55] *See, e.g.*, Van Meter Decl., *supra*, at ¶¶ 144–48, 152–71; Dickerson Decl. ¶¶ 109–12, 118–19, 137–57; Dassow Decl. ¶¶ 4–5, 36, 41–45, 47.

[56] Abigail Shrier, *Irreversible Damage: The Transgender Craze Seducing Our Daughters* (Regnery 2020).

comfortable in their own bodies, rather than rushed and pushed into lifelong medicalizations.

Moreover, all women and girls will suffer from the proposed rule, even those who do not themselves seek procedures like mastectomies or abortions. As detailed in the attached Title IX comments on women's privacy and safety, which address many of the same issues in housing and athletics, "gender identity" mandates like the proposed rule have far-reaching consequences that threaten to erode women's advances in society.

Mandates like the proposed rule burden women's equal opportunities by denying them the necessary accommodations to equally access healthcare and other societal programs. Sex is not fungible: and removing sex-separated programs or facilities ends the accommodations necessary for women to have equal access, especially in medical settings where biological sex has great importance. The proposed rule allows patients to access single-sex programs and facilities, by "gender identity" and not by biological sex, such as mental health therapy groups, breastfeeding support groups, post-partum support groups, educational sessions, changing areas, restrooms, communal showers, residential wards, hospital rooms, exams, testing, and other single-sex programs and spaces.

In practice, this means an end to single-sex programs and facilities because women and girls cannot and will not share these programs and intimate spaces with men. And, as discussed above, it means that women and parents no longer may select the provider or medical chaperone of their choice, which creates serious risks to women and girls' safety, dignity, and privacy. Women are likely to forgo treatment, avoid hospital stays, avoid support groups, and avoid restroom use rather than risk privacy violations, such as being exposed in states of undress to men. Parents are less likely to trust providers and chaperones around children if they lack control over the choice of provider or chaperone, and the lack of appropriate providers and chaperones of a parents' choice will inevitably increase the overall risk of sexual abuse in healthcare settings.

What is more, many of the coerced forms of speech related to these mandates have a disproportionate impact on women. In practice, mandates like the proposed rule tend to remove female words and impose neutral or male words instead, such as replacing words like mothers and pregnant women with "birthing parents" or "pregnant persons" and words like breastfeeding with "chest feeding." Even for marketing or advertising, statements like "labor and delivery ward for pregnant

women" would be a violation. None of these changes are required because the ACA expressly uses the term "pregnant women."[57]

The Department in sum should expressly consider and state whether its mandates require the promotion of the interventions listed above, whether it would prohibit single-sex programs and facilities, and whether it would restrict female-centric forms of speech like "mothers," "women," "pregnant woman," and "breastfeeding." If the Department refuses to take a position, it should consider the costs and benefits of the proposed rule under both possibilities. These concerns are important for all women and girls in society, and they also raise a unique potential for conflict for providers and patients from traditional religious backgrounds, whose religions forbid them from being in any state of undress in front of males.

G. The proposed rule threatens parental rights.

The proposed rule threatens parental rights over their children's medical decisions. It impairs their ability to provide informed consent. It threatens the rights of all patients to access quality healthcare providers who will provide the best medical information and judgment. And it threatens parental rights by easing the removal of parental consent and involvement from medical decision making, in violation of parents' fundamental rights under the Fourteenth Amendment.

By imposing a nationwide standard of care, and by requiring all providers to follow that standard of care in all situations—even involving minors—the proposed rule is creating a collision course for parental rights. This is because in many States minors can access healthcare without parental consent, and minors can obtain insurance payments from their parents' insurance plans without parental notification on an explanation of benefits.

Right now, if a minor sought to access abortion or other harmful procedures, a healthcare provider can play an important role as a check on immature decision making or rash choices. But if minors can access abortions and other treatments without parental involvement—and the federal government will penalize providers who try to be the only person advising the minor in that medical decision—then there is no check at all on young people from requesting abortions and other harmful procedures on demand.

This concern is made even more acute when certain states are seeking to become "sanctuary states" for minors in other states, whose parents object to having

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[57] *See, e.g.*, 124 Stat. at §§ 511, 1943, 2301, 2951, 2303, 2801, 2952, 10213.

abortions or other procedures performed on their children. Under some proposed state laws, a minor can travel independently or via one parent to a "sanctuary" state, and receive whatever procedures that minor or parent wishes—even if one or both parents object in the home state. And the Department must explain if this rule means that in Medicaid, minors could even receive all of these procedures for free without the parent ever knowing or paying. This concatenation of laws poses serious challenges to the rights of parents to have custody and control over their children.

Another problem in the proposed rule is that its abortion mandate ignores the role of parental notification and consent in the unique context of abortion. Every unborn child has two parents: the mother and the father. And, when the mother herself is a minor, her parents are involved as well. Each affected parent should be guaranteed a right to be involved in any abortion decision making. But the proposed rule excludes all parents, leaving mothers and children on their own—and at the same time, removing the safeguards that should be in place in the form of healthcare providers who will care for the mother and the child. This scenario threatens to violate not just parents' fundamental Fourteenth Amendment rights but also their rights under state abortion laws providing for parental notification or consent—laws that the Department must follow and that it lacks the authority to preempt.

Under the proposed rule's view of Title IX, federal law also enables school health clinics to exclude parents from their children's lives, including through "gender support plans" created and implemented in secret. ADF's attached Title IX comments address these problems for parental rights caused by the Department's proposed rule under Title IX, in education. Because this proposed rule applies equally through HHS funding in educational institutions, the Department must consider all of those impacts, explain its rationale, and calculate the costs of compliance.

H. The proposed sexual orientation mandate conflicts with the understanding of marriage as between one man and one woman.

The proposed rule threatens to drive out of business all covered entities who do not share the federal government's views on marriage and sexuality.

One of the most troubling applications of this redefinition of sex concerns the application of a sexual orientation mandate to residential programs. The application of this mandate would require religious organizations to recognize as marriages relationship that are contrary to their religious beliefs of marriage between one man and one woman. For example, a religious long-term care home would have to

allow two men or two women to cohabit in a single room, even though the home's beliefs are that sexual activity and relationships are limited to a marriage between one man and one woman. Likewise, religious healthcare providers, including those providing fertility care, would have to use various treatments to enable reproduction outside the context of a marriage between one man and one woman, both to unmarried persons and to persons in relationships that conflict with their religious beliefs.

The proposed rule should not make codes of conduct unlawful in residential settings—especially codes of sexual conduct. Many of these codes of conduct are informed by religious principles. But many codes of conduct are informed by experience and rest on secular principles.

By extending sex to encompass sexual activity, HHS threatens to remove the ability of any covered entity to have codes of sexual conduct in the workplace, leaving only in place non-preempted legal regulations of sexual activity. This can open a Pandora's box of unintended consequences. HHS thus should consider that these entities will be harmed, and, at the very least, describe their obligations specifically, quantify the resulting costs and effects, and explain why these costs are justified.

Many of these conflicts with the religious beliefs of providers have already arisen in HHS's attempt to impose a similar mandate on human services programs. In 2016, HHS imposed a similar mandate through its overarching grants regulation,[58] which partly overlaps and partly surpasses the Section 1557 mandate in many health contexts.

ADF is challenging the HHS grants rule in two cases: *American College of Pediatricians v. Becerra* and *Holston United Methodist Home for Children v. Becerra*.[59] In *American College of Pediatricians*, the HHS grants rule imposes similar mandates as the Department's view of Section 1557, as applied to healthcare entities receiving federal grants, such as community health centers. In

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[58] 45 C.F.R. § 75.300.

[59] The legal infirmities with imposing this sexual orientation mandate on grant recipients such as foster care agencies are discussed in detail in the cases' filings. The filings in these cases are attached and uploaded as separate documents, and they are also incorporated into these comments. Rather than duplicate these detailed legal issues, a brief summary of these cases follows, and the Department can refer to the legal filings for the detailed legal infirmities in the proposed rule's application in these contexts.

Holston Home, the HHS grants rule imposes a new and freestanding mandate on a foster care agency receiving federal foster care grant funding.

In *Holston Home*,[60] a Tennessee Christian children's home filed a federal lawsuit against the Biden administration to challenge its rule that requires the agency to violate its religious beliefs or lose needed funding. Holston United Methodist Home for Children is a nationally accredited Christian nonprofit that operates throughout East Tennessee and Southwest Virginia by caring for abused and neglected children through its residential and foster care services.

Holston United Methodist Home for Children has been in operation since 1895 and has helped more than 8,000 children by reuniting them with their families, placing them for adoption, or helping them transition to adulthood. "In the late 1800s, a widow of very modest means named Elizabeth Wiley answered the call of the Lord to start an orphanage to care for hurting children," explained Holston Home President Bradley Williams. "That kind of inspirational and courageous faith for a woman in that era is such a testimony of God's faithfulness and our rich heritage of traditional Wesleyan values. Today, we remain committed to these long-held biblical convictions and our calling to care for the most vulnerable young people in Jesus' name."

Holston Home receives some of its reimbursement for services through Title IV-E, administered by HHS, to help sustain its child-placement activities. The 2016 HHS grants rule issued at the end of the Obama administration required the faith-based agency to violate its religious beliefs by placing children in homes that do not align with their faith, such as non-Christian families; same-sex couples; or unmarried, cohabitating couples. During the Trump administration, HHS issued religious exemptions to this rule so faith-based agencies could operate according to their religious beliefs, but HHS recently rescinded all of those religious exemptions. HHS also withdrew its rule (already published and final) that would have repealed the grants rule.

Holston Home is a force for good, living out the words of Christ to care for children and 'the least of these.' It is vital that Holston Home, as a religious organization, remains free to keep placing at-risk children in loving, Christian families, according to its deeply held beliefs, without fear of government punishment. The Biden administration is wrong to remove religious exemptions to its unlawful grants rule. This leaves Holston Home and other faith-based nonprofits

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[60] ADF, *Holston United Methodist Home for Children v. Becerra*, https://adfmedia.org/case/holston-united-methodist-home-children-v-becerra.

with an untenable choice to violate their religious beliefs or lose critical grants necessary to their operations, which benefit everyone, including the government.

The Supreme Court has recognized the harms to children and society of expelling faith-based agencies from foster care and adoption programs, and now it's time this administration follows suit by respecting Holston Home's constitutionally protected religious freedoms, abandoning the proposed rule, and repealing the 2016 grants rule. The U.S. Supreme Court recently held that the city of Philadelphia violated the First Amendment rights of a faith-based foster-care agency by invoking non-discrimination laws to force the organization to operate in violation of its religious beliefs.

This concern about religious freedom is all the more heightened given the proposed rule's expansive understanding of what makes an entity covered under the rule. As described below, the proposed rule seeks to draw in more and more entities under its scope, and this expansion of the rule's reach is destined to create more and more conflicts.

HHS thus must consider this potential effect of its change to the Section 1557 rule to include sexual orientation, including by expressly delineating the rule's requirements, by quantifying its costs for these entities, and by expressly considering the Supreme Court's binding precedent in this area.

All this is to say what the 2020 ACA Rule stated: the 2016 ACA Rule "exceeded its authority under Section 1557, adopted erroneous and inconsistent interpretations of civil rights law, caused confusion, and imposed unjustified and unnecessary costs."[61] As a result, before HHS can enforce in 2022 what it correctly said in 2020 was an unlawful and burdensome mandate, HHS has a duty to provide a reasoned analysis of why its new enforcement and new proposed rule would not create these same legal and practical problems again.

I. The Department should consider these important issues and reliance interests.

The Department must consider these policy questions about the proper standard of care. When engaging in rulemaking, an agency must consider reliance interests.[62] Here HHS failed to adequately consider the new mandate's impact on

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[61] 85 Fed. Reg. at 27,849.

[62] *Biden v. Texas*, No. 21A21, 2021 WL 3732667, at *1 (Aug. 24, 2021) (citing *Dep't of Homeland Sec. v. Regents of the Univ. of Ca.*, 140 S. Ct. 1891, 1909–15 (2020).

doctors and medical associations with medical, ethical, conscientious, and religious objections to it, or their reliance interests in not being subject to such a mandate.

As it is, the proposed rule is arbitrary and capricious on these grounds:

- For failing to adequately consider and find that, in medical practice, sex is a biological reality, and there is an evolving state of medical knowledge about these interventions that the federal government should not circumvent by rulemaking.
- For failing to adequately consider that it requires providers to treat patients by providing harmful practices.
- For relying on facts and studies only from one side of the issue, and for ignoring experts who point out that there is not enough evidence to require the provision of life-altering procedures.
- For ignoring the impact on doctors and medical associations with medical, ethical, conscientious, and religious objections to it, or their reliance interests in not being subject to such a mandate.
- For ignoring the harm to patients in general, or to patients who want to keep receiving care from objecting providers.
- For failing to consider alternative policies that respect the interests of doctors and medical associations with medical, ethical, conscientious, and religious objections to the mandate.
- For ignoring the disproportionate impact of these mandates on women and girls, who will lose safety, privacy, respect, and sex-separate facilities and programs.

