



November 1, 2024

Secretary Xavier Becerra
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Financial Resources
Attention: HHS Grants Rulemaking
Washington, DC 20201
Via regulations.gov

RE: Comment on Interim Final Rule, Health and Human Services Adoption of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 89 Fed. Reg. 80,055 (October 2, 2024) Docket ID HHS-OS-2024-0016

Dear Secretary Becerra,

Alliance Defending Freedom (ADF) opposes the Biden-Harris administration's continued effort to rewrite federal sex discrimination laws across federal healthcare, human services, and education programs. The U.S. Department of Health and Human Services (HHS) was correct to rescind its Obama-era grants rule that coerces religious foster care providers earlier this year. But HHS replaced one bad rule with another in its 2024 Grants Rule.¹

Now, by combining codification of the 2024 Grants Rule and the Office of Management and Budget (OMB) guidance² in this interim final rule,³ HHS exacerbates the harm of the unlawful 2024 Grants Rule. But rather than ignore the serious issues in the provisions, under the Administrative Procedure Act (APA), HHS should reconsider them based on the growing evidence of these regulations' harms and unlawfulness.

Instead HHS should respect the law, religious liberty, free speech, and parental rights—HHS should not continue to seek to redefine sex in federal law in ways that harm women and children in grant programs like Head Start.

¹ Health and Human Services Grants Regulation, 89 Fed. Reg. 36,684 (May 3, 2024)

² Guidance for Federal Financial Assistance, 89 Fed. Reg. 30,046 (April 22, 2024).

³ Health and Human Services Adoption of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 89 Fed. Reg. 80,055 (Oct. 2, 2024).

I. HHS should consider the 2024 Grants Rule’s harmful mandates.

In the first place, the interim final rule suffers from serious procedural flaws—its process raises serious concerns that HHS has failed to undertake reasoned decision-making as required under the APA.

In this rulemaking, HHS seeks to codify language from the 2024 Grants Rule and the OMB guidance without following the APA’s notice-and-comment procedures. Because HHS recently completed the 2024 Grants Rule, HHS purports to have good cause for this action via an interim final rule.⁴ But OMB’s guidance was just that—guidance—the comments submitted on that guidance do not satisfy notice and comment requirements for imposing the guidance in HHS specifically. And good cause is not satisfied when HHS closes its mind to substantive comments submitted now by saying “HHS will not respond to comments regarding OMB’s 2020 or 2024 modifications to 2 CFR part 200, or on existing HHS specific provisions merely being moved to 2 CFR part 300, as those provisions have already been subject to public input and comment and the latter have been finalized in existing promulgated rules.”⁵ “HHS will also not respond to comments related to the content of the HHS-specific modifications at 2 CFR 300, as these provisions are existing HHS regulations that have been promulgated and maintained at 45 CFR part 75, not new requirements for the HHS applicant and recipient community.”⁶

None of this complies with the spirit of public participation in agency rulemaking reflected in the APA’s notice-and-comment procedures. Nor does this process reflect reasoned decision-making under the APA. Courts require the agency to respond to relevant and significant public comments and to explain how the agency resolved any significant problems raised by the comments.

HHS should consider important issues about these provisions, including their harms and their illegality. As HHS explained in the preamble to the interim final rule, HHS reconsidered all of its grants regulations in this rulemaking: HHS made a deliberate decision to adopt the OMB uniform grantmaking guidance, but to modify this guidance to include the 2024 Grants Rule, and to draft a new C.F.R. section with the 2024 Grants Rule’s provisions in a new codification.⁷ And, in fact,

⁴ 89 Fed. Reg. at 80,058.

⁵ 89 Fed. Reg. at 80,058.

⁶ 89 Fed. Reg. at 80,058.

⁷ 89 Fed. Reg. at 80,055 (“The Department of Health and Human Services (HHS) adopts with this rule OMB’s Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, to include 12 existing HHS-specific modifications. This rule also repeals HHS’

HHS rescinded many other prior grants regulations rather than include them as modifications to the OMB guidance. But HHS decided to keep much of the 2024 Grants Rule rather than rescind it.⁸ By this decision—reconsidering and recodifying the 2024 Grants Rule in the interim final rule as selected modifications to OMB’s intervening uniform guidance—HHS opened the question of whether to retain these regulations. This requires HHS to consider the alternatives and the issues relevant to the 2024 Grants Rule.

HHS cites a single case, *Priests for Life v. HHS*, 772 F.3d 229 (D.C. Cir. 2014), in support of its decision to skip notice-and-comment rulemaking. This does not support HHS’s decision for four reasons. *First*, HHS ignores that the D.C. Circuit held in *Priests for Life* that HHS could issue an interim final rule in that circumstance in part because HHS agreed to accept comments on the rule: as the court noted, “HHS will expose its interim rule to notice and comment before its permanent implementation.” *Id.* at 276. HHS here refuses to do exactly that, excluding important concerns from this interim comment process. *Second*, the D.C. Circuit approved of HHS actions in *Priests for Life* because they responded to court decisions holding a prior rule unlawful and providing for greater religious-freedom exemptions: a Supreme Court decision “obligating it to take action to further alleviate any burden on the religious liberty of objecting religious organizations.” *Id.* Here HHS refuses to modify its regulations in light of recent court decisions explaining that HHS’s legal position is incorrect, as discussed below. *Third*, the rulemaking in *Priests for Life* considered important issues in its prior iteration. *Id.* But HHS refused to do so adequately in the 2024 Grants Rule, especially refusing to address cases showing the correct understanding of the statute or evidence showing the harms of its provisions for women and children. And HHS again refuses to do so here. *Fourth*, the scope of the decision at issue differs. In *Priests for Life* HHS changed one part of a prior rule, *id.*, but here *HHS reconsidered and decided to retain the entire set of prior provisions*—while rescinding many other provisions.

existing regulations governing the administration of HHS financial assistance awards. The existing HHS-specific modifications are described in the rule’s preamble.”); *id.* at 80,056 (“With this interim final rule, HHS will forgo the separate codification, fully adopt 2 CFR part 200, reduce the total number of HHS-specific changes, and codify those changes in 2 CFR part 300.”); *see also id.* (listing prior HHS regulations that HHS would rescind, including various prior regulatory changes to OMB guidance that HHS would now discard).

⁸ 89 Fed. Reg. at 80,056 (“HHS will include only twelve HHS-specific modifications to the Uniform Guidance that are currently codified in 45 CFR part 75.... HHS retains the following HHS-specific modifications in 2 CFR part 300, making minor changes to previously-promulgated regulations to align with the text of the Uniform Guidance With these twelve additions, HHS will adopt 2 CFR part 200 in its entirety.”).

For the same reasons, HHS lacks good cause to forgo prior notice and public comment and to issue the rule as an interim final rule. There is a portion of the interim final rule, which adopted the OMB guidance, on which HHS may be willing to accept some types of comments.⁹ This OMB guidance seeks to unlawfully redefine HHS sex discrimination statutes, in just the same way as the 2024 Grants Rule.¹⁰ But, as just shown, HHS has no good reason to skip the APA's procedures for public participation.

