

**Note: This is an unofficial version of the final rule. The official version has been sent to the Office of the Federal Register and is being scheduled for publication.**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**45 CFR Parts 75**

**RIN: 0945-AA19**

**Health and Human Services Grants Regulation**

**AGENCY:** Department of Health and Human Services (HHS); Office for Civil Rights (OCR) and the Office of the Assistant Secretary for Financial Resources (ASFR).

**ACTION:** Final rule.

**SUMMARY:** The Department of Health and Human Services (HHS or the Department) is issuing this final rule to repromulgate and revise certain regulatory provisions of the HHS, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, previously set forth in a final rule published in the Federal Register on December 12, 2016 (2016 Rule).

**DATES:** This rule is effective on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**FOR FURTHER INFORMATION CONTACT:**

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*Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record:* Upon request, the Department will provide an accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for the final rule. To schedule an appointment for this type of accommodation or auxiliary aid, please call (202) 795-7830 or (800) 537-7697 (TDD) for assistance or email [hhsocrgrants@hhs.gov](mailto:hhsocrgrants@hhs.gov).

## **SUPPLEMENTARY INFORMATION:**

This **Federal Register** document is also available from the **Federal Register** online database through <http://www.govinfo.gov>, a service of the U.S. Government Publishing Office.

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## **I. Background**

### **A. Regulatory History**

On December 26, 2013, the Office of Management and Budget (OMB) issued the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (UAR or uniform regulations) that “set standard requirements for financial management of Federal awards across the entire federal government.” *See* 78 FR 78590 (Dec. 26, 2013). On December 19, 2014, OMB and other Federal award-making agencies, including the Department, issued an interim final rule to implement the UAR. 79 FR 75867 (Dec. 19, 2014). On July 13, 2016, the Department issued a Notice of Proposed Rulemaking (2016 NPRM) proposing changes to its adoption of the 2014 UAR Interim Final Rule. *See* 81 FR 45270 (July 13, 2016). On December 12, 2016, the Department finalized the 2016 NPRM and the final rule went into effect on January 11, 2017 (2016 Rule). *See* 81 FR 89393.<sup>1</sup> On November 19, 2019, the Department issued a Notice of Nonenforcement, which stated that the Department would not enforce the regulatory provisions adopted or amended by the 2016 Rule. *See* 84 FR 63809 (Nov. 19, 2019). On the same day, the Department issued an NPRM proposing to “repropulgate some of the provisions of the [2016] Final Rule, not to repromulgate others, and to replace or modify certain provisions that were included in the Final Rule