J. The Department should adopt alternative approaches.

As a result, the Department should consider several other healthcare-related alternatives, such as (1) delaying compliance dates; (2) grandfathering existing categories of healthcare; (3) exempting religious institutions; or (4) crafting privacy exemptions.

The Department should also consider the alternative of using the biological definition of sex, and it must consider that the statute does not address "gender identity" or sexual orientation on any theory. It must explain why that biological definition cannot be retained. And it must consider the many harms that will follow from this redefinition.

The Department should provide a safe harbor for healthcare providers who seek to use their best medical judgment, including with categorical judgments about the best treatments. Providers should be allowed to impose rigorous gatekeeping procedures before interventions. And HHS should recognize the validity of various forms of treatment for gender dysphoria, such as watchful waiting, treatment for other mental health issues, and counseling. The Department should also allow for alternate diagnoses. It must examine and consider the science supporting alternate treatments and it should expressly permit doctors to use their best judgment to select what they think is the best treatment to provide.

The Department likewise should expressly exclude children under 18 from any mandates about these life-altering procedures. The Department should not apply a single standard to treatment for children, adolescents, and adults. Even clinicians who promote experimental new practices agree that children and adolescents should not be treated as mini-adults and instead require standards and treatment protocols that reflect the different developmental needs of children and adolescents.[63]

The Department should provide that the proposed rule neither displaces requirements for parental informed consent for minors' medical treatments nor precludes giving parents full information about their child's healthcare nor prevents parents from selecting a healthcare provider or medical chaperone of the sex of their choice for their child, especially for sensitive medical exams or inpatient care. In particular, parents of student athletes should be able to select the sex of the healthcare provider or medical chaperone performing examinations, providing therapy, or otherwise having access to young people in private settings, especially when a parent is not present. Likewise, a patient should be able to select whether care for intimate activities, such as showering or toileting, is performed by person of the same sex as the patient, that is, by a biological male or female. It also should provide express carve-outs for women's private spaces and programs in healthcare facilities, including hospital wards, breastfeeding programs, post-partum support groups, lactation programs, breast cancer groups, and other areas.

The agency should consider and say whether its proposed provisions on "gender identity" and sex stereotyping protect against healthcare discrimination against detransitioners: persons who seek to desist from identifying with a gender opposite their biological sex, often after undergoing medical interventions to support that identity. These concerns are particularly acute given the phenomenon

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[63] EPPC, Comments at 4–5, https://eppc.org/news/eppc-scholars-oppose-hhs-proposed-insurance-mandate-for-transgender-puberty-blocking-drugs-cross-sex-hormones-and-surgeries/.

of rapid-onset gender dysphoria and the skyrocketing rates of children, often young girls, confused about their sex, and who are rushed into interventions with no gatekeeping.[64] These young people will come to regret their interventions, and support is needed for them to restore in their bodies what can be restored.

Education and healthcare discrimination against detransitioners is rampant. "When these young adults transitioned, they received affirmation from doctors, mental health practitioners, and the trans and queer community. After transitioning back, they report feeling abandoned by the surgeons and hormone providers that irrevocably altered their bodies and the therapists who refuse to take responsibility for the dangers of 'gender affirming' care."[65] The Department should expressly consider whether to clarify that it is sex discrimination for educators and providers to withdraw support and their best health efforts from a student or patient when the student or patient states that they regret their interventions and now wishes to be affirmed in their sex.

Therapy that is not considered under the vague umbrella of "gender affirming care," but helps patients live with their own biological sex, should be available on the same basis as other healthcare. The denial of such therapy would appear to be sex discrimination, under the Department's logic, and yet the proposed rule would appear to prohibit any care not considered "gender affirming." If it is unlawful not to provide treatment for patients uncomfortable with their sex, surely the most unfortunate case of needed treatment for discomfort with one's sex occurs when a patient needs therapy to undo the effects of procedures or practices that sought to surgically remove healthy sexual organs or to suppress puberty or sex-based hormones.

The Department must answer a simple question: Is it not sex discrimination if a patient cannot receive this same type of medical care if the patient has a congruent sex and gender identity? Why should cosmetic and other procedures be available only to people who identify as the opposite sex, rather than also to people who are uncomfortable with their own sex? Of course, this issue merely exposes the internal contradictions in the Department's definition of sex.

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[64] Abigail Shrier, *Irreversible Damage: The Transgender Craze Seducing Our Daughters* (Regnery 2020).

[65] Ginny Gentles, Detransitioners and Parents vs. Gender Ideology (March 30, 2022), https://www.iwf.org/2022/03/30/detransitioners-and-parents-vs-gender-ideology%EF%BF%BC/.

III. The proposed redefinition of sex discrimination is unlawful.

The proposed rule lacks any legal authority to expand Section 1557 to address abortion, sexual orientation, and gender identity. In particular, the Department lacks any authority to require abortion or other controversial, life-altering procedures.

A. The proposed redefinition of sex conflicts with many federal laws.

The proposed redefinition of the meaning of "sex" and sex discrimination is first of all a violation of the ACA itself, in which Congress repeatedly speaks of sex as a biological binary. The redefinition also violates many other laws, including: the Administrative Procedure Act, the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb-1, the First Amendment's Free Speech and Free Exercise of Religion Clauses, other constitutional doctrines, and many other statutes.

This section will address many of these legal infirmities in detail. To summarize:

- The proposed Section 1557 mandate exceeds the authority of Section 1557, the Affordable Care Act, and Title IX of the Education Amendments of 1972, as amended, all of which limit discrimination on the basis of sex and do not encompass discrimination on the basis of gender identity, sexual orientation, or abortion.
- The proposed Section 1557 gender identity and sexual orientation mandate exceeds the authority of Title IX, as incorporated into Section 1557, which does not apply when it would violate the religious tenets of an organization.
- The proposed Section 1557 mandate conflicts with the ACA's provision that "[n]othing in this Act shall be construed to have any effect on Federal laws regarding (i) conscience protection."[66]
- *Bostock v. Clayton County*[67] did not interpret the ACA or Title IX, and does not require a Section 1557 abortion, gender identity, or sexual orientation mandate.

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[66] 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).

[67] 140 S. Ct. 1731 (2020).

- The proposed Section 1557 mandate conflicts with Section 1554 of the ACA,[68] specifically: parts (1)–(2) and (6) because it pressures providers out of federally funded health programs and the practice of healthcare; parts (3)–(4) because it requires providers to speak in affirmance of abortion and other harmful procedures and refrain from speaking in accordance with the unborn child's humanity and a patient's biological sex and related medical needs; part (5) because it requires providers to deprive patients of informed consent by preventing them from warning patients of the dangers of abortions and interventions; and also part (5) because it forces providers to violate their ethical and conscientious standards as healthcare professionals.
- The proposed Section 1557 mandate violates 42 U.S.C. § 300a-7(d) because it compels providers, within health service programs funded by HHS, to provide abortions, sterilizations, and other harmful procedures, interventions, and information in violation of their religious beliefs and moral convictions.
- The proposed Section 1557 mandate violates the Medicare statute's restriction that it may only pay for items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,"[69] and it removes the authority of states to declare that interventions, such as life-altering surgeries, such as a mastectomy or sterilization, or life-altering procedures, such as puberty blockers or testosterone suppression, are not covered under Medicaid and Medicaid Expansion CHIP programs, in violation of 42 U.S.C. § 1396d(r)(5).
- The proposed Section 1557 mandate conflicts with the First Amendment and to the Religious Freedom Restoration Act, because it substantially burdens the exercise of religion by religious providers and is not the least restrictive means of advancing a compelling government interest.

ADF represents medical providers in court raising these claims against HHS. The American College of Pediatricians, the Catholic Medical Association, and an OB-GYN doctor who specializes in caring for adolescents have filed suit in federal court to challenge the HHS gender identity mandates requiring doctors to perform life-altering surgeries, such as a mastectomy or sterilization—on any patient, including a child—or life-altering procedures, such as puberty blockers or

[68] 42 U.S.C. § 18114.

[69] 42 U.S.C. § 1395y(a)(1)(A).

testosterone suppression, if the intervention violates a doctor's medical judgment or religious beliefs.[70]

This section now will provide more information about the key legal infirmities in the proposed rule, infirmity by infirmity.

B. The proposed redefinition of sex lacks statutory authority.

Section 1557 provides:

> Except as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of title 29, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.

None of the anti-discrimination statutes mentioned in Section 1557 prohibit discrimination on account of gender identity or sexual orientation. Among the statutes cited in Section 1557, the only one that prohibits discrimination on the basis of sex is Title IX of the Education Amendments of 1972 (Title IX).

1. The proposed rule violates the texts of Section 1557 and Title IX.

Many provisions in the ACA show that Congress understood "sex" to mean the biological binary of male and female, and not to encompass the concept of

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[70] ADF, American College of Pediatricians v. Becerra, https://adflegal.org/case/american-college-pediatricians-v-becerra; *see American College of Pediatricians v. Becerra*, No. 1:21-cv-00195 (E.D. Tenn.).

gender identity.[71] Likewise, language throughout Title IX reflects that Congress understood "sex" as a biological binary and not as including gender identity.[72]

For example, the ACA requires the provision of "information to women and health care providers on those areas in which differences between men and women exist."[73] In another instance, in Section 3509 of the ACA includes the statute's only express references to the term "sex." Congress created the Office of Women's Health within the FDA, and instructed the Director of the Office to provide "analysis of [clinical trial] data by sex," "analysis of data by sex in [Food and Drug] Administration priorities," and "estimates of funds needed to monitor clinical trials and analysis of data by sex."[74] And Congress instructed the Office to "provide information to women and health care providers on those areas in which differences between men and women exist."[75] The text of the ACA includes other language showing Congress legislated using a binary sex construct. The statute teems with references to "women," "mothers," and variants of the same. There are one hundred thirty-seven references to "women," twelve references to "woman," eight references to "mother" and "mothers," and ten references to "maternal."[76]

The ACA also incorporates a binary sex understanding of the biologically binary nuclear family in the ACA. For example, Congress defined a primary care provider as "a clinician" responsible for "providing preventative and health promotion services for men, women, and children of all ages."[77] Likewise, under Section 2951 of the ACA titled "Maternal, Infant, and Early Childhood Home Visitation Programs," Congress defined "eligible family" to include "a woman who is pregnant, and the father of the child if the father is available."[78] So, too, a provision barring certain health insurance plans from requiring a referral for obstetrics and

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[71] *See, e.g.*, 124 Stat. at 261, 334, 343, 551, 577, 650, 670, 785, 809, 873, 890, 966.

[72] *See, e.g.*, 20 U.S.C. §§ 1681(a)(2); 1681(a)(8), 1686.

[73] 124 Stat. at 536–37.

[74] *Id.*

[75] *Id.* at 536.

[76] *See, e.g.*, *id.* at 551 (referring to "pregnant women"); *id.* at 577 (providing reasonable break time for nursing mothers).

[77] *Id.* at 650.

[78] *Id.* at 334, 343.

gynecological care applies only to a "female participant, beneficiary, or enrollee" who seeks this care.[79]

The ACA furthermore features the use of binary, gendered pronouns, rather than concepts of sex or gender on a spectrum. The ACA's amendment to the Fair Labor Standards Act for instance provides "a reasonable break time for an employee to express breast milk for her nursing child."[80] The ACA in fact uses the sex binary "his or her" at least seven times, by:

- barring certain "discrimination against any employee with respect to his or her" employment;[81]
- providing, to calculate clinical time, "up to 50 percent of time spent teaching by such member may be counted toward his or her service obligation";[82]
- providing "[n]othing in this subtitle shall be construed to interfere with or abridge an elder's right to practice his or her religion";[83]
- requiring "the representative [to] inform[ ] the reference product sponsor . . . of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph";[84]
- providing for "[c]ash benefits paid into a Life Independence Account of an eligible beneficiary shall be used to purchase nonmedical services and supports that the beneficiary needs to maintain his or her independence";[85] and
- allowing a "physician or other eligible professional . . . to review his or her individual results before they are made public."[86]

Section 1557 says nothing about gender or gender identity. The terms "gender" and "gender identity" appear nowhere in Section 1557.

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[79] *Id.* at 890.

[80] 124 Stat. at 577.

[81] *Id.* at 261.

[82] *Id.* at 670, 1003.

[83] *Id.* at 785.

[84] *Id.* at 809.

[85] *Id.* at 873.

[86] *Id.* at 966.

In contrast, elsewhere in the ACA, Congress used the term "gender" to mean something other than sex. In section 5306 of the ACA, Congress conditioned grants based on recipients showing participation of "different genders and sexual orientation" in their programs.[87] Congress had a chance to make Section 1557 address gender identity, along with biological sex, but Congress chose to incorporate Title IX's definition of "sex," which also does not include gender identity.