HHS is also incorrect that prior notice-and-comment rulemaking sufficed to air these issues. The OMB guidance's comments were not particular to HHS, and because it was merely guidance the comments inherently did not consider the impact of making the language mandatory at HHS. The 2024 Grants Rule and the OMB guidance also both had major changes from the proposed rules to the final rules.¹¹ The public thus did not have an original chance to comment on the final language, which was not proposed. But HHS assumes that these prior comment periods were sufficient.

The OMB guidance and the 2024 Grants Rule moreover have interrelated provisions, and so HHS needs to engage in reasoned-decision-making to decide whether to adopt the OMB guidance. The OMB guidance seeks to impose the same unlawful mandates as the 2024 Grants rule by redefining HHS grant statutes' sex-discrimination provisions to address sexual orientation and gender identity—or at least, by requiring or encouraging HHS to retain the 2024 Grants Rule. HHS thus considered the 2024 Grants Rule as part of its decision to adopt the OMB guidance. So HHS needs to give its reasons for this decision and allow the public to comment on that decision.

For all these reasons, HHS's stated refusal to consider comments about its decision and to engage in reasoned decision-making to arrive at this rulemaking decision is thus arbitrary and capricious.

⁹ 89 Fed. Reg. at 80,058 (“As the Secretary issues this rule as an interim final rule with comment, HHS will consider and address comments on HHS's plan and timeline for implementation, including the provision of two effective dates, that are received within 30 days of the date this IFR is published in the Federal Register.”). On this point, HHS should delay the plan and timeline for implementation indefinitely to respond to the many concerns in this comment.

¹⁰ 2 C.F.R. § 200.300.

¹¹ See Rachel N. Morrison, *When Public Comment Matters*, National Review Online: The Corner (April 8, 2024, 7:35 PM), <https://www.nationalreview.com/corner/when-public-comment-matters/>.

Worse yet, it appears that regulations.gov did not have *any* comment button to collect comments during some of this comment period. In fact, there was no actual way to comment on this rule at least through October 17, 2024, midway through the comment period. As a result, the comment period should be republished and reopened proportionately to allow for the full extent of time.

Finally, the interim final rule raises two other procedural concerns. *First*, HHS should abide by other procedural requirements in the final rule. HHS should perform a family policymaking assessment under Treasury & General Government Appropriations Act of 1999, Pub. L. 105-277. HHS also should certify compliance with a new tribal consultation with affected tribal grantees.¹² *Second*, given HHS's self-confessed failure to disclose irregularities in the 2020 Grants Rule,¹³ HHS should identify its process of reading and responding to comments, including by disclosing in the preamble of the final rule any methods of sampling or other anomalies.

II. HHS was correct to rescind the 2016 Grants rule, which unlawfully burdened religious foster care agencies.

A proper consideration of the issues in the interim final rule involves considering the troubling regulatory history of HHS's attempts to use grantmaking powers to coerce grantee compliance with harmful policies. This unlawful federal overreach began with the 2016 Grants Rule, issued at the end of the Obama administration.¹⁴

Religious agencies who help children find loving homes should be supported and protected, not sidelined for their faith. That is why many foster care agencies receive reimbursement through Title IV-E of the Social Security Act, 42 U.S.C. §§ 670–679c, to help sustain their child-placement activities.

But the 2016 Grants Rule required agencies receiving these funds to violate their religious beliefs by placing children in homes that do not align with their faith. After the Biden-Harris administration rescinded religious exemptions to this rule in

¹² Exec. Orders 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999) & 13,175, 65 Fed. Reg. 67,249 (Nov. 6, 2000).

¹³ Health and Human Services Grants Regulation, 84 Fed. Reg. 63,831 (proposed Nov. 19, 2019); Health and Human Services Grants Regulation, 86 Fed. Reg. 2,257, 2,261 (Jan. 12, 2021).

¹⁴ HHS, Health and Human Services Grants Regulation, 81 Fed. Reg. 89,393 (Dec. 12, 2016).

2021,¹⁵ ADF client Holston United Methodist Home for Children had to sue HHS over this unwise—and unlawful—government coercion.¹⁶

The 2016 Grants Rule disregarded foster care agencies’ religious liberty and free speech—triggering strict scrutiny that the rule could not satisfy. *First*, the First Amendment’s Free Exercise Clause subjected the rule to strict scrutiny because HHS can give exemptions from grant conditions in its discretion for any reason,¹⁷ but no religious exemptions were made. *Fulton v. City of Philadelphia*, 593 U.S. 522 (2021). *Second*, the Religious Freedom Restoration Act (RFRA), 42 U.S.C. § 2000bb et seq., subjected the rule to strict scrutiny because of its burden on religious exercise. *Third*, the concomitant burdens on speech and expressive association triggered strict scrutiny under the First Amendment’s Free Speech Clause. *303 Creative LLC v. Elenis*, 600 U.S. 570, 588, 598 (2023)). But HHS could not satisfy strict scrutiny under any of these laws. The past availability of discretionary exemptions undermined any interest in coercing religious foster care agencies. *Fulton*, 593 U.S. at 540–42.

What is more, the 2016 Grants Rule lacked statutory authority. Title IV-E addresses “race, color, or national origin.” 42 U.S.C. § 671(a)(18)(A)–(B). Neither this statute—nor any other—addressed sex, sexual orientation, or gender identity in Title IV-E grants. The *only* authority HHS ever relied on is the multi-agency housekeeping statute, 5 U.S.C. § 301, which lets an agency head regulate “the government of his department.”¹⁸ This statute only let agencies “regulate [their] own affairs.” *Chrysler Corp. v. Brown*, 441 U.S. 281, 309 (1979). It did not mention protected classes or allow HHS to regulate externally. *United States ex rel. O’Keefe v. McDonnell Douglas Corp.*, 132 F.3d 1252, 1254–56 (8th Cir. 1998).¹⁹

¹⁵ See Health and Human Services Grants Regulation, 88 Fed. Reg. 44,750, 44,752 (proposed July 13, 2023) (reporting revocation of religious exemptions in November 2021).

¹⁶ This case’s complaint and response brief detailed the legal infirmities with the 2016 Grants Rule. Compl., *Holston United Methodist Home For Children, Inc v. Becerra*, No. 2:21-cv-185 (E.D. Tenn. Dec. 2, 2021), ECF No. 1; Pl.’s Opp’n to Def.s’ Mot. to Dismiss, *Holston Home*, No. 2:21-cv-185 (E.D. Tenn. June 22, 2022), ECF No. 29; see also *Holston Home*, No. 2:21-cv-185, 2022 WL 17084226 (E.D. Tenn. Nov. 18, 2022) (finding the rule defunct).