The federal executive branch historically has shared this understanding of the text, because HHS refers many times in its Title IX regulations to "members of one sex" and "members of the other sex."[88] For example, HHS's Title IX regulations provide an exception for "separation of students by sex within physical education classes or activities during participation in wrestling, boxing, rugby, ice hockey, football, basketball and other sports the purpose or major activity of which involves bodily contact."[89] HHS also allows classes on human sexuality to "be conducted in separate sessions for boys and girls."[90] HHS likewise allows choral classes "based on vocal range or quality which may result in a chorus or choruses of one or predominantly one sex."[91] Among many other examples, HHS also allows separate athletic scholarships "for members of each sex [to] be provided as part of separate athletic teams for members of each sex."[92]

For all these reasons, Section 1557 does not address sexual orientation or gender identity. As the court held in *Texas v. EEOC*, HHS lacks the authority it claims.[93] As here, HHS interpreted Section 1557 of the Affordable Care Act to prohibit federally funded entities from "restricting an individual's ability to receive medically necessary care, including gender-affirming care, from their health care provider solely on the basis of their sex assigned at birth or gender identity."[94] But,

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[87] *Id.* at 626. This section added a new section 756, 42 U.S.C. 294e-1, where Congress used those terms expressly.

[88] 45 C.F.R. § 86.7; *see* 45 C.F.R. § 86.1 *et seq*.

[89] 45 C.F.R. § 86.34(c).

[90] 45 C.F.R. § 86.34(e).

[91] 45 C.F.R. § 86.34(f).

[92] 45 C.F.R. § 86.37(c)(2).

[93] *State of Texas v. EEOC*, No. 74 Civ. 2:21-CV-194-Z at *6 (N.D. Tex. Oct. 1, 2022). This opinion is attached to this comment.

[94] *Id*. at *2.

as the court held, the guidance at issue in that case, just like the position set forth in proposed rule, "exceeds Section 1557's requirements."[95]

Finally, all of these considerations equally apply to any other source of federal law, such as disability law, that the Department might rely on, under any theory, to impose similar mandates involving abortion, "gender identity," or "sexual orientation." All of these concerns apply to attempts to address these issues through other protected classes added by the rule, such as marital status, association, sex stereotypes, sex characteristics.[96] And all of these concerns apply to the other protected classes in the other laws incorporated by reference into Section 1557.

The Department thus should not try to shoehorn these mandates into any other laws, such as Section 54 of the Rehabilitation Act or the Americans with Disabilities Act (ADA).[97] The ADA in fact expressly excludes gender identity disorders from the definition of the term "disability."[98]

As the court in *Texas v. EEOC* held, HHS in fact acted unlawfully when it suggested that these disability laws require healthcare providers to perform (and others to pay for) these harmful procedures.[99] The March 2 Guidance interpreted Section 504 of the Rehabilitation Act and Title II of the Americans with Disabilities Act (ADA), warning "[r]estrictions that prevent otherwise qualified individuals from receiving medically necessary care on the basis of their gender dysphoria, gender dysphoria diagnosis, or perception of gender dysphoria may . . . also violate Section 504 and Title II of the ADA."[100] But the proposed rule, like "the March 2 Guidance leaves the reader with the impression that Section 504 generally defines gender dysphoria as a disability—subject to some exceptions—even though the opposite is true."[101] This "misstatement of the law" was grounds for vacating the guidance.[102]

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[95] *Id*. at *20.

[96] *Id*. at *2.

[97] *Williams v. Kincaid*, 45 F.4th 759, 769 (4th Cir. 2022).

[98] 42 U.S.C. § 12211(b).

[99] *See State of Texas v. EEO*C, No. 74 Civ. 2:21-CV-194-Z at * 13 (N.D. Tex. Oct. 1, 2022) (sex stereotyping.

[100] *Id*. at *2.

[101] *Id*. at 18.

[102] *Id*.

2. Substantive canons of interpretation preclude the proposed rule's definition of sex and sex discrimination.

What is more, the Constitution's clear-notice canon bars the government's interpretation. Neither the ACA nor Title IX nor any other statute prohibits gender identity discrimination in healthcare programs receiving federal financial assistance or grants. Congress must expressly decide any major issue, such as whether to require all doctors nationwide to offer, perform, refer for, and affirm abortions, sterilizations, life-altering surgeries (such as a mastectomy), or life-altering procedures (such as puberty blockers or testosterone suppression). And here, Congress did not do that.

Under what former-Professor Barrett called a "time-honored" substantive canon of statutory interpretation,[103] the Constitution limits statutes that preempt traditional state police-power regulations, such as over medicine, healthcare, education, and real estate,[104] or that impose grant conditions[105] to those requirements "unambiguously" set forth on the face of the statute.[106] A "clear and manifest" statement is necessary for a statute to preempt "the historic police powers of the States."[107] Congress thus must deliberate and resolve each specific term.[108]

This canon imposes "a particularly strict standard."[109] Unlike the ordinary clarity required for regular statutes, Congress must make "its intention" "'unmistakably clear in the language of the statute,'"[110] measured at the time of enactment.[111] Congress may not use "expansive language"[112] to impose "a burden of unspecified proportions and weight, to be revealed only through case-by-case

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[103] Amy Coney Barrett, *Substantive Canons and Faithful Agency*, 90 B.U.L. Rev. 109, 143–150, 173 (2010).

[104] *Bond v. United States (Bond II)*, 572 U.S. 844, 858 (2014).

[105] *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17, 24 (1981).

[106] *Id.* at 17.

[107] *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

[108] *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 551 (1985).

[109] *Port Auth. Trans-Hudson Corp. v. Feeney*, 495 U.S. 299, 305 (1990).

[110] *Gregory v. Ashcroft*, 501 U.S. 452, 460, 464 (1991) (citation omitted).

[111] *Carcieri v. Salazar*, 555 U.S. 379, 388 (2009).

[112] *Bond II*, 572 U.S. at 857–58, 860.

adjudication."[113] Nor may the federal government "surpris[e] participating States with post acceptance or 'retroactive' conditions."[114]

These structural principles protect not only the states but "the individual as well."[115] This "division of power is not about preserving state power, so much as it is about promoting individual liberty."[116] Each statute subject to this canon thus "must be read consistent with principles of federalism inherent in our constitutional structure" in all applications.[117] The Supreme Court thus applies this canon to protect private parties because anytime the government "intrudes into an area that is the particular domain of state law," Congress must " 'enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power and the power of the Government over private property."[118]

The Constitution imposes this canon on the ACA and HHS grants laws because the ACA and any grants statute are spending statutes that displace traditional state regulations over medicine, healthcare, constitutional liberties, and real estate use—and thus intrudes on an "area[ ] of traditional state responsibility."[119] HHS purports to preempt the prerogative of States not only to regulate the healing professions, but also to maintain standards of care that rely on the medical judgment of health professionals as to what is in the best interests of their patients.

But Congress did not unmistakably address gender identity in the 2010 ACA, or the 1972 Title IX, or in any other relevant statutes, let alone did Congress unmistakably force anyone—let alone every religious healthcare provider nationwide—comply with its new mandates. It is a major question to decide whether to mandate that providers offer, provide, and affirm abortions, sterilizations, and other services on demand, especially when those services could

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[113] *Bd. of Educ. of Hendrick Hudson Cent. Sch. Dist. v. Rowley*, 458 U.S. 176, 190 n.11 (1982); *Arlington Cent. Sch. Dist. Bd. of Edu. v. Murphy*, 548 U.S. 291, 296 (2006); *Dellmuth v. Muth*, 491 U.S. 223, 232 (1989).

[114] *Pennhurst*, 451 U.S. at 25.

[115] *Bond v. United States*, 564 U.S. 211, 222 (2011); *see also New York v. United States*, 505 U.S. 144, 181 (1992).

[116] *Ohio v. Yellen*, No. 1:21-CV-181, 2021 WL 2712220, at *10 (S.D. Ohio July 1, 2021).

[117] *Bond II*, 572 U.S. at 856–60.

[118] *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) (citation omitted).

[119] *Bond II*, 572 U.S. at 858.

include life-altering surgeries, such as a mastectomy or sterilization, or life-altering procedures, such as puberty blockers or testosterone suppression. It is even more of a major question to decide to impose this mandate regardless of a provider's medical judgment or religious beliefs. Nor are these mandates in accord with the understanding that existed among the public or the courts when the States and doctors first chose to begin accepting federal grants or accepting Medicare, Medicaid, and CHIP as payment for medical services. No one could unmistakably know or "clearly understand" at that time that HHS would impose the conditions created by HHS that apply in the objectionable ways described above—indeed, these procedures remain experimental. Because Congress did not "in fact face[ ], and intend[ ] to bring into issue," the mandate's particular disruption of state and private authority, its impositions violate the clear notice rule.[120]

The major questions doctrine buttresses this interpretation. In adding sex discrimination to the Title IX in 1972, Congress cannot be found to have overturned the longstanding practice that doctors treat patients by biological sex—Congress does not hide "elephants in mouseholes."[121] This sea change in medicine was not within the government's discretion under the ACA. It is "a question of deep 'economic and political significance'" that Congress did not "expressly" assign to the executive branch.[122] Under this substantive canon, Congress must speak clearly to grant powers of "vast 'economic and political significance.'"[123]

Here, any alleged discretion to impose the mandate's new mandate is excluded by the canon of constitutional avoidance. If an act is subject to "competing plausible interpretations,"[124] the statute must be construed "to avoid not only the conclusion that it is unconstitutional but also grave doubts upon that score."[125] Under these canons, any ambiguity requires adopting "the less expansive reading."[126]

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[120] *United States v. Bass*, 404 U.S. 336, 349 (1971).

[121] *Wittmer v. Phillips 66 Co.*, 915 F.3d 328, 336 (5th Cir. 2019) (Ho, J., concurring) (quoting *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001)).

[122] *King v. Burwell*, 576 U.S. 473, 474 (2015).

[123] *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489 (citation omitted).

[124] *Clark v. Martinez*, 543 U.S. 371, 381 (2005).

[125] *Almendarez-Torres v. United States*, 523 U.S. 224, 237–328 (1998) (quotation omitted).

[126] *Kollaritsch v. Mich. State Univ. Bd. of Trustees*, 944 F.3d 613, 629 (6th Cir. 2019) (Thapar, J., concurring).

Were HHS to have the power to impose its mandates about abortion, sexual orientation, and gender identity, its rule would exceed Congress's Article I enumerated powers and transgress on the reserved powers of the State under the federal constitution's structural principles of federalism and the Tenth Amendment.[127] The public and the States thus unconstitutionally lacked clear notice when the laws were passed or the grants were made that the statutes would apply in this way.[128] If Section 1557's mandates are not construed narrowly under the clear-notice canon, it will effectively coerce or commandeer the public and the States, including in grant conditions and in the States' historical and well-established regulation of healthcare, freedom of speech, conscience protection, and religious freedom.[129]

For these reasons, the proposed rule should also receive no deference by a court.[130] Any deference only applies in the event of ambiguity.[131] Here, the textual tools of statutory interpretation, including substantive canons, remove any arguable ambiguity. But, if there were any ambiguity, these canons would compel a narrow reading.

3. Bostock *does not support the proposed rule.*

Bostock v. Clayton County[132] is not to the contrary. *Bostock* did not address abortion, and *Bostock* did not interpret the ACA or Title IX. Nor did *Bostock* consider the "particularly strict" effect of the clear-notice canon when it interpreted Title VII.

Just because a federal law addresses sex discrimination does not mean it is "materially identical" to Title VII, and even less does it mean that it incorporates the government's aggressive and retroactive sex stereotyping and gender identity theories in every detail, and even less does it mean that the law did so with unmistakable clear notice at passage.

In fact, in *Bostock*, the Supreme Court rejected the claim "that our decision will sweep beyond Title VII to other federal or state laws that prohibit sex

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[127] U.S. Const. art. I, § 8, cl. 1; *id.* amend. X.

[128] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[129] *New York v. United States*, 505 U.S. at 162.

[130] *Auer v. Robbins*, 519 U.S. 452 (1997).

[131] *Kisor v. Wilkie*, 139 S. Ct. 2400, 2408 (2019).

[132] 140 S. Ct. 1731.

discrimination."[133] As the Supreme Court warned, "none of these other laws are before us; we have not had the benefit of adversarial testing about the meaning of their terms, and we do not prejudge any such question today."[134] Even under Title VII, the Court did "not purport to address bathrooms, locker rooms, or anything else of the kind," such as intimate settings in medicine.[135] The Court was also "deeply concerned with preserving" the constitutional and statutory rights of religious institutions.[136]

According to HHS, none of the Supreme Court's stated limits on *Bostock* matter.[137] But, even if these limits were not there, the reasoning of *Bostock* still would not support the new Section 1557 mandates.