¹⁷ HHS may grant “[e]xceptions on a case-by-case basis for individual non-Federal entities,” 45 C.F.R. § 75.102(b), as may OMB on a program-wide basis, *id.* § 75.102(a).

¹⁸ 81 Fed. Reg. at 89,395.

¹⁹ The same would be true were HHS to seek to exercise general rulemaking authority under Section 1102(a) of the Social Security Act, 42 U.S.C. 1302(a). See 89 Fed. Reg. 36,689.

In the 2024 Grants Rule, issued in the final year of the Biden-Harris administration, HHS recognized that it lacked authority for the 2016 Grants Rule.²⁰ So HHS rescinded the 2016 Grants Rule and imposed different requirements. Activists will no doubt urge HHS to bring back the 2016 Grants Rule or argue that the interim final rule has the same effect on religious foster care agencies. But the 2016 Grants Rule lacks any constitutional or statutory authority. HHS should not bring back that rule, in whole or in part.

And to ensure clarity on this issue, HHS should say in the interim final rule's preamble that no foster care agency receiving funds under Title IV-E is subject to nondiscrimination requirements other than those listed in Title IV-E itself. HHS made this important clarification in the proposed and final 2024 Grants Rule.²¹ HHS should do so again here. This approach respects the reliance interests of foster care agencies like Holston Home in continued funding.²²

III. HHS should not rewrite federal sex-discrimination laws to address matters not included by Congress.

A. The interim final rule reflects HHS's attempt to rewrite federal sex-discrimination laws to address sexual orientation and gender identity.

Like the 2024 Grants Rule, HHS's interim final rule seeks to dramatically rewrite thirteen federal sex discrimination provisions in grants programs other than Title IV-E.²³ The 2024 Grants Rule stated, in these thirteen statutes "that

²⁰ See 89 Fed. Reg. at 36,690.

²¹ 89 Fed. Reg. at 36,686 ("We note that § 75.300(e) does not include the Title IV-E Foster Care Program, which, along with applicable laws and regulations, bars discrimination on the basis of race, color, national origin, disability, and age."); *id.* at 36,687 ("the Department's interpretation set forth in § 75.300(e) is limited to the scope of HHS awards authorized by the statutes listed, which prohibit discrimination on the basis of sex. This list does not include Title IV-E"); 88 Fed. Reg. at 44,758 (Section "75.300(e) does not apply to the foster care programs at issue.").

²² See ADF, *Holston United Methodist Home for Children v. Becerra*, <https://adflegal.org/case/holston-united-methodist-home-children-v-becerra> (video testimony).

²³ The thirteen statutes are: 8 U.S.C. § 1522 (Authorization for programs for domestic resettlement of and assistance to refugees); 42 U.S.C. § 290cc-33 (Projects for Assistance in Transition from Homelessness); 42 U.S.C. § 290ff-1 (Children with Serious Emotional Disturbances); 42 U.S.C. § 295m (Title VII Health Workforce Programs); 42 U.S.C. § 296g (Nursing Workforce Development); 42 U.S.C. § 300w-7 (Preventive Health and Health Services Block Grant); 42 U.S.C. § 300x-57 (Substance Use Prevention, Treatment, and Recovery Services Block Grant; Community Mental Health Services Block Grant); 42 U.S.C. § 708 (Maternal and Child Health Block Grant); 42 U.S.C. § 5151 (Disaster Relief); 42 U.S.C. § 8625 (Low Income Home Energy Assistance Program); 42 U.S.C.

HHS administers which prohibit discrimination on the basis of sex,” HHS “interprets those provisions to include a prohibition against discrimination on the basis of sexual orientation and gender identity, consistent with the Supreme Court’s decision in *Bostock v. Clayton County*, 590 U.S. 644 (2020), and other Federal court precedent applying *Bostock*’s reasoning that sex discrimination includes discrimination based on sexual orientation and gender identity.”²⁴

HHS likewise plans to adopt the OMB guidance in the interim final rule. This guidance contains a new provision, 2 C.F.R. § 200.300, that suggests that HHS should redefine the same thirteen HHS sex discrimination on the unlawful same theory as the 2024 Grants Rule.²⁵ The OMB guidance states, “In administering Federal awards that are subject to a Federal statute prohibiting discrimination based on sex, the Federal agency or pass-through entity must ensure that the award is administered in a way that does not unlawfully discriminate based on sexual orientation or gender identity if the statute’s prohibition on sex

§ 9849 (Head Start); 42 U.S.C. § 9918 (Community Services Block Grant Program); 42 U.S.C. § 10406 (Family Violence Prevention and Services).

²⁴ 89 Fed. Reg. at 80,062 (to be recodified at 2 C.F.R. Section 300.300(c)).

²⁵ 2 C.F.R. § 200.300. This portion of the OMB guidance states:

Subpart D—Post Federal Award Requirements

§ 200.300 Statutory and national policy requirements.

(a) The Federal agency or pass-through entity must manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with the U.S. Constitution, applicable Federal statutes and regulations—including provisions protecting free speech, religious liberty, public welfare, and the environment, and those prohibiting discrimination—and the requirements of this part. The Federal agency or pass-through entity must communicate to a recipient or subrecipient all relevant requirements, including those contained in general appropriations provisions, and incorporate them directly or by reference in the terms and conditions of the Federal award.

(b) In administering Federal awards that are subject to a Federal statute prohibiting discrimination based on sex, the Federal agency or pass-through entity must ensure that the award is administered in a way that does not unlawfully discriminate based on sexual orientation or gender identity if the statute’s prohibition on sex discrimination encompasses discrimination based on sexual orientation and gender identity consistent with the Supreme Court’s reasoning in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020).

(c) In administering awards in accordance with the U.S. Constitution, the Federal agency must take account of the heightened constitutional scrutiny that may apply under the Constitution’s Equal Protection guarantee for government action that provides differential treatment based on protected characteristics.

Id.

discrimination encompasses discrimination based on sexual orientation and gender identity consistent with the Supreme Court’s reasoning in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020).”²⁶

Although the precise import of this rule for HHS is not explained in HHS’s notice, this provision either requires or encourages HHS to retain the 2024 Grants Rule, or it functionally duplicates the 2024 Grants Rule. This provision thus seems to add a new authority that may make HHS retain the 2024 Grants Rule. At a minimum, it provides context to HHS’s decision to retain and recodify the 2024 Grants Rule rather than discard it like other grants provisions.

B. The interim final rule threatens to harm women and children.

HHS should not proceed with the interim final rule in any of these ways. By redefining sex to mean sexual orientation and gender identity in federal grants statutes, the interim final rule threatens harm to women and children.

Abandoning the binary understanding of sex means abandoning reality. And when the government abandons reality, people get hurt. HHS’s new rule thus will hurt women, children, patients, grantees, program participants, and parents. We know this for at least four reasons.