Bostock considers "transgender status" relevant only if it is part of "sex" discrimination, such as when an employer fires an employee for conduct or personal attributes on these bases that it would tolerate in a person of the opposite biological sex.[138] Even under *Bostock*, Title VII allows an employer to take employment actions based on conduct or personal attributes that it would not tolerate in employees of either biological sex.[139] This means, for example, that employers may make decisions even after *Bostock* based on biology, so long as the employer regards treats men and women equally.[140] Employers just must apply rules equally to both sexes. An employer, for example, may decide not to employ any person, male or female, who takes hormones to alter body features cosmetically to resemble the other sex—whether taken by a biological man who wants to appear as a woman, or by a biological woman who wants to appear as a man, or by a biological woman who wants to appear more feminine, or by a biological man who wants athletic advantages. This policy would not be "sex" discrimination as defined in *Bostock* because the rules apply equally to both sexes.[141]

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[133] *Id.* at 1753.

[134] *Id.*

[135] *Id.*

[136] *Id.* at 1753–54.

[137] May 10, 2021 Notice of Enforcement at 2.

[138] *Bostock*, 140 S. Ct. at 1741–42.

[139] *Id.* at 1740, 1742.

[140] *Id.*

[141] *Id.* at 1746–47 ("We agree that homosexuality and transgender status are distinct concepts from sex.").

Outside the specific context of hiring and firing to which *Bostock* applied, the reasonableness of this distinction between sex discrimination and what HHS considers gender identity discrimination is readily apparent in many non-controversial ways. Doctors who refuse to abort any child, male or female, do not discriminate by sex. Doctors who refuse to amputate any healthy organs, male or female, do not discriminate by sex. Doctors who refuse to give puberty blockers to any kids, male or female, do not discriminate by sex. Nor do doctors discriminate by sex if they refuse to prescribe hormones to any healthy patient, male or female, to alter body features cosmetically to resemble the other sex. Even less do doctors treat one sex worse than the other when they refuse to let any member of one sex, male or female, access medical programs or private spaces reserved for the other sex.

The same is true for speech. If doctors refer to all patients by the correct sex, including by using biologically correct pronouns, they do not discriminate against any patient, male or female, by sex. Doctors who code, chart, and treat all patients, male or female, by biological sex do not discriminate against men or women. Nor do doctors discriminate by sex if they give full information warning all patients, male or female, about the risks and permanent effects of abortions and life-altering interventions.

The inapplicability of *Bostock* to Section 1557 is set forth in the recent decision in *Texas v. EEOC*, which rejected the view of *Bostock* on which HHS's proposed rule rests.[142]

HHS's March 2 guidance announced that HHS has adopting in practice the same legal position about Section 1557 as the proposed rule seeks to codify in federal regulations. The March 2 Guidance interprets Section 1557 of the Affordable Care Act to prohibit federally funded entities from "restricting an individual's ability to receive medically necessary care, including gender-affirming care, from their health care provider solely on the basis of their sex assigned at birth or gender identity."[143]

The *Texas v. EEOC* court held that this March 2 guidance lacks any support from *Bostock*. As the court recognized, "the crux of the" disagreement about the

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[142] *State of Texas v. EEOC*, No. 74 Civ. 2:21-CV-194-Z at *6 (N.D. Tex. Oct. 1, 2022). This opinion is attached to this comment. *See also Olivarez v. T-mobile USA, Inc.*, 997 F.3d 595,601 (5th Cir. 2021) (Under Title VII, a "plaintiff must plead sufficient facts to make it plausible that he was discriminated against 'because of his protected status" - not because of mere "associated" conduct.).

[143] *Id.* at *2.

correct meaning of *Bostock* "distills down to one question: is the non-discrimination holding in *Bostock* cabined to "homosexuality and transgender status" or does it extend to correlated conduct," such as sex-specific dress, restroom, pronoun, and healthcare practice? And, as the court held, HHS officials "misread *Bostock* by melding 'status' and 'conduct' into one catchall protected class covering all conduct correlating to 'sexual orientation and gender identity.' Justice Gorsuch expressly did not do that."[144] Justice Gorsuch instead denied that *Bostock* "would reach at least seven categories of Title VII litigation: (1) bathrooms, locker rooms, or anything else of the kind; (2) women's sports; (3) housing; (4) employment by religious organizations; (5) healthcare; (6) freedom of speech; and (7) constitutional claims.[145] Plus, "Justice Gorsuch's majority *presumes* there will be Title VII cases where the protected class 'sex' may not reach particular conduct."[146] The Court "draws a distinction between things that are 'inextricably' related and those that are related in 'some vague sense.'"[147] And so, the court concluded, this is why HHS "cannot rely on the words and reasoning of *Bostock* itself to explain why the Court prejudged what the Court expressly refused to prejudge."[148]

As a result, HHS's March 2 guidance, just like the proposed rule, "exceeds Section 1557's requirements and is not justified by *Bostock*."[149]

4. HHS's interpretation in the 2020 rule was correct.

HHS thus correctly concluded in the 2020 ACA Rule, after consideration of and responses to public comments, that the mandate in the proposed rule (and in the 2016 rule) was unlawful and unwarranted. For example, the 2020 ACA Rule concluded:

- The redefinition of sex to address abortion, gender identity, and sexual orientation "are essentially legislative changes that the Department lacked the authority to make. They purported to impose additional legal requirements on covered entities that cannot be justified by the text of Title IX, and in fact are in conflict with express exemptions in Title IX, even

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[144] *Id*. at *6.

[145] *Id*. at *7–8.

[146] *Id*. at *11.

[147] *Id*. at *11 (citation omitted).

[148] *Id*. at *8.

[149] *Id*. at *20.

though Title IX provides the only statutory basis for Section 1557's provision against discrimination "on the basis of sex."[150]

- Because the Department's failure to incorporate the abortion neutrality language at 20 U.S.C. 1688 (hereinafter "abortion neutrality") and the Title IX religious exemption formed part of the *Franciscan* court's reasoning when it vacated parts of the 2016 Rule, this final rule amends the Department's Title IX regulations to explicitly incorporate relevant statutory exemptions from Title IX, including abortion neutrality and the religious exemption.[151]
- "'Sex' according to its original and ordinary public meaning refers to the biological binary of male and female . . . ."[152]
- "The Department disagrees with commenters who contend that Section 1557 or Title IX encompass gender identity discrimination within their prohibition on sex discrimination."[153]
- "The text of Title IX also demonstrates that it is not susceptible to an interpretation under which it would prohibit gender identity discrimination."[154]
- "For most of the history of Title IX case law, the commonplace practices that account for real physiological differences between the sexes without treating either sex less favorably were uncontroversial and not considered discriminatory."[155]
- "Distinctions based on real differences between men and women do not turn into discrimination merely because an individual objects to those distinctions. Title IX does not require covered entities to eliminate reasonable distinctions on the basis of sex whenever an individual identifies with the other sex, or with no sex at all, or with some combination of the two sexes . . . ."[156]

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[150] 2020 Rule, 85 Fed. Reg. at 37,162.

[151] *Id.*

[152] *Id.* at 37,178.

[153] *Id.* at 37,183.

[154] *Id.*

[155] *Id.* at 37,184.

[156] *Id.* at 37,185-86.

There is no reason to depart from the 2020 rule's interpretation. The 2020 rule was correct on the law, and any difference in a policy view is not enough to justify changing course and ignoring the law.

These important interpretive matters about the proposed rule's lack of statutory authority are discussed in greater detail, especially as to Title IX, in the attached ADF comments and legal filings. These analyses are incorporated by reference, rather than being duplicated in full and at greater length here.

C. The proposed mandates violate statutory conscience protections.

The proposed rule also conflicts with statutory conscience protections in violation of the ACA's provision that "[n]othing in this Act shall be construed to have any effect on Federal laws regarding (i) conscience protection."[157]

- The Church Amendments protect in various ways the conscience rights of individuals who object to abortion or sterilization procedures.
- Federally funded programs may not require an "individual to perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions."[158]
- "No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions."[159]
- The ACA states that "nothing in this title (or any amendment made by this title), shall be construed to require a qualified health plan to provide [abortion coverage] as part of its essential health benefits for any plan year."[160]

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[157] 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).

[158] 42 U.S.C. § 300a-7(b).

[159] 42 U.S.C. § 300a-7(d).

[160] 42 U.S.C. § 18023; *see also* 42 U.S.C. §§ 280h-5(a)(3)(C), 280h-5(f)(1)(B).

- Section 245 of the Public Health Service Act, prohibits the federal government and any state or local government receiving federal financial assistance from discriminating against any healthcare entity because the entity refuses to perform abortions, provide referrals for abortions, or to make arrangements for such abortions.[161]

Under the Weldon Amendment, which has been readopted or incorporated by reference in every HHS appropriations act since 2005, no funds may be made available under an HHS appropriations act to a government entity that discriminates against an institution or individual physician or healthcare professional because the entity or individual "does not provide, pay for, provide coverage of, or refer for abortions."[162]

The Public Health Service Act prohibits the Department from discriminating against anyone who refuses to: undergo training in the performance of induced abortions; require or provide such training; perform such abortions; provide referrals for such training or such abortions; or make arrangements for such activities. It also prohibits HHS from discriminating against someone because they attend (or attended) a post-graduate physician training program, or any other program of training in the health professions, that does not (or did not) perform induced abortions or require, provide, or refer for training in the performance of induced abortions, or make arrangements for the provision of such training.[163]

The Emergency Medical Treatment and Labor Act (EMTALA) also protects unborn children. It requires emergency room doctors to stabilize the care of both the mother and the unborn child. Emergency room physicians can, and do, treat ectopic pregnancies and other life-threatening conditions. Elective abortion is not life-saving care—it ends the life of the unborn—and the government can't force doctors to perform procedures that violate their conscience and religious beliefs.

A federal district court has thus issued an order in *State of Texas v. Becerra* against the Department that blocks the Biden administration's attempt to force emergency room doctors to perform abortions even if doing so violates their

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[161] 42 U.S.C. § 238(n).

[162] Weldon Amendment, Consolidated Appropriations Act, 2009, Pub. L. No. 111-117, 123 Stat 3034.

[163] Section 245, contained in 42 U.S.C. § 238n.

conscience or religious beliefs.[164] The court determined that the State of Texas and two groups of pro-life physicians are likely to prevail in their case against HHS. In that case, ADF represents the American Association of Pro-Life Obstetricians & Gynecologists and the Christian Medical & Dental Associations. ADF asked the court to halt the Department from employing the Emergency Medical Treatment and Labor Act to force doctors to provide elective abortions in the emergency room while their lawsuit proceeds. The injunction applies in Texas and to the members of AAPLOG and CMDA. As the court held, HHS's guidance "goes 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." And the court found that "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."

With its effort to turn EMTALA from a shield for children into a sword against them, the Department is needlessly, illegitimately, and illegally working to turn emergency rooms into walk-in abortion facilities. Doctors get into their line of work to save lives and care for people—and that's exactly what they are ethically, morally, and legally required to do. ADF will continue to defend those in the medical profession who wish to respect and save lives, not take them. HHS should not address or incorporate language currently at the center of litigation, until the cases conclude.

This mandate also conflicts with limits on federal funds, which cannot go in some circumstances to programs where abortion is a method of family planning. Title X of the PHS Act, 42 U.S.C. § 300a-6, provides that "None of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning." The Department must explain how prohibiting "termination of pregnancy discrimination" in Title X family planning programs (without Title IX's or Section 1303's abortion neutrality provisions) will *not* make those programs into programs where abortion is a method of family planning in violation of the Title X statute.

The Department must explain whether HHS OCR's letter to pharmacies—telling them they are required to stock and dispense abortion drugs—is an implementation of this proposed rule, or will be a requirement if this proposed rule

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[164] ADF, *Court halts Biden admin's attempt to turn ERs into abortion facilities*, https://adflegal.org/press-release/court-halts-biden-admins-attempt-turn-ers-abortion-facilities. More information about the proper interpretation of EMTALA is attached from the case's documents.

is finalized.[165] The Department must clarify how it reached that legal conclusion, and how it complies with the laws discussed herein.

Section 1303 of the ACA has a host of restrictions that preclude Section 1557 and this rule from being used to prohibit "termination of pregnancy discrimination" in the way the Department proposes. The Department must specifically address how this proposed rule complies with Section 1303's statements that:

- "A State may elect to prohibit abortion coverage in qualified health plans offered through an Exchange in such State if such State enacts a law to provide for such prohibition." *How is it **not** termination of pregnancy discrimination under this proposed rule for a State to enact such a law?*
- "[N]othing in this title (or any amendment made by this title),[ ] shall be construed to require a qualified health plan to provide coverage of services described in subparagraph (B)(i) or (B)(ii) as part of its essential health benefits for any plan year." *How does this proposed rule **not** require those plans to provide coverage of those abortions?*
- "[S]ubject to subsection (a), the issuer of a qualified health plan shall determine whether or not the plan provides coverage of services described in subparagraph (B)(i) or (B)(ii) as part of such benefits for the plan year." *How does this proposed rule **not** take this choice away from QHPs and require them to cover abortions?*
- "If a qualified health plan provides coverage of services described in paragraph (1)(B)(i), the issuer of the plan shall not use any amount attributable to any of the following for purposes of paying for such services." *How does this proposed rule **not** force QHPs to fund abortion services from all available funds rather than restricting the funds that may be used to cover them?*
- "No qualified health plan offered through an Exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions." *How does this proposed rule **not** require QHPs to discriminate against health care providers and facilities that do not provide, pay for, provide coverage of, or refer for abortions, due to this proposed rule requiring the QHP to ensure the services it offers include abortions?*

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[165] https://www.hhs.gov/sites/default/files/pharmacies-guidance.pdf

- "Nothing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor." *How does this proposed rule **not** purport to preempt state pro-life laws by requiring provision of abortion in States where doing so is illegal?*
- "Nothing in this Act shall be construed to have any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion." *How does this proposed rule **not** have effects on Federal laws protecting individuals and entities from being involved in abortions, when it prohibits them from engaging in "termination of pregnancy discrimination"?*

42 U.S.C. § 18023.

Rather than deal with any of these conscience statutes, or with any of these other restrictions on abortion funding, the Department simply glosses over them, and appears willing to do so until otherwise ordered by a court. The Department seems intent on enacting a maximalist view of its power to promote abortion through exceedingly vague language. But, as with other regulations, the Department must consider the effects of its proposal up front and to tailor its regulation to avoid conflicts with these other laws restricting abortion and protecting conscience.