First, the rule threatens women and girls with the loss of equal opportunities, privacy, and safety. In recent Title IX-related rulemaking, HHS and the Department of Education have both sought to require schools nationwide to open sex-specific spaces and programs based on gender identity, to allow biological males to play against girls in sports and P.E. class, to assign females to the health class covering the male reproductive system, to use preferred rather than sex-reflective pronouns, and to permit males in girls’ bathrooms, showers, and overnight accommodations.²⁷ Now, by seeking to redefine sex in Title IX and similar sex-discrimination statutes for HHS grant programs, HHS seeks to threaten women’s equal access to sports teams, classes, facilities, and housing in HHS grant programs covering preschools, public schools, children’s residential homes, and public universities with medical and nursing schools, and many other contexts. For instance, by redefining sex in women’s healthcare programs like Maternal and

²⁶ *Id.* § 200.300(b).

²⁷ See Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37,522 (May 6, 2024); Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance, 89 Fed. Reg. 33,474 (Apr. 29, 2024).

Child grant programs, the rule threatens to allow any male who self-identifies as a mother to access female facilities and access benefits meant exclusively for mothers.

Second, by seeking to redefine sex in healthcare programs like the Community Mental Health grants and other block grants for medical programs, the rule harms patients who struggle with their bodies, and it censors providers who seek to help them. In similar recent rulemakings, by redefining sex to mean gender identity in Title IX, HHS interpreted Section 1557 of the Affordable Care Act to force certain doctors to perform and affirm harmful gender-transition procedures on children.²⁸ The interim final rule threatens to do the same: to require healthcare providers to endorse and refer patients—even children—for radical, life-altering gender interventions such as puberty blockers, cross-sex hormones, and surgeries to remove healthy reproductive organs. And the rule threatens to silence healthcare providers who seek to share the risks and harms of transition procedures.

Third, by seeking to redefine sex across human services programs, the rule threatens to coerce grantees, employees, and program participants to adopt a false view of sex and to use pronouns and titles that do not match a person's sex. At the same time, the rule threatens to censor the views of healthcare providers who seek to help patients achieve their own goals of being at peace with their bodies.

Fourth, by seeking to redefine sex in children's programs, the rule threatens to erode parental rights. In particular, by seeking to redefine sex in Head Start's universal preschool programs for low-income families, the rule threatens to require preschools to expose very young children to inappropriate material and to teach them to question their gender—regardless of parents' views or knowledge.

All in all, by restricting funding programs that Congress did not impose—nondiscrimination on the basis of sexual orientation and gender identity—HHS wrongly limits the scope of the program. In particular, faith-based recipients of funds will be less able to serve beneficiaries where this restriction prohibits them from participating in programs. Ejecting faith-based groups from programs will lead to fewer children served, not more children served.

ADF serves many non-profit organizations covered or potentially covered by the interim final rule because they receive or participate in federal grants or agreements. Many have belief-based policies and practices that might be seen as inconsistent with the interim final rule. HHS's incorrect interpretation of law and of agencies' legal authority to impose these policy restrictions thus will inflict

²⁸ 89 Fed. Reg. 37,522 (May 6, 2024).

substantial burdens on large numbers of dissenting organizations. This burden raises significant issues under the First Amendment, RFRA, 42 U.S.C. § 2000bb et seq., and the APA, e.g., 5 U.S.C. §§ 553, 706.

C. The interim final rule is unlawful.

HHS moreover lacks any legal authority to impose these dramatic changes on programs like Head Start. Congress has never given HHS the authority to redefine these or any other statutes to address sexual orientation and gender identity.²⁹

1. Congress never addressed sexual orientation or gender identity in the statutory text.

The statutes listed in the proposed Section 75.300(e) are sex-discrimination provisions, not sexual-orientation or gender-identity provisions. Some statutes have standalone sex-discrimination provisions that HHS seeks to redefine. *E.g.*, 8 U.S.C. § 1522(a)(5); 42 U.S.C. §§ 290cc-33(a)(2), 290ff-1(e)(2)(C), 295m, 296g, 300w-7(a)(2), 300x-57(a)(2), 708(a)(2), 5151(a), 8625(a), 9849(a)–(b), 9918(c)(1), 10406(c)(2)(B)(i). Five of these statutes operate by incorporating Title IX’s sex-discrimination prohibition, either as the program’s sole sex-discrimination provision or in addition to freestanding program sex-discrimination provisions. *E.g.*, 42 U.S.C. §§ 290cc-33(a)(1), 300w-7(a)(1), 300x-57(a)(1), 708(a)(1), 10406(c)(2)(A). In the interim final rule, HHS relies on *Bostock v. Clayton County*, 590 U.S. 644 (2020), to redefine the term sex in each to mean sexual orientation and gender identity.

But these grant statutes contain no textual basis to redefine sex to mean gender identity or sexual orientation. The original understanding of the word sex in these statutes—as well as their purpose, structure, and context—points to a binary, biological understanding. For instance, the Children with Serious Emotional Disturbances program’s sex discrimination provision “may not be construed ... to prohibit a system of care ... from requiring that, in housing provided by the grantee ... males and females be segregated to the extent appropriate in the treatment of the children involved.” 42 U.S.C. § 290ff-1(e)(3)(A)(i). The refugee assistance program likewise requires “that women have the same opportunities as men to participate in training and instruction.” 8 U.S.C. § 1522(a)(1)(A). In the same way, the Title VII Health Workforce Programs refers to a medical school

²⁹ These arguments equally apply to the 2024 Grants Rule’s preamble’s expansive language about sex characteristics, intersex traits, gender expression, sex stereotypes, and perceived status. 89 Fed. Reg. at 36,689; 88 Fed. Reg. at 44,753 n.11. But, because the interim final rule’s text does not mention these traits, the interim final rule does not include them. HHS cannot broaden a rule’s scope through preamble language, let alone preamble language from a separate rulemaking.

“changing its status as an institution which admits only female students to that of an institution which admits students without regard to their sex.” 42 U.S.C. § 295m(1). So too the Maternal and Child Health Block Grant focuses on “maternal and prenatal health,” 42 U.S.C. § 711(c)(1), defining an eligible family, in part, as “a woman who is pregnant, and the father of the child,” 42 U.S.C. § 711(l)(2)(a). The Head Start program also repeatedly considers the needs of “pregnant women.” 42 U.S.C. §§ 9840(a)(5)(A)(iii) & (d)(3), 9840a(c)(1) & (i)(2)(G), 9852b(d)(2)(C).

And even though HHS seeks to redefine Title IX, as incorporated by these statutes, Title IX does not define sex to mean sexual orientation or gender identity either.³⁰ Congress passed Title IX to ensure equal educational opportunities for “women.” *Cohen v. Brown Univ.*, 101 F.3d 155, 165 (1st Cir. 1996). In 1972, the word “sex” referred to biological differences, not “gender identity.” *Adams ex rel. Kasper v. Sch. Bd. of St. Johns Cnty.*, 57 F.4th 791, 811–17 (11th Cir. 2022) (en banc). Title IX thus forbids differential treatment that disfavors, denies, or treats one sex worse than the other. *Id.* at 813.