D. The proposed rule infringes on speech and religious exercise rights.

The Department also lacks authority to redefine sex to address sexual orientation, gender identity, or abortion under the U.S. Constitution and related protections for religious freedom and conscience.

1. The proposed rule burdens free speech and religious exercise.

The proposed rule threatens to burden free speech and religious exercise in many ways. These burdens will arise under the redefinition of sex when the Department seeks to coerce providers to offer, perform, endorse, and refer for abortions or other serious interventions; to use inaccurate pronouns; to use irrelevant medical screening questions; to adopt inaccurate medical coding and record keeping practices; to make unethical referrals; to avoid counseling patients

to preserve the life of the unborn child, to accept their biological sex, and/or to be comfortable with sexual relations between a man and a woman; to take on new conforming policies governing speech and information at their medical practices; to issue assurances of compliance with Section 1557; to provide mandatory staff training; and to give mandatory notices of compliance with Section 1557.

The proposed rule will burden speech in healthcare. It will prohibit healthcare providers from using their best medical, ethical, and religious judgments in speaking and giving information to patients. In the past, many providers have conveyed medical views and concerns, in appropriate and patient-sensitive ways, to their patients and their families in the context of their clinical practice. But under the proposed rule, the government might consider this speech to be harassment, indicative of a hostile environment, or discrimination on the basis of gender identity. In particular, for counselors, the government is likely to prohibit all counseling to accept one's biological sex or to be comfortable with sexual relations between a man and a woman—even counseling on these topics sought by the patient—as "conversion therapy," even though they can be in a patient's best interest.

The proposed rule would prevent conversations between providers and their patients, and would constitute a credible threat of government prosecution over those conversations. It would chill a healthcare professional of ordinary firmness from (1) engaging in full and frank conversations on alternatives to abortions, sexuality, medical procedures, and interventions; (2) using proper descriptions of sex in coding and medical records according to biological sex; and (3) the spoken and written use of biologically correct pronouns. It would prohibit providers from engaging in speech that affirms a policy that healthcare is based on biological sex, and that patients are treated based on what their biological sex is. At the same time any mandate requires speech saying the opposite. It could prohibit pro-life speech reflecting the humanity of the unborn child and the best interests of mothers. And it could require providers to support and provide counseling on abortion. Doctors can tell a patient that they have, or prefer to have, healthcare practices promoting abortion and affirming "gender identity," but they cannot tell a patient that they have, or prefer to have, healthcare practices based on protecting unborn life or on biological sex.

If the doctors disregard the mandates, they may lose employment, would jeopardize federal funding, would have to defend lawsuits brought by private citizens, would face investigations brought by the OCR or the Attorney General,

may incur False Claims Act liability, and could even face criminal penalties.[166] HHS' "regulatory scheme for Section 1557 clearly prohibits [their] conduct, thus, putting them to the impossible choice of either defying federal law and risking serious financial and civil penalties, or else violating their religious beliefs.[167] "Because the interpretations of Section 1557 [threaten] to penalize" healthcare providers "for adhering to their beliefs, a substantial burden weighs on the exercise of religion."[168]

The proposed rule's mandates put doctors to an impermissible choice: (A) comply with the mandates and violate your religious beliefs and convictions, or (B) follow your beliefs and risk civil or criminal liability, loss of funding, punitive damages, attorney's fees, costs, and injunctions. That is no choice. Thus, in past cases, the government did not even dispute "that the current Section 1557 regulatory scheme threatens to burden Christian [ ] religious exercise in the same way as the 2016 scheme."[169]

2. The proposed rule violates the Free Speech Clause of the First Amendment.

The proposed rule thus will conflict with the First Amendment's Free Speech Clause. Under the Free Speech Clause, the government may not restrict speech because of its content or viewpoint.[170] But these mandates prohibit talk therapy. And they force healthcare providers to communicate a message that they believe is false—that the unborn child is not a precious member of the human family; that abortion helps women and does not harm them; that "gender identity," rather than biological reality, fundamentally shapes and defines who we truly are as humans; that our sex can change; and that a woman who identifies as a man really is a man, and vice versa. For instance, a doctor would have to pretend that the unborn child is not a living human person. Or a doctor would have to call a biological male a female, or vice versa. Or the provider would have to use any of the other dozens of pronouns upon demand. Or a counselor would have to avoid helping a patient who

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[166] 20 U.S.C. § 1682; 31 U.S.C. § 3729; 18 U.S.C. § 1035.

[167] *Franciscan All., Inc. v. Becerra*, No. 7:16-CV-00108-O, 2021 WL 3492338, at *9 (N.D. Tex. Aug. 9, 2021).

[168] *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1147-48 (D.N.D. 2021).

[169] *Franciscan All.*, 2021 WL 3492338, at *10.

[170] *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2227 (2015).

seeks to accept one's biological sex or to be comfortable with sexual relations between a man and a woman.

A healthcare professionals' speech and expression is protected under the First Amendment because the Free Speech Clause protects "professionals," such as healthcare providers.[171] The government seeks to "suppress unpopular ideas or information" and impose its own views of proper healthcare.[172] Open communication in healthcare is "critical" because "[d]octors help patients make deeply personal decisions," and yet "[t]hroughout history, governments have manipulated the content of doctor-patient discourse to increase state power and suppress minorities."[173] It is thus essential in the medical context that doctors have the freedom to maintain "good-faith disagreements, both with each other and with the government, on many topics in their respective fields. . . . [T]he people lose when the government is the one deciding which ideas should prevail."[174] "An integral component of the practice of medicine is the communication between a doctor and a patient. Physicians must be able to speak frankly and openly to patients."[175] Plus, given that the doctors' policies are statutorily and constitutionally protected, their speech implementing and supporting their policies implement protected activities.[176]

For all providers, secular and religious, "gender identity" is a "sensitive political topic[]" and "undoubtedly" a matter of "profound value and concern to the public."[177] And religious doctors' "First Amendment interests are *especially* strong" because their healthcare policies and speech, including the use of pronouns, derive from their core religious beliefs and protected exercise.[178]

These First Amendment interests also implicate providers' rights to expressive association (or freedom of assembly). On pain of being driven out of healthcare, HHS compels them to participate in facilities, programs, and other

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[171] *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2371-72 (2018).

[172] *Id.* at 2373-76.

[173] *Id.* at 2374 (cleaned up).

[174] *Id.* at 2374-75.

[175] *Conant v. Walters*, 309 F.3d 629, 636 (9th Cir. 2002).

[176] *Bigelow v. Virginia*, 421 U.S. 809, 822 (1975) (invalidating restriction on abortion advertisement because "the activity advertised pertained to constitutional interests").

[177] *Janus v. AFSCME Council 31*, 138 S. Ct. 2448, 2476 (2018).

[178] *Meriwether v. Hartop*, 992 F.3d 492, 509 (6th Cir. 2021) (emphasis added).

healthcare-related endeavors contrary to their religious beliefs and expressive identities—and to associate with messages on these topics that they disagree with.

The Department might claim that this provider-patient speech is unprotected, just because officials consider this speech to be "discrimination," but, no historical evidence or tradition finds providers' policies and speech to be like unprotected categories of speech, such as obscenity or fighting words. If that were the case, "wide swaths of protected speech would be subject to regulation," contrary to precedent.[179] Speech on the subject of gender identity is not "unprotected" but receives strong protection.[180]

Plus, even unprotected or lesser-protected commercial speech is still protected from viewpoint and content discrimination, which apply here.[181] Even when there is a commercial aspect to speech, that speech does not "retain[ ] its commercial character when it is inextricably intertwined with otherwise fully protected speech."[182]

The proposed mandates thus violate patients and providers' First and Fifth Amendment rights both facially and as-applied. None of these restrictions and requirements advance a compelling governmental interest nor are they narrowly tailored. The mandates thus also impose an unconstitutional condition on the receipt of federal funding.

HHS must prove that it has a compelling interest of the highest order in prohibiting objecting doctors from being excused from its abortion, sexual orientation, and gender identity mandates. But no government interest requires censoring or compelling doctors to express views contrary to their best medical judgment or religious beliefs. Nor is it plausible for the government to maintain that speech that Congress had always allowed in healthcare is now suddenly not

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[179] *Telescope Media Grp. v. Lucero*, 936 F.3d 740, 752 (8th Cir. 2019).

[180] *Loudoun Cnty. Sch. Bd. v. Cross*, No. 210584, slip op. at *9–10 (Va. Aug. 30, 2021) (citations omitted).

[181] *Matal v. Tam*, 137 S. Ct. 1744, 1767–69 (2017) (five justices agreeing that lower scrutiny did not apply to viewpoint-based restrictions on commercial speech); *Wandering Dago, Inc. v. Destito*, 879 F.3d 20, 39 (2d Cir. 2018) (interpreting *Matal* this way); *accord R A.V. v. City of St. Paul*, 505 U.S. 377, 389 (1992) ("State may not prohibit only that commercial advertising that depicts men in a demeaning fashion.").

[182] *Riley v. Nat'l Fed'n of the Blind*, 487 U.S. 781, 796 (1988).

only prohibited, but prohibited as an interest "of the highest order."[183] The government lacks any compelling interest in ensuring that patients never hear views that they do not share. "[R]egulating speech because it is discriminatory or offensive is not a compelling state interest."[184] The government lacks any legitimate objective "to produce speakers free" from bias,[185] and so any non-discrimination "interest is not sufficiently overriding as to justify compelling" speech.[186] Far from being "always" a "compelling interest," this interest is "comparatively weak" in the context of pronouns.[187]

And any government interest could be achieved in more narrowly tailored ways. Patients can visit many other doctors eager to comply with HHS's mandates. Furthermore, as shown below under RFRA and the Free Exercise Clause, these mandates also fail strict scrutiny because of their many religious-targeted exemptions, inconsistencies, and known alternatives.

In sum, the government is in no place to dictate the standard of care for highly debatable and evolving medical procedures, as HHS admitted only two years ago.[188] If a healthcare provider recognizes the reality of a biological binary of sex, he or she should be able to speak to patients in her best medical judgment and in accord with her conscientious and religious beliefs. HHS "mandates orthodoxy, not anti-discrimination."[189]

3. The proposed rule violates religious exercise rights under the First Amendment and Religious Freedom Restoration Act.

In much the same way, the proposed rule will conflict with the Religious Freedom Restoration Act and the First Amendment's Free Exercise Clause.

RFRA prohibits HHS from substantially burdening a person's exercise of religion, unless the government proves that the burden is the least restrictive

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[183] *Reagan Nat'l Advert. of Austin, Inc. v. City of Austin*, 972 F.3d 696, 710 (5th Cir. 2020) (quoting *Republican Party of Minn. v. White*, 536 U.S. 765, 780 (2002)).

[184] *Telescope Media*, 936 F.3d at 755.

[185] *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*, 515 U.S. 557, 578–79 (1995).

[186] *Brush & Nib Studio, LC v. City of Phoenix*, 448 P.3d 890, 914–15 (Ariz. 2019).

[187] *Meriwether*, 992 F.3d at 510.

[188] 85 Fed. Reg. at 37,187 (quoting 81 Fed. Reg. at 31,429).

[189] *Ward v. Polite*, 667 F.3d 727, 735 (6th Cir. 2012).

means of furthering a compelling government interest.[190] As the Supreme Court said in *Bostock*, "[b]ecause RFRA operates as a kind of super statute, displacing the normal operation of other federal laws, it might supersede [a statute's] commands in appropriate cases."[191] In addition, under the First Amendment, a law or regulation that burdens religious practice and that is not neutral and generally applicable also violates the Free Exercise Clause unless it satisfies "the most rigorous of scrutiny."[192]

The proposed rule would substantially burden the exercise of religion and would not be the least restrictive means of advancing a compelling government interest. Many doctors exercise their religion when they provide healthcare services but exclude offering, performing, referring for, or affirming harmful interventions like testosterone suppression or puberty blockers. They exercise their religion by serving low-income and underserved populations in health programs and activities funded by HHS, such as Medicaid, Medicare, CHIP, and federally qualified health centers.[193] And they exercise their religion by offering their full and frank medical opinions on abortion, sex, and sexuality, by sharing their medical, ethical, and religious positions on these interventions, and by not affirming false narratives, such as by disregarding the sanctity of life, by using inaccurate pronouns, or by miscoding patients in charts and records.[194] Many religious beliefs prohibit them from providing, offering, facilitating, or referring for abortions or other interventions, such as sterilizations.[195] The government has no legitimate interest in coercing doctors to perform abortions or other dangerous interventions. The government's mandates contain statutory and discretionary limits and exemptions, undermining any claim of a general applicability or a compelling interest, let alone a narrowly tailored interest.

HHS has impermissibly exempted non-religious actions while refusing to exempt the doctors' religious exercise in violation of RFRA and the Free Exercise

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[190] 42 U.S.C. § 2000bb-1(a).

[191] 140 S. Ct. at 1754.

[192] *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520 (1993); U.S. Const. amend. I, V.

[193] Van Meter Decl., *supra* at ¶¶ 152–55; Dickerson Decl. ¶¶ 118–19, 154–56; Dassow Decl. ¶¶ 4–5, 36, 44–45.

[194] Van Meter Decl., *supra* at ¶¶ 144–48, 156–71; Dickerson Decl. ¶¶ 109–12; Dassow Decl. ¶¶ 41–43, 47.

[195] Van Meter Decl., *supra* at ¶¶ 29, 38, 86, 155; Dickerson Decl. ¶¶ 35, 69; Dassow Decl. ¶¶ 32.

Clause.[196] A regulation is not generally applicable if it treats "any comparable secular activity more favorably than religious exercise."[197] Any discretionary exceptions or "categorical exemptions" in a law will "trigger strict scrutiny."[198]

HHS's gender identity mandates are not neutral or generally applicable because they have not been evenly enforced and because HHS permits exceptions for many secular and non-secular reasons, while denying faith-based providers an exemption. Section 1557 exempts many entities, such as the military's TRICARE health insurance, and it incorporates the exemptions listed in Title VI, VII, IX, and various other statutes.[199] It excludes healthcare providers that do not receive Federal funds.[200] But a religious healthcare provider that receives Federal funds is "comparable" to other healthcare providers (religious or not) receiving or not Federal funds, because any government interest in "ensuring nondiscriminatory access to healthcare" would equally apply to public and private services.[201] Likewise, the Department's grants mandate has not been evenly enforced, and it too is subject to categorical and discretionary exemptions.[202] It is subject to past notices of non-enforcement, such as the 2020 Notice of Non-Enforcement. It is also subject to program-wide and discretionary granting of exemptions by federal officials.[203] This lack of even application is shown, for example, by three RFRA waivers that HHS granted and then arbitrarily revoked while stating it would not give out any future religious waivers.

By promulgating and enforcing the proposed rule's mandate—and by doing so without including any religious exemptions—the Department has targeted and shown hostility to religious beliefs and practices. A law is not neutral toward religion if its "object" "is to infringe upon or restrict practices because of their religious motivation."[204] A law or regulation may appear neutral on its face, but officials may not gerrymander the effect of the law primarily or particularly to

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[196] *Fulton v. City of Philadelphia*, 141 S. Ct. 1868, 1878 (2021).

[197] *Tandon v. Newsom*, 141 S. Ct. 1294, 1296 (2021) (per curiam).

[198] *Blackhawk v. Pennsylvania*, 381 F.3d 202, 211 (3d Cir. 2004).

[199] 45 C.F.R. § 92.6.

[200] 45 C.F.R. § 92.3(b).

[201] *Religious Sisters*, 513 F. Supp. 3d at 1148.

[202] 45 C.F.R. § 75.102.

[203] *Id.*

[204] *Lukumi*, 508 U.S. at 533.

coerce religious providers.[205] "Apart from the text, the effect of a law in its real operation is strong evidence of its object."[206]

Make no mistake: the chief effect of HHS's mandates in "real operation" is to force religious doctors to be complicit in harmful interventions and to suppress and target religious speech. The mandates disproportionately affect doctors who, for reasons of faith and belief, refuse to perform or endorse harmful, life-altering interventions.

HHS knew this gerrymandering effect would happen, and HHS welcomed it. Comments in response to the proposed incorporation of Title IX's religious exemption in the 2020 ACA Rule and to the 2016 Grants Rule showed incredible hostility toward religion—but HHS in 2021 adopted these comments' position, and so this hostility continues to pervade the entire enforcement process.[207] Commenters on the 2016 Grants Rule likewise said that "permitting entities to withhold services on the basis of religious or moral objection constitute a gross violation of accepted ethical standards for medical care," and "[p]ermitting contracting organizations to deny individuals information, referrals, and health care services on the basis of religious or moral objection undermines program goals and increased stigma and discrimination throughout society."[208]

HHS must prove that it has a compelling interest in applying the mandates to the religious doctors—"the particular claimant[s] whose sincere exercise of religion is being substantially burdened."[209] No broadly stated interest "in ensuring nondiscriminatory access to healthcare" is enough.[210] Instead, courts must

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[205] *Id.* at 534.

[206] *Id.* at 535.

[207] *See* 2020 Rule, 85 Fed. Reg. at 37,160-01, 37,205 (commenters "asserted that preventing discrimination on the basis of gender identity . . . is more critical than religious freedom rights, which should be more heavily scrutinized for pretextual discrimination"); *see also id.* at 37,206; *id.* at 37,188; 81 Fed. Reg. at 31, 379 (noting that commenters "opposed any religious exemption on the basis that it would potentially allow for discrimination"); 81 Fed. Reg. at 31,380 (accepting the recommendation of these commenters and adding that "the government has a compelling interest in ensuring that individuals have nondiscriminatory access to health care," which would supersede any religious-freedom concerns).

[208] *E.g.*, Council for Global Equality, Comment No. HHS-OS-2016-0012-0008 (Aug. 23, 2016), https://www.regulations.gov/comment/HHS-OS-2016-0012-0008.

[209] *Burwell v. Hobby Lobby Stores, Inc,*, 573 U.S. 682, 726 (2014) (quoting *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 430-31 (2006)).

[210] *Religious Sisters*, 513 F. Supp. 3d at 1148.

"scrutinize[ ] the asserted harm of granting specific exemptions to particular religious claimants and to look to the marginal interests in enforcing the challenged government action in that particular context."[211] But, in past cases, HHS never argued that exempting the plaintiffs would harm the government's interests.[212]

The government cannot satisfy this burden. The Department's proposed rule fails strict scrutiny under the Free Exercise Clause for the same reasons it fails strict scrutiny under the Free Speech Clause.

It has no compelling interest to justify the proposed rule. Plus, in the context of religious exercise claims, "[t]he creation of a system of exceptions . . . undermines the [government's] contention that its nondiscrimination policies can brook no departures."[213] The government grants exemptions to many people, but not for doctors with religious objections. If anything, the government has a strong 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.[214]

Nor is this proposed rule narrowly tailored. "To satisfy the least restrictive means test, the government must 'come forward with evidence' to show that its policies 'are the only feasible means . . . to achieve its compelling interest."[215] This test is "exceptionally demanding."[216] It is met only "if no alternative forms of regulation would accomplish those interests without infringing on a claimant's religious-exercise rights."[217] "Put another way, so long as the government can achieve its interests in a manner that does not burden religion, it must do so."[218]

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[211] *Id.* (quoting *Holt v. Hobbs*, 574 U.S. 352, 363 (2015) (cleaned up)).

[212] *Id.*; *Franciscan All.*, 2021 WL 3492338 at *10 (cleaned up) ("government asserts no harm in granting specific exemptions to Christian Plaintiffs").

[213] *Fulton*, 141 S. Ct. at 1881–82.

[214] Van Meter Decl., *supra*, at ¶¶ 144–48, 152–71; Dickerson Decl. ¶¶ 109–12, 118–19, 137–57; Dassow Decl. ¶¶ 4–5, 36, 41–45, 47.

[215] *Religious Sisters*, 513 F. Supp. 3d at 1148 (quoting *Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927, 943 (2015).

[216] *Hobby Lobby*, 573 U.S. at 728.

[217] *Religious Sisters*, 513 F. Supp. 3d at 1148 (internal quotation marks omitted) (quoting *Sharpe Holdings*, 801 F.3d at 943).

[218] *Fulton*, 141 S. Ct. at 1881.

Several alternative forms of regulation could accomplish any claimed governmental interest while still protecting the doctors' religious freedom. For example, if the government's interest is to increase access to certain services by increasing the number of doctors providing them, then "'the most straightforward way of doing this would be for the Government to assume the cost of providing gender-transition procedures for those 'unable to obtain them,'"[219] either by universally subsidizing them or by providing them itself. The government could provide "subsidies, reimbursements, tax credits, or tax deductions" for these procedures or could pay for them "at community health centers, public clinics, and hospitals with income-based support."[220] Or the government can offer insurance coverage for these services through its own healthcare exchanges.[221] Either way would be much less restrictive and encourage broader access than forcing objecting doctors to provide them on demand. And if the government wishes to make obtaining certain services easy, it can help individuals wanting those services find the many places that provide them.[222] After all, there is a "growing number of healthcare providers who offer and specialize in those services."[223]

Four courts have thus already recognized that the Section 1557 mandate is illegal and enjoined it in favor of plaintiffs in those cases.[224]

ADF represents the Christian Employers Alliance in one of these victories. The Alliance is challenging two Biden administration mandates that force religious nonprofit and for-profit employers to pay for or perform life-altering surgeries, procedures, counseling, and treatments in violation of their religious beliefs.[225] "No

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[219] *Religious Sisters*, 513 F. Supp. 3d at 1149 (quoting *Hobby Lobby*, 573 U.S. at 728).

[220] *Sharpe Holdings*, 801 F.3d at 945.

[221] *Religious Sisters*, 513 F. Supp. 3d at 1149 (quoting *Sharpe Holdings*, 801 F.3d at 945).

[222] *Religious Sisters*, 513 F. Supp. 3d at 1149.

[223] *Franciscan All.*, 227 F. Supp. 3d at 693; *see also Franciscan All.,* 2021 WL 3492338 at *10.

[224] *State of Texas v. EEOC*, No. 74 Civ. 2:21-CV-194-Z (N.D. Tex. Oct. 1, 2022); *Franciscan All.*, 2021 WL 3492338; *Religious Sisters*, 513 F. Supp. 3d at 1139; *Christian Emps. All. v. EEOC*, No. 1:21-CV-195, 2022 WL 1573689 (D.N.D. May 16, 2022). When the Fifth Circuit upheld the decision in *Franciscan Alliance*, the court noted that, in the context of the harms alleged by the plaintiffs against HHS in the context of its interpretation of Section 1557, "the loss of freedoms guaranteed by the First Amendment, RLUIPA, and RFRA all constitute per se irreparable harm." *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 380 (5th Cir. 2022)

[225] ADF, Christian Employers Alliance v. EEOC, https://adflegal.org/case/christian-employers-alliance-v-equal-employment-opportunity-commission.

government agency ought to be in the business of evaluating the sincerity of another's religious beliefs," the court wrote in its order. The court continues:

> HHS Guidance 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.

"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."[226]

In the recent decision of *Texas v. EEOC*, the Northern District of Texas vacated the HHS guidance that adopts the same position as the proposed rule and noted the serious problems for religious liberty in the Biden administration's aggressive interpretation of federal sex discrimination laws.[227] This opinion reiterates that HHS may not simply regulate at will, leaving questions of religious liberty to judicial enforcement. As the court held, "Justice Gorsuch expressly stated *Bostock* did not decide 'future cases' affecting religion and arising under Title VII's religious-employer exemption, the Religious Freedom Restoration Act, or the 'ministerial exception' defined in Hosanna-Tabor."

4. The Department must provide exemptions to prevent these burdens.

The proposed rule thus must tailor its scope to avoid these clashes with free speech and free exercise. The Department could do so by avoiding imposing any broad mandates or by narrowly tailoring those mandates to avoid effects on speech

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[226] *Christian Emps. All.*, 2022 WL 1573689.

[227] *State of Texas v. EEOC*, No. 74 Civ. 2:21-CV-194-Z at *8 (N.D. Tex. Oct. 1, 2022).

or religious exercise. Or the Department could create broad exemptions for patients and providers with different views.

But the proposed rule sidesteps these concerns and instead offers what it describes as a process for raising conscience and religious freedom objections. Recipients of federal financial assistance (not individual employees or patients) could allegedly notify OCR of their belief that the application of a specific provision or provisions of Section 1557 would violate their rights under federal conscience or religious freedom laws. The Department then would consider those views in responding to any complaints, either at the start of an enforcement action or sometime later on. The Department does not guarantee that it would respect religious exercise, merely that it would consider it.