Title IX moreover allows and sometimes requires sex distinctions to ensure equal opportunity. “Discrimination” in education programs refers not to “differential” treatment, but to “less favorable” treatment based on sex, *Jackson v. Birmingham Bd. of Educ.*, 544 U.S. 167, 174 (2005) (cleaned up), where nothing justifies “the difference in treatment,” *CSX Transp., Inc. v. Ala. Dep’t of Revenue*, 562 U.S. 277, 287 (2011). It means treating a person “worse than others who are similarly situated.” *Students for Fair Admissions, Inc. v. President & Fellows of Harvard Coll.*, 600 U.S. 181, 288 (2023) (Gorsuch J., concurring). Immutable differences between males and females mean the two often are not similarly situated. Indeed, the statute recognizes that sex-based distinctions can be necessary to equalize educational opportunity. It states: “[N]othing ... [in Title IX] shall be

³⁰ Many reasons why Title IX, Section 1557 of the Affordable Care Act, and similar statutes must be interpreted narrowly and to protect liberty are set forth in ADF comments on other rulemakings and are incorporated by reference. See *ADF 2024 Grants Rule Comment* (Aug. 30, 2023), <https://www.regulations.gov/comment/HHS-OCR-2023-0011-0019> (explaining how the similar 204 Grants Rule lacked authority and would harm women and children); *ADF Title IX Rule Comment* (Sept. 11, 2022), <https://www.regulations.gov/comment/ED-2021-OCR-0166-200280> (explaining how redefining sex in Title IX lacks legal authority, hurts female athletes, undermines parental rights, harms unborn children and women, and violates freedoms of speech and religion); *ADF Section 1557 Rule Comment* (Oct. 3, 2022), <https://www.regulations.gov/comment/HHS-OS-2022-0012-68192> (comment on Title IX, Section 1557 of the Affordable Care Act, and the proposed religious liberty notification process); *ADF Title IX Sports Rule Comment* (May 15, 2023), <https://www.regulations.gov/comment/ED-2022-OCR-0143-141953> & <https://www.regulations.gov/comment/ED-2022-OCR-0143-150698> (explaining how Title IX cannot be changed administratively and how redefining sex harms female athletes).

construed to prohibit any educational institution ... from maintaining separate living facilities for the different sexes.” 20 U.S.C. § 1686. This “[i]nterpretation” principle, as Congress titled it, *id.*, isn’t listed among the statutory exceptions, 20 U.S.C. § 1681(a)(1)–(9). It’s an interpretive command that forbids any part of Title IX from being “construed” to prohibit traditional sex distinctions that respect privacy.

Courts across the country and the judiciary have thus held that the Biden-Harris administration lacks any authority to redefine Title IX. Three district courts have enjoined HHS’s rule purporting to reinterpret Title IX and Section 1557. *Tennessee v. Becerra*, No. 1:24cv161, 2024 WL 3283887, at *13–14 (S.D. Miss. July 3, 2024); *Texas v. Becerra*, No. 6:24-cv-211, 2024 WL 3297147, at *12 (E.D. Tex. July 3, 2024); *Florida v. HHS*, No. 8:24-cv-1080, 2024 WL 3537510, at *20–21 (M.D. Fla. July 3, 2024), staying portions of Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37,522 (May 6, 2024). Eight district courts have likewise preliminarily enjoined enforcement of the Department of Education’s rule rewriting Title IX in 26 states and thousands of additional schools. *Alabama v. U.S. Sec’y of Educ.*, No. 24-12444, 2024 WL 3981994, at *1–2, *1 n.2 (11th Cir. Aug. 22, 2024) (per curiam) (collecting cases). In refusing to stay these Title IX injunctions pending appeal, every Supreme Court justice “accept[ed] that the plaintiffs were entitled to preliminary injunctive relief” at least in part. *Dep’t of Educ. v. Louisiana*, 144 S. Ct. 2507, 2509–10 (2024) (per curiam).

Of the 13 statutes that the 2024 Grants Rule affected, at most only one program, about family violence, addresses sexual orientation or gender identity, and it does so only because of limited—and separate—amendments. This program’s sex discrimination provision, 42 U.S.C. § 10406, does not address sexual orientation or gender identity. Other amendments expanded the scope of the program to address sexual orientation or gender identity. 34 U.S.C. § 12291; 45 C.F.R. Pt. 1370. This provision shows that when Congress seeks to address sexual orientation or gender identity in grant statutes, it will do so expressly. *See also* 42 U.S.C. § 294e-1(b)(2).

This interim final rule, the 2024 Grants Rule, and the OMB guidance as imposed in HHS regulations. are arbitrary and capricious for imposing gender identity and sexual orientation nondiscrimination rules through sex discrimination statutes.

HHS also acts illegally by imposing those rules as a “public policy” requirement. Labeling a mandate as “public policy” is simply a euphemism for legislating. But HHS has no statutory authority to impose nondiscrimination requirements under statutes where Congress has prohibited sex discrimination but not these

categories of discrimination. It is also well-settled that the housekeeping statute gives HHS no authority to impose substantive mandates.

2. Congress never provided clear notice in the statutory text of a gender-identity mandate.

For two reasons, the lack of clear statutory authority for HHS's new interpretation of these statutes should end the analysis.

First, whether HHS may rewrite sex discrimination laws to add new protected classes across its hundreds of millions of dollars of grant programs is a major question of vast political and economic significance. Under the Supreme Court's major questions doctrine, HHS must have clear statutory authority to impose this mandate. *See, e.g., Biden v. Nebraska*, 143 S. Ct. 2355, 2358 (2023); *West Virginia v. EPA*, 597 U.S. 697 (2022).

Second, the federalism clear-notice canon applies because each grants statute falls under the Spending Clause, *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17, 24 (1981), and displaces a traditional area of state authority. Congress thus must use "exceedingly clear language if it wishes to significantly alter the balance between federal and state power." *Sackett v. EPA*, 598 U.S. 651, 679–80 (2023) (cleaned up). HHS cannot add any grant conditions unless they were "unmistakably clear in the language of the statute," *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (cleaned up), at the time of enactment, *Carcieri v. Salazar*, 555 U.S. 379, 388 (2009). HHS may not surprise grantees "with post acceptance or 'retroactive' conditions." *Pennhurst*, 451 U.S. at 25. Each State "has a significant role to play in regulating the medical profession," *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007), as well as "an interest in protecting the integrity and ethics of the medical profession," *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997). Education is also a context "where States historically have been sovereign." *United States v. Lopez*, 514 U.S. 549, 564 (1995).

Yet here, HHS appears to seek to override state authority over a vast array of topics like medical procedures, locker rooms, restrooms, physical education, and speech on a controversial issue. HHS conceded a lack of a clear authority to do that in the 2024 Grants Rule, saying that the 2024 Grants Rule sought to make grant

conditions more clear, certain, stable, predictable, and simple.³¹ With no unmistakably clear statutory notice, HHS lacks authority.³²

3. *Bostock* does not apply.

Bostock v. Clayton County, 590 U.S. 644 (2020) is not to the contrary. It does not extend to sex discrimination provisions in the relevant statutes here, particularly in comparison to Title IX.

Bostock does not extend beyond hiring and firing under Title VII. In *Bostock*, the Supreme Court rejected that its “decision will sweep beyond Title VII to other federal or state laws that prohibit sex discrimination.” 590 U.S. at 681. The court warned that “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.” *Id.* Even under Title VII, *Bostock* excluded intimate spaces: the Court did “not purport to address bathrooms, locker rooms, or anything else of the kind.” *Id.* Nor did *Bostock* consider the “particularly strict” effect of the clear-notice federalism canon. *Port Auth. Trans-Hudson Corp. v. Feeney*, 495 U.S. 299, 305 (1990). *Bostock* thus did not displace longstanding limits on grant conditions or on laws preempting traditional areas of state responsibility.

Bostock thus expressly disavowed the implication that its rationale translates to Title IX. 590 U.S. at 681. And for good reason. *Bostock* dealt with hiring and firing employees under Title VII; Title IX concerns educational opportunities. Title VII treats an individual’s sex in employment like race and religion, where none of these factors are “relevant.” *Bostock*, 590 U.S. at 660. No one thinks Title VII allows business owners to hire only male accountants or assign men and women to different office floors. But sex distinctions are common in schools—like boys’ and girls’ gym class. *See Adams*, 57 F.4th at 808; *cf. L.W. ex rel. Williams v. Skrmetti*,

³¹ 89 Fed. Reg. at 36,702; 88 Fed. Reg. at 44,753–54, 44,756–58. For instance, HHS added “paragraph (e) to 45 CFR 75.300 to clarify the Department interprets preexisting prohibition against discrimination on the basis of sex to include discrimination on the basis of sexual orientation and gender identity.” *Id.* at 44,757 (emphasis added). *See also* 89 Fed. Reg. at 80,058 (“The single set of Federal financial assistance requirements at 2 CFR part 200 and 2 CFR part 300 resulting from this interim final rule will *lessen confusion* and reduce burden for HHS applicants and recipients that apply for and receive financial assistance from other Federal agencies outside of HHS.”) (emphasis added).

³² Plus, because grantees are not already under these mandates and because these mandates displace state authority (including by imposing new mandates on state grantees), HHS must quantify these mandates’ economic costs and analyze their federalism implications, rather than assuming the new rule lacks any additional economic impact or lacks federalism implications. 89 Fed. Reg. at 80,058–59.

83 F.4th 460, 484 (6th Cir. 2023), *cert. granted sub nom. United States v. Skrmetti*, 144 S. Ct. 2679 (2024) (mem.) (refusing to extend *Bostock*'s reasoning beyond Title VII). As the Eleventh Circuit explained, transplanting *Bostock* to Title IX ignores that "Title IX and its implementing regulations prohibit discrimination on the basis of sex, but they also explicitly permit differentiating between the sexes in certain instances." *Adams*, 57 F.4th at 814.

On top of that, Title IX repeatedly allows schools to "treat[] males and females comparably as groups," while Title VII does not. *Bostock*, 590 U.S. at 665 (rejecting this reading of Title VII). Title IX exempts "father-son or mother-daughter activities" so long as "opportunities for reasonably comparable activities [are] provided for students of [both sexes]." 20 U.S.C. § 1681(a)(8). Housing for each sex must be "[c]omparable in quality and cost to the student." 34 C.F.R. § 106.32(b)(ii); *see also id.* § 106.32(c)(2)(ii) (similar). "[T]oilet, locker room, and shower facilities" must likewise be comparable. 34 C.F.R. § 106.33. And schools must "provide equal athletic opportunity for members of both sexes." *Id.* § 106.41(c). The list goes on. *See, e.g., id.* §§ 106.31(c), 106.34(b)(2), 106.37(c). Under *Bostock*'s logic—and thus the rule's—all these long-standing regulations would violate Title IX because all of them rely on noticing an individual's sex. Instead, these regulations show that Title IX is not blind to sex—HHS's reading is wrong.

Importantly, *Bostock* did not create any new protected classes. *See, e.g., Texas v. EEOC*, 633 F. Supp. 3d 824, 831 (N.D. Tex. 2022); *Stollings v. Tex. Tech Univ.*, No. 5:20-CV-250-H, 2021 WL 3748964, at *10 (N.D. Tex. Aug. 25, 2021). But the interim final rule's new definition does just that, elevating "gender identity" and other characteristics to protected-class status under Title IX and other sex-discrimination laws.

HHS fails to acknowledge the many courts that have not accepted its expansive view of *Bostock* outside the Title VII context. *Alabama v. U.S. Sec'y of Educ.*, 2024 WL 3981994, at *1–2, *1 n.2 (per curiam) (collecting cases). But, as these decisions show, case law interpreting Title IX or other sex-discrimination statutes is more relevant than case law about Title VII. Indeed, *Bostock* admitted that its interpretation of Title VII was "unexpected," "momentous," and "unanticipated at the time of the law's adoption." 590 U.S. at 649, 660, 679 (cleaned up). That admission dooms the rule under clear notice canons applicable to this Spending Clause, state sovereignty, and major question context.

4. HHS should engage in further analysis.

Rather than analyze these or other decisions against it, HHS refuses to engage in reasoned decision-making—whether in this interim final rule or in the

2024 Grants Rule. But HHS should rescind this interim final rule and the 2024 Grants Rule until courts resolve the correct understanding of Title IX, and until the Supreme Court resolves the correct understanding of the equal protection guarantee in *Skrmetti*.³³ Nor should HHS prejudge future laws by adding similar language redefining yet-to-be-passed statutes, as HHS has considered in the 2024 Grants Rule and some activists may urge.³⁴

Furthermore, HHS should clarify two important aspects of the interim final rule. *First*, does each newly redefined sex discrimination statute in fact impose operation-wide mandates, like Title IX, such that any public school district that accepts Head Start grants must abide by this grant condition in all aspects of its operations—including high school sports teams or services by school nurses? It would help future grantees if HHS makes its expectations known. *Second*, if so, does HHS purport to displace contrary state laws with these grant conditions, such that any contrary state law is preempted? For example, if a school district accepts Head Start funds, are state laws protecting women’s sports preempted or state laws restricting transition procedures on children preempted? The answer to this question will determine whether many grantees are eligible to seek funding. HHS thus should quantify the number of grantees who will lose funding and be excluded from grants because of HHS’s harmful and unlawful rulemaking.