This is wholly insufficient to ensure that the Department does not chill the exercise of protected rights. Indeed, it is just an attempt to coerce as much compliance as possible by trying to avoid granting any exemptions and by trying to avoid judicial review of the proposed rule by suggesting that any clash with religious freedom is speculative before enforcement proceedings.

As one commenter has already noted about the proposed rule's new notification process, "[t]his process is seen by many as a sham since HHS under Secretary Xavier Becerra has systematically targeted or ignored conscience and religious freedom protections, such as by sidelining HHS's Conscience and Religious Freedom Division, abandoning the case of a nurse illegally forced to participate in abortion," and "proposing to rescind conscience protection regulations." "Indeed, HHS refused in federal court to 'disavow enforcement' of Section 1557 to require medical professionals to perform gender transition surgeries or abortions in violation of their sincerely held religious beliefs."[228]

More importantly, under the APA, the actual impact of liberty-protecting laws like RFRA must be considered in reasoned decision making, including whether a rule must affirmatively respect exemptions at the outset. Even the *Bostock* Court was "deeply concerned with preserving" religious institutions' freedom as an important aspect of the problem to consider.[229] HHS's failure to "overtly consider" these conscience and religious freedom reliance interests—and tailor its regulation

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[228] Rachel Morrison, *HHS's Proposed Nondiscrimination Regulations Impose Transgender Mandate in Health Care*, https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-in-health-care-1.

[229] 140 S. Ct. at 1753–54.

to provide exemptions—thus renders it fatally flawed.[230] Because consideration of these protections is required, and because these exemptions are legally required up front, the Department cannot ignore them and choose to leave faithful doctors and others to engage in piecemeal litigation against the Department to protect their freedoms.

Nor does HHS intend to self-enforce RFRA or the First Amendment on itself, even if objections are raised, either before the agency or in court. On the recommendation of the OCR, HHS ended any enforcement by the HHS OCR of religious liberty and constitutional protections—all, again, because of HHS's radical view that RFRA requires no affirmative agency compliance or enforcement beyond what a court orders.[231] HHS also will not issue new waivers for any religious objections.

So rather than voluntarily following RFRA and rather than applying a RFRA decision beyond the parties to a case to similarly situated parties, the proposed rule will force each religious provider in America to undergo years of litigation. This goal is religious targeting, and it is unlawful under the Constitution, RFRA, and the APA.

Finally, the proposed notification process raises several procedural concerns. *First*, despite the withdrawal of RFRA delegation from OCR, OCR would be doing some religious liberty work. Does OCR have the authority to do this? Will a new delegation be made? *Second*, it is unclear who will evaluate claims. Will the Conscience and Religious Freedom Division of OCR be involved, and who will make the final decision? The involvement of the career professionals in this division should be guaranteed and stated explicitly in regulations. *Third*, there is no appeal process. Will appeals be allowed? *Fourth*, the agency views non-discrimination as compelling interest. Does this process likely result in any exemptions, under that view? *Fifth*, this notification process involves the loss of anonymity and privacy, much like the process for an assurance of exemption under Title IX. It thus is ripe

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[230] *Little Sisters of the Poor v. Pennsylvania*, 140 S. Ct. 2367, 2383 (2020).

[231] HHS, Delegation of Authority, 86 Fed. Reg. 67,067 (Nov. 24, 2021); Sam Dorman, *HHS memo shows department moving to undo Trump-era action aimed at better protecting religious liberty* (Nov. 17, 2021), https://www.foxnews.com/politics/hhs-ocr-memo-rfra-trump-religious-liberty ("Under 'Noteworthy Elements about Equity,' the memo reads: 'While nothing in RFRA legally restricts an agency to work proactively to address a complainant's (or 'would be' complainant's) religious needs or rights, there is a serious concern that such an approach broadens the effect of RFRA in a way that may not be legally required and while causing significant detriment to civil rights and public health protections. . . . RFRA is meant to be a shield to protect the freedom of religion, not a sword to impose religious beliefs on others without regard for third party harms, including civil rights.' ").

for abuse under the Freedom of Information Act, where activists will seek to obtain religious information to conduct name-and-shame harassment campaigns—or worse. *Sixth*, the very act of having a public process of this kind has a chilling effect. It is not required by law to undertake this process to get an exemption, because the agency should pro-actively comply with law. The effect of the existence of this process thus will be to suggest that notification is required and to chill religious exercise in the absence of participating in the process.

IV. The proposed rule suffers from other legal and procedural flaws.

A. The proposed rule unlawfully seeks to expand HHS's regulatory reach to cover new programs and activities.

In several ways, the proposed rule unlawfully departs from the 2020 Rule, 85 Fed. Reg. 37160 (June 19, 2020), which properly limited the scope of Section 1557's nondiscrimination requirements to only those programs and activities to which the ACA applies: those conducted by the Department under Title I of the ACA. Interpreting Section 1557 to cover all of the health programs and activities administered by the Department is not the best reading of the statutory language, as the 2020 Rule set forth.

1. The proposed rule unlawfully attempts to encompass insurers and those involved in health coverage not covered by Section 1557.

Extending the application of Section 1557 nondiscrimination requirements to health insurance issuers as such exceeds the Department's authority under Section 1557, as the 2020 Rule explained. The statute does not apply to all health insurance issuers that receive federal financial assistance. Nor should the proposed rule interpret Medicare Part B as federal financial assistance, as the 2020 Rule also explained.

Section 1557 applies to "health programs and activities," meaning health care. Health insurance is not health care, health insurance is payment for health care. The 2020 Rule interpreted this correctly, but this proposed rule signals the Department will vastly increase its regulatory authority without congressional approval.

The proposed rule exacerbates this problem when the Department suggests that under the "health program or activity" definition proposed, it will apply Section 1557 to all the operations of an entity engaged in health insurance, even if only one of its products receives federal financial assistance from the Department. This would mean any product sold by that insurer could not operate in a way that the

Department considers is discriminatory. This creates serious problems, including that employers who object to certain practices in their health plans would be excluded from the health insurance market due to all issuers being subject to Section 1557. Indeed, the conflict between the proposed rule and these guidelines are a strong reason to conclude that Congress did not intend to impose sweeping mandates of this kind on insurance. The Department has lost several cases trying to impose the contraceptive mandate on employers—for the same reasons it will lose in court if it seeks to impose abortion coverage and other intervention coverage mandates on insurers of employer-sponsored plans that object.

By adding insurers as such, and all of their products, the proposed rule creates insurance coverage mandates: insurance cannot have any categorical exclusions (of abortions or other harmful interventions) and they cannot have an age limitation. That means if an insurer accepts one form of coverage—say a mastectomy for cancer or a dilation and curettage for non-abortion reasons—then denies a mastectomy approved by a psychologist for purposes of altering one's appearance as a man or as a woman, or a dilation and curettage for abortion of a living unborn child, the Department appears to consider that exclusion to be sex discrimination. The result is an across-the-board mandate to cover abortions and other harmful related interventions.

All the problems of the proposed rule come to the forefront when these mandates are imposed on insurers: the Department is requiring insurers and health plans to pay for one-sided counseling, followed by experimental puberty blockers or a lifelong course of hormones, and paired with life-altering surgical procedures. And it seemingly prohibits them from offering better counseling and medicine instead. This one-size-fits-all 'solution' to gender dysphoria or sex discomfort is unsupported by the evidence. And, by mandating the easy payment of all these practices, it will dramatically increase the number of impressionable youth and adults harmed by these practices. Instead, insurers who care about patients should refuse to pay for procedures with known harms, especially when those practices obscure underlying causes of distress.

Before requiring coverage, much less as an essential health benefit, the Department has the burden to prove that something is medically necessary or the standard of care. But, as discussed above, the Department does not prove this, and the best evidence suggests other practices are more appropriate, such as watchful waiting, but the Department seems to deem those to be prohibited because they are not "gender affirming." The proposed mandates will harm patients, providers, parents, women, girls, and the public at large.

The proposed rule also does not address the practical problems of mandating this insurance coverage. Is a gender dysphoria diagnosis required for insurance coverage payments for related interventions? If not, is anything required other than a patient demand? Can insurers or doctors interpose any categorical or individual requirements of medical necessity, cost-containment, or mandatory consideration of alternative treatments? How is the responsibility to decide any medical justification to be divided among different doctors, specialists, and counselors?

The problem with extending the proposed rule to insurers only is made worse by the Department's abortion mandate, which suffers from serious vagueness problems discussed above. The Department should make clear that it is not imposing a nationwide mandate for abortion insurance coverage. If the Department declines to take a position on this question, it must consider the harms and costs coming from coercing virtually every insurer in the country to subsidize abortion on demand in violation of state law and with no requirement of parental consent for minors.

It also is unclear if abortions and the other practices and procedures at issue would be eligible for tax-preferential treatment in healthcare savings accounts or in flexible spending accounts. The Department must clarify this effect of its proposed rule. If abortions and these other procedure and practices are covered, the Department must calculate the tax effect of diverting spending and the increase in the overall number of harmful effects from this financial incentive.

Moreover, imposing this mandate on all insurers will seriously burden those who purchase and use health insurance and who disagree with the Department about its understanding of sexuality and the human person. The proposed rule makes it almost impossible for people to obtain insurance that conforms with their medical, moral, or religious beliefs.

This is of particular concern because the Department is likely to claim that any exemptions apply only to a patient, provider, or purchaser, and not to an insurer unless the insurer shares the medical, moral, or religious objection—which will make it functionally impossible for much of the country to obtain health insurance that respects their beliefs and does not require them to violate their best medical judgment, consciences, or religious beliefs.

The proposed rule threatens to be used as a basis to require all employers to cover abortions and other harmful procedures. Court decisions, such as the decision in ADF's *Christian Employers Alliance* case discussed above, precluded this outcome when the EEOC sought to impose a similar mandate, so HHS should

expressly discuss these cases and explain why it would not also be similarly precluded.

Finally, the proposed rule threatens that non-religious insurers will not be permitted to provide religious organizations with insurance plans that do not cover procedures that violate their sincerely held religious beliefs. If that is not the Department's intent, the Department should say so to avoid serious free exercise problems. But if that is the Department's intent, the Department must say so, and it must justify the benefits of this approach and frankly acknowledge its many costs. If the Department prefers to leave this ambiguous, it still must examine both possible effects from the proposed rule.

2. The proposed rule unlawfully attempts to encompass other HHS programs

For the same reasons as the Department should not extend its mandates to insurers, the Department also should not reverse the 2020 rule's provisions and re-extend mandates in other regulations and programs operated or funded by HHS.

It should not reinstate the prohibitions on sexual orientation and gender identity discrimination at issue in the Centers for Medicare and Medicaid Services (CMS) regulations. These provisions included regulations governing Medicaid and the Children's Health Insurance Program (CHIP); Programs of All Inclusive Care for the Elderly (PACE); health insurance issuers and their officials, employees, agents, and representatives; States and the Exchanges carrying out Exchange requirements; agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees; issuers providing essential health benefits (EHB); and qualified health plan (QHP) issuers. The provisions had no statutory basis in those programs and are improper exercises of the Department's regulatory authority in those programs. Reinstating these mandates is an attempt to go beyond the limited reach of Section 1557. Nor should the Department amend CMS regulations extending its new mandates to CHIP and to Medicaid fee-for-service programs and managed care programs.

Imposing wide-ranging mandates in the regulations of many programs serves as best to duplicate the Section 1557 regulation itself, and at worst seeks to aggrandize power to the Department that Congress did not give it. Duplicating the same mandates in many regulations is unnecessary legally, if Section 1557 covers them. So the only effect is to confuse the Department's extent of authority and coerce as much compliance as possible without congressional authorization for entities in programs where Section 1557 does not apply. It is more orderly to have one regulation on this topic, limited precisely to the exact reach of the statute.

3. The proposed rule unlawfully attempts to encompass human services grant programs

The Department also lacks any authority for mandates that extend to human services grant programs. The proposed rule invites comments on whether the Department should require the same result as Section 1557—but beyond healthcare and for all HHS grant programs—by re-interpreting Section 1557 to reach all health or human services programs.

This exceeds the Department's authority under Section 1557. That statute only applies to "health" programs and activities. Human services programs are not health programs, they are welfare programs. The longstanding distinction between health and welfare is well-understood, and has been understood by the Department itself, including in 2016 when the Department declined to extend the Section 1557 rule to human services programs. In other words, both the Obama and Trump administrations agreed that Section 1557 does not apply to HHS's human services grant programs. Under the major questions doctrine, Congress cannot be found to have clearly given the Department authority to impose Section 1557 on non-health programs. Doing so also would violate the clear notice canon, under which states cannot be found to have agreed to abide by Section 1557 of the ACA in accepting funds under various human services programs run by divisions of HHS.

As discussed above, the HHS grants rule—which imposed a sexual orientation and gender identity nondiscrimination rule to all HHS grants including those for human services—has already created many unnecessary conflicts with religious exercise. The text of Section 1557 provides no authority for the statute to sweep in non-health programs or activities.