Of course, HHS should not purport to have the power to preempt state laws through grant conditions, whether under a claim of statutory authority or by this regulation. Congress lacks the authority under the Spending Clause to preempt state law. An agency may not pay anyone to violate state law. Instead, if state law prevents the spending of federal funds in a certain way, the only thing an agency may do is disallow funds. *Health & Hosp. Corp. of Marion Cnty. v. Talevski*, 599 U.S. 166, 183 (2023). HHS should make clear that its rulemaking lacks any preemptive power.

IV. HHS should provide robust free-speech, religious-liberty, and parental-rights protections in the rule.

In at least eight ways, the interim final rule threatens religious liberty, conscience, free speech, and parental rights. HHS thus should recognize express up-front exemptions in the regulatory text—and HHS’s assurance-of-exemption process is no substitute for up-front exemptions.

³³ *United States v. Skrmetti*, No. 23-477 (U.S.).

³⁴ See 89 Fed. Reg. 36,689.

First, at least five of the affected programs incorporate by reference Title IX, including Title IX’s religious exemption. *E.g.*, 42 U.S.C. §§ 290cc-33(a)(1), 300w-7(a)(1), 300x-57(a)(1), 708(a)(1), 10406(c)(2)(A). Title IX does not apply to entities controlled by a religious organization if its application would be inconsistent with the organization’s religious tenets. 20 U.S.C. § 1681(a)(3). When the 2016 Section 1557 rule adopted under Title IX omitted this exemption, it was held unlawful. “By not including these exemptions, HHS expanded the ‘ground prohibited under’ Title IX that Section 1557 explicitly incorporated.” *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 691 (N.D. Tex. 2016) (quoting 42 U.S.C. § 18116(a)). The interim final rule thus must incorporate Title IX’s up-front categorical religious exemption as to these five statutes.

Second, in the past, HHS has acknowledged its duty to abide by what it calls a First Amendment “nondiscrimination principle” and not to disqualify religious recipients from public benefits programs because of their religious character.³⁵ HHS should amend the interim final rule to respect that same nondiscrimination principle. Any discrimination by HHS on the basis of religion among program participants or service providers is unconstitutional. *See, e.g., Carson ex rel. O.C. v. Makin*, 596 U.S. 767 (2022); *Espinoza v. Mont. Dep’t of Revenue*, 591 U.S. 464 (2020); *Trinity Lutheran Church of Columbia, Inc. v. Comer*, 582 U.S. 449 (2017).

Third, at least nine of these statutes include religious nondiscrimination provisions, which can be even broader than the First Amendment or RFRA. *E.g.*, 8 U.S.C. § 1522(a)(5); 42 U.S.C. §§ 290cc-33(a)(2), 290ff-1(e)(2)(C), 300w-7(a)(2), 300x-57(a)(2), 708(a)(2), 5151(a), 9849(a), 10406(c)(2)(B); *see also* 42 U.S.C. §§ 290kk–290kk-3, 300x-65; 42 C.F.R. pts. 54 & 54a; 44 C.F.R. § 206.11. It is arbitrary to add non-statutory gender identity or sexual orientation mandates, while ignoring statutory religious protections. HHS should make clear that these religious nondiscrimination provisions to protect religious grantees, parents, and participants take priority over HHS’s new non-statutory grant conditions.

Fourth, the APA requires HHS to consider *now*—in the preamble—the effect of liberty-protecting laws like the First Amendment, RFRA, Title IX’s religious exemption, religious non-discrimination statutes, and the Fourteenth Amendment’s protection of parental rights. Even the *Bostock* Court was “deeply concerned with preserving” religious institutions’ freedom. *Bostock*, 590 U.S. at 681–82. HHS’s failure thus far to “overtly consider” all these interests—and tailor its regulation to

³⁵ Partnerships With Faith-Based and Neighborhood Organizations, 88 Fed. Reg. 2395, 2401 (Jan. 13, 2023).

provide up-front exemptions—renders it fatally flawed. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 681–82 (2020).

HHS cannot defer the consideration of these important questions to case-by-case enforcement. As courts held the last times that HHS tried to sidestep its constitutional and statutory duties to protect liberty, HHS’s vague promises “to ‘comply with’” all applicable laws and RFRA’s balancing test does not negate its mandate’s injuries. *Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 604 (8th Cir. 2022) (quoting *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 377 (5th Cir. 2022)). Moreover, “the hypothetical chance that the Government could advance a compelling government interest sometime in the future” in case-by-case scrutiny does not defeat requests for RFRA protection against an existing mandate. *Id.* (quoting *Franciscan All.*, 47 F.4th at 380).

Fifth, after consideration of these protections, HHS must change the interim final rule to avoid coercing or burdening religious grantees, parents, and program participants under the Free Speech Clause, the Free Exercise Clause, the Fourteenth Amendment, and RFRA. HHS lacks any interest in regulating speech and religious exercise, or impairing a group’s expressive identity, such as by requiring an entity to affirm statements that are not true, requiring a speaker to use biologically incorrect pronouns, or “compel[ling] an individual to create speech she does not believe.” *303 Creative LLC*, 600 U.S. at 578–79. HHS may not “coerce an individual to speak contrary to her beliefs on a significant issue of personal conviction.” *Id.* at 598. And HHS has elsewhere acknowledged that it must respect parental rights—“the fundamental role that parents play in raising their children.”³⁶ See *Troxel v. Granville*, 530 U.S. 57, 65 (2000) (plurality opinion); *Pierce v. Soc’y of Sisters*, 268 U.S. 510, 535 (1925).

As discussed above in the context of the 2016 Grants Rule, HHS’s burdens on speech and religious exercise are subject to strict scrutiny. But HHS has not applied these statutes this way before this year, which undermines any claim that its policy “can brook no departures.” *Fulton*, 593 U.S. at 542.

In non-binding advisory preamble language, HHS recognized that the 2024 Grants Rule is subject to full case-by-case exemptions, reconsideration, or modifications for any entity—secular or religious—which is fatal for the lawfulness of the 2024 Grants Rule and the interim final rule. HHS said in the 2024 Grants Rule that “§ 75.300(e) expresses the Department’s current interpretation of the

³⁶ 89 Fed. Reg. at 36,692.

listed statutes; a member of the public will, upon proper request, be accorded a fair opportunity to seek modification, rescission, or waiver of § 75.300(e).”³⁷

Because these rules allow for broad secular case-by-case exemptions or reconsideration, HHS must satisfy strict scrutiny. *Fulton*, 593 U.S. at 541. And, under strict scrutiny, HHS may not rely on a “broadly formulated” interest in “equal treatment” or in “enforcing its non-discrimination policies generally,” but must establish a narrowly tailored compelling interest of the highest order “in denying an exception” for each grantee. *Id.* (cleaned up).

But HHS’s “creation of a system of exceptions ... undermines” any purported compelling interest. *See id.* at 1881–82. The government may not treat secular activity better than religious activity. *Tandon v. Newsom*, 593 U.S. 61, 62 (2021) (per curiam). And under RFRA’s least-restrictive-means requirement, “religious freedom cannot be encumbered on a case-by-case basis.” *Christian Emps. All. v. EEOC*, 719 F. Supp. 3d 912, 926 (D.N.D. 2024).