Nor is there any other source of authority for HHS to extend its mandates to all human services grant programs. The 2016 Grants Rule relied as its sole source of authority on the multi-agency "housekeeping statute," which states that an agency head may "prescribe regulations for the government of his Department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property."[232] Originally "'enacted to help General Washington get his administration underway by spelling out the authority for executive officials to set up offices and file Government documents,'" and consolidated into one multi-agency statute in 1874, the

[232] 5 U.S.C. § 301.

housekeeping statute only governs internal operations.[233] This housekeeping statute does not allow HHS to regulate anything outside a department's internal functions.[234] It is just "a 'housekeeping statute,' authorizing what the APA terms 'rules of agency organization procedure or practice' as opposed to 'substantive rules.'"[235] All that is left, then, of HHS's authority for the grants rule is its claim that it may impose this mandate as a matter of public policy. But HHS's public policy preferences are not a source of legal authority. Neither the agency nor this Court "is empowered to incorporate such a preference into the text of a federal statute."[236]

The Department should decline to expand the Section 1557 rule to human services programs. This attempt to codify the 2016 HHS grants rule under the aegis of Section 1557 is illegal and will cause HHS to lose court challenges.

4. The proposed rule unlawfully attempts to encompass entities not primarily in the business of providing healthcare

Relatedly, HHS asks for comment on whether its rule should be extended to programs and activities not primarily in the business of providing health. This would be a large power grab by the Department and would suffer from a vague and imprecise scope. Is offering employee health insurance enough to make an entity subject to Section 1557 even if it is not in the healthcare business? If so every employer in the country would be subject to Section 1557 if it offers health insurance. This was not in the scope of Congress' language in Section 1557, and it would cause the Department to face, and lose, many more lawsuits.

Is offering first aid kits for employees, or offering any number of other health and safety measures in compliance with OSHA, enough to make an entity a health program or activity under this theory? Does offering vaccines to employees—as mandated by the federal contractor mandate—make an employer a health program subject to Section 1557? Is it enough that caregivers provide children in the entity's custody bandages or necessary first aid if required? How about providing sex

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[233] *Chrysler Corp. v. Brown*, 441 U.S. 281, 309 n.39 (1979) (quoting H.R.Rep. No. 1461, 85th Cong., 2d Sess., 1 (1958)).

[234] 5 U.S.C. § 301; *see, e.g.*, *United States ex rel. O'Keefe v. McDonnell Douglas Corp.*, 132 F.3d 1252, 1254–56 (8th Cir. 1998).

[235] *Chrysler Corp.*, 441 U.S. at 310–11; *accord In re Bankers Tr. Co.*, 61 F.3d 465, 470 (6th Cir. 1995) (same).

[236] *14 Penn Plaza LLC v. Pyett*, 556 U.S. 247, 267 (2009).

education, if that education involves information on human anatomy? What if an entity takes federal funds from another U.S. government agency, but also engages in one of these ancillary healthcare activities—does this rule apply?

To enact the proposed rule to cover these situations, HHS would have to cure the vague scope of how such a rule would apply—but it cannot do so, and thus HHS should abandon the proposal. In practical effect, this proposal would turn Section 1557 into a rule that covers the entire U.S. economy whether or not it is a health program or activity. The major questions doctrine, and basic canons of statutory construction, preclude such an approach.

HHS should limit its rule's reach to the reach of the 2020 Rule. This means that (1) HHS should not extend its rule to any health programs or activities not funded or operated by HHS; (2) HHS should not extend its rule to health insurance rather than health care; (3) HHS should not extend its rule to the activities of an entity not primarily in the health*care* business if those activities get no HHS funds; and (4) HHS should not extend its rule to human services or other non-healthcare programs or activities.

5. The Department must clarify its position on federal financial assistance and tax-exempt status.

The Department must clarify whether tax-exempt status constitutes federal financial assistance. As discussed in the attached comments submitted by ADF on Title IX, recent federal court decisions have called into question whether all nonprofit organizations are considered to be recipients of federal financial assistance, and thus covered by Title IX (and by extension Section 1557).[237] The proposed rule suggests that an entity receiving federal financial assistance is covered even if its healthcare activities are incidental, that is, even if the entity is not primarily engaged in the business of healthcare. Paired together, these principles could mean that virtually every nonprofit organization in the nation is considered subject to Section 1557, so long as some attenuated link to health can be discerned in the organization's operations.

The Department thus should make clear that tax exempt status does not constitute federal financial assistance under Title IX and Section 1557. What if a healthcare entity is a tax-exempt organization, but otherwise receives no funds from

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[237] *See also* Greg Baylor, *Shoehorning Tax-Exempt Status Into Title IX Threatens Nonprofits That Won't Pretend Boys Are Girls*, The Federalist (Aug. 12, 2022), https://thefederalist.com/2022/08/12/shoehorning-tax-exempt-status-into-title-ix-threatens-nonprofits-that-wont-pretend-boys-are-girls.

HHS—is it subject to this proposed rule? If the Department says tax-exempt status is FFA under Title IX and Section 1557, it must examine the proposed rule's costs and effects both (1) assuming that tax exempt status does not constitute federal financial assistance and (2) tax exempt status does constitute federal financial assistance.

In particular, the Department must expressly consider and address whether pro-life pregnancy centers fall under the proposed rule, including its abortion mandate. These centers should not be covered under Section 1557. But, even though most do not take federal funding and simply rely on a tax-exempt status, under recent federal court decisions, they could be considered covered entities. The Department needs to clarify its position on such entities and whether Section 1557 applies to them.

6. Employment practices should not be covered.

Finally, ADF supports the Department's proposal that Section 1557 would not apply to any covered entity's employment practices. Both the prior rules applied to employment under narrow circumstances; the 2016 rule, for instance, would have applied to some employee health benefits programs (when, for instance, offered by health providers or insurers). HHS should state clearly in its proposed rule that it will not interfere in these matters. If HHS nevertheless provides that Section 1557 should cover employment practices, HHS must take account of recent court decisions governing Title VI and Section 1557, as well as the church autonomy doctrine.[238]

B. The proposed rule fails to give adequate definitions of key terms.

The proposed rule fails to define the terms used to add new protected classes to Section 1557—both terms used directly in the new rule and terms incorporated by reference. The Department must tell the public what it means by the new terms of its mandates by defining the terms "sex stereotypes," "sex characteristics," "pregnancy or related conditions," "sexual orientation," and "gender identity." But the rule does not define these terms in any meaningful way. This rule does not even define what is a man or what is a woman. The proper definition is, of course, by biological sex. No theory of interpretation—such as a sex-stereotyping theory—

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[238] These points are also discussed in greater detail in the attached comments on Title IX addressing religious schools.

should incorporate concepts of gender identity or sexual orientation without precise definitions.

The final rule must address these currently vague issues and define, in a non-circular way, what is a man and what is a woman. If the rule fails to do so, the Department is failing to address key issues and is failing to act with reasoned decision-making. This makes the Department susceptible to challenge because the regulated community would lack clear notice of its obligations.

In particular, key terms like "gender identity" and "transgender status" must be defined in ways that show how they comport with Section 1557 and Title IX, and in ways that are not vague or malleable. It should explain frankly whether and how they address persons who identify as having detransitioned, or those who identify as gender non-conforming.

The final rule must also address the inherent contradiction of reinterpreting "sex" (an immutable reality) to include "gender identity" and "transgender status" (subjective self-identifiers based on a person's rejection of his or her own biological sex). And, as discussed above, the final rule must define "termination of pregnancy" and what discrimination on that basis means. As written, it is impossible to know what the abortion related mandate may require under this proposed rule.

If the government does not provide definitions, it should explain why it will not do so, and explain why its current proposed text will not create problems of vagueness, due process violations, lack of notice required to the public, and contradictions within the text of the proposed rule itself. The Department should also reopen the comment period to allow comment on the definitions it is proposing.

C. The proposed rule must undertake a full analysis of the implications for redefining Title IX to reach abortion, sexual orientation, and gender identity.

The proposed rule if finalized would be arbitrary and capricious because it fails to undertake the necessary analysis of the import of its position that "sex" in Title IX, as incorporated into Section 1557, includes abortion, sexual orientation, and gender identity. The Department is staking out important and aggressive legal ground by claiming that Title IX addresses these matters. Under the APA's requirements of reasoned decision making, the Department cannot do so without considering important aspects of this new interpretation of Title IX.

The important aspects of this interpretation of Title IX are many. They concern women's privacy and safety in athletics, restrooms, and housing; parental

rights; life and healthcare in educational settings; free speech and religious exercise; and common issues of statutory and constitutional law. They also involve overlapping factual matters of evidence in their policy implications and overlapping empirical questions of economics in their cost-benefit analyses.

By staking out a position on Title IX in this Section 1557 rulemaking, HHS has created for itself a duty to consider all of the important questions raised in the Department of Education's Title IX rulemaking. HHS must consider all of those issues because the legal position taken in this Section 1557 rulemaking will either be aligned with the interpretation of Title IX, or will diverge from it; and the federal government needs to interpret its Title IX laws consistently.[239] This includes examining important legal and empirical cost-benefit questions about athletics, housing, parental rights, free speech, religious exercise, and other critical areas affected by redefining sex in Title IX. For HHS to take a shortcut and ignore the implications of its legal position on Title IX programs at other agencies, and in relation to the views of the Department of Justice, would be arbitrary and capricious.

These important questions are addressed in detail in the attached comments filed by ADF to the Department of Education on its recent proposed rule redefining sex in Title IX in similar way.[240] ADF thus encourages HHS to carefully review the attached Title IX comments, which provide hundreds of pages of important information about the implications of this redefinition of Title IX.

D. The proposed rule must conduct additional cost-benefit analyses.

The proposed rule is also procedurally deficient because it fails to assess the true costs of the rule and then conduct an appropriate cost-benefit analysis. These costs include costs for covered entities, for patients, and for healthcare providers. A key aspect of these costs are the costs imposed on those patients, providers, insurers, and purchasers of insurance who cannot comply with the proposed rule, either in their best medical judgment, as a matter of their consciences, and for reason of their religious beliefs. The rule is likely to leave many patients without care or insurance, or with poor care or objectionable coverage; it is likely to drive countless providers out of medicine and indeed many pre-med students are already

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[239] See Executive Order 12,250 (Nov. 2, 1980).

[240] These comments are also available at ADF, *ADF to Biden: Hands off Title IX: ADF submits formal comments to U.S. Dept. of Education opposing proposed changes, defending women, parental rights, free speech*, https://adflegal.org/press-release/adf-biden-hands-title-ix.

choosing not to enter medicine for fear of being compelled to acquiesce to mandates on abortion and dangerous procedures for those who identify as another sex, such as mastectomies, puberty blockers, or testosterone suppression.

Assessing these costs requires the Department to obtain and set forth detailed economic and empirical information and, once this information is in hand, the Department must conduct a close assessment of the relationship between the resulting costs and benefits. The rule must also take account of and quantify the costs of malpractice suits and other liability by providers who perform these dangerous procedures, especially given the high number of people with regret. The rule must quantify the cost per practice or procedure—both episodic and lifelong care—all of which it should factor into the costs for insurers and for premium increases. The Department must also quantify the harms to parental rights, given how many parents will lose custody of their children over this mandate. The many other types of information and assessment necessary to provide this form of reasoned decision making was submitted by ADF to the Department in pre-publication meetings on this rule and on the proposed rule to repeal HHS's conscience rule (including detailed analysis as to the effects on conscience in healthcare). And, as to the impact on Title IX, this information was also submitted to the Department of Education in ADF's detailed Title IX comments. Rather than repeat this extensive economic analysis in this comment, these original economic-focused comments are attached in separate documents and incorporated by reference.

Finally, the proposed rule should conduct and submit for comment a Family Impact Analysis.[241] The Department has a duty to define what the current and proposed norms are in this area, and to explain the effect of this proposed rule on families. This would include, but not be limited to, the effect of the proposed rule on depriving parents of information and knowledge of their children's healthcare.

The proposed rule would harm families and children. The proposed rule impacts the stability or safety of the family, particularly in terms of marital commitment, by precluding institutions from relying on the understanding of marriage as between one man and one woman and by eroding parental rights over the care of children. Rather than helping the family perform its functions, the proposed rule allows for medical and educational decisions to be made independent of the parents or without adequate informed consent. Children could be severely and irreversibly harmed, including children's health. The proposed rule's poor

[241] Section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105-277, sec. 654, 112 Stat. 2681 (1998).

standard of care for medicine imposes healthcare costs on families, especially mental health care costs from abortion regret and lifelong medical costs from the consequences of procedures like the removal of healthy sexual organs. This proposed rule corrodes the behavior and personal responsibility of youth and the norms of society by confusing children about their sex and by promoting abortion, as well as other life-altering procedures or forms of non-marital sexual conduct.

Thank you for your consideration of these important concerns.

Respectfully Submitted,

Julie Marie Blake
Senior Counsel for Regulatory Litigation
Alliance Defending Freedom