Sixth, the assurance-of-exemption process for individual entities with religious-liberty or conscience concerns in Section 75.300(f), now proposed in Section 300.300(d), will not avoid chilling the exercise of these protected rights. As just discussed, an assurance-of-exemption process is no substitute for up-front exemptions under the Constitution, RFRA, and other statutes. The Constitution and RFRA govern in all instances, and Title IX’s robust religious exemption likewise applies automatically by law. *Maxon v. Fuller Theological Seminary*, 549 F. Supp. 3d 1116, 1125 (C.D. Cal. 2020). Citizens need not obtain government permission to exercise their rights without fear of liability. If anything, the existence of this assurance-of-exemption process shows that HHS knows that its mandates will unlawfully burden and chill protected rights.

Worse, even if an entity embarks upon the assurance-of-exemption process, HHS does not guarantee that upon notification of a grantee’s religious freedom concerns HHS *will* respect free speech or religious exercise—the assurance-of-exemption process states merely that HHS will *consider* opining on these issues. The regulatory text does not state how or when any statutory or constitutional protections apply, or even what HHS understands these protections to require.

And make no mistake: once an assurance of a RFRA exemption is sought, HHS seems unlikely to respond, issue religious waivers, or self-enforce RFRA because, in HHS’s view, RFRA requires no affirmative agency compliance or

³⁷ 89 Fed. Reg. at 36,690.

enforcement beyond what a court orders.³⁸ As one commenter explained about the draft Section 1557 rule’s similar process for notifying the Office for Civil Rights (OCR) of religious freedom conflicts, “[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.”³⁹

On top of this, the separate assurance-of-exemption process holds out the possibility of religious or conscience exemptions for *some* religious or conscientious entities, but not *all*. This assurance-of-exemption process thus not only provides another basis for why the regulations will not pass strict scrutiny but independently raises serious constitutional equal-protection concerns. Religious freedom does not depend on one’s zip code or other factors that HHS may consider relevant in enforcement proceedings.

Worse, as HHS makes clear in the severability clause in § 75.300(g) (now proposed in Section 300.300(e)), HHS will not only fail to voluntarily follow RFRA, but also will not apply any adverse RFRA ruling beyond the parties protected in a case to similarly situated entities. Even if HHS allows for an interim assurance of exemption while the process proceeds, the interim final rule thus seeks to force *each* religious grantee to undergo years of uncertainty about the final state of its rights—potentially risking at any moment new unexpected compliance costs and unknown enforcement proceedings followed by years of litigation. All of this threatens to deter would-be grantees from seeking grants or assurances of exemption.

Far from helping grantees gain certainty about whether HHS will respect their rights, this process seeks to enable HHS to argue to a court that any clash with religious freedom is speculative—so HHS can evade or postpone judicial review. This is religious targeting, and it is unlawful. *Masterpiece Cakeshop, Ltd. v. Colo. C.R. Comm’n*, 584 U.S. 617 (2018). It would never fly in the context of any other protected right.

³⁸ Delegation of Authority, 86 Fed. Reg. 67,067 (Nov. 17, 2021); Sam Dorman, *HHS Memo Shows Department Moving to Undo Trump-era Action Aimed at Better Protecting Religious Liberty*, Fox News: Politics (Nov. 17, 2021, 6:35 AM), <https://www.foxnews.com/politics/hhs-ocr-memo-rfra-trump-religious-liberty> (“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.”).

³⁹ Rachel N. Morrison, *HHS’s Proposed Nondiscrimination Regulations Impose Transgender Mandate in Health Care*, Federalist Soc’y: FedSoc Blog (Sept. 8, 2022), (<https://fedsoc.org/commentary/fedsoc-blog/hhs-s-proposed-nondiscrimination-regulations-impose-transgender-mandate-in-health-care-1>).

Seventh, the assurance-of-exemption process does not address any protections or burdens on third parties beyond the grant applicant or recipient itself. The interim final rule, for instance, does not address burdens on the protected rights of a grantee's employee, owner, vendor, corporate sibling, or other associated entities. Nor does the interim final rule explain why HHS can or should use grantees as a tool to coerce third parties in violation of or in circumvention of these third parties' religious liberty, conscience, and free-speech rights.

Eighth, the assurance-of-exemption process raises several procedural concerns.

- Despite the withdrawal of RFRA delegation from OCR, OCR would be doing some religious liberty work—including as applied to laws enforced by other HHS components. Does OCR have, or will it receive, delegated authority to do this under the interim final rule?
- Who will evaluate claims and make final decisions? Will the career professionals from the now-disbanded Conscience and Religious Freedom Division of OCR be involved, and if not, why not?
- OCR has no set deadline or duty to respond to exemption requests. What will ensure prompt responses—or any responses at all? How will a grant application receive an assurance in time to make an informed decision about whether to apply for a grant and to meet deadlines for grant applications and contracts? The assurance-of-exemption process does not require HHS to provide any decision to the entity, let alone require HHS to provide a final decision within a reasonable or defined time frame. So even if grantees may get interim protection they will lack the ultimate certainty necessary for making important business decisions about seeking or continuing grant participation.
- HHS views non-discrimination as a compelling interest. Can this process result in *any* exemptions, under HHS's view? If so, HHS should explain how.
- This process involves the loss of anonymity and privacy, much like the process for an assurance of exemption under Title IX, where, under the Freedom of Information Act (FOIA), activists obtain information about exempt entities to conduct harassment campaigns.⁴⁰ How is the process not at risk of First Amendment problems under *Ams. for Prosperity Found. v. Bonta*, 594 U.S. 595 (2021)?

⁴⁰ See 89 Fed. Reg. at 36,694–95 (acknowledging that exemption requests are subject to disclosure under FOIA).

- This is not required for an exemption, but the existence of this assurance-of-exemption process will suggest that seeking an assurance is required. So creating this assurance-of-exemption process likely has chilled and will chill religious exercise by those not participating in it. How will HHS address this chilling effect? Will HHS respect religious liberty if this process is not followed? How? And will HHS abide by court orders against its interim final rule?
- How many entities will request exemptions and how much will it cost each entity to undertake the assurance-of-exemption process? What form will these costs take? As with the recent Section 1557 rule,⁴¹ HHS should quantify these compliance costs in the rule's preamble.

In conclusion, ADF supports rescinding the 2016 Grants Rule. ADF strongly opposes redefining sex discrimination laws in the OMB guidance, the 2024 Grants Rule, and the interim final rule. HHS should withdraw the interim final rule, engage in further deliberation after the Supreme Court resolves whether Title IX encompasses gender identity, and at least extend the comment period to account for the significant time when no comment button was available on the government's websites for this rule.

Respectfully Submitted,

Matthew S. Bowman
Director of Regulatory Practice

⁴¹ 89 Fed. Reg. at 37,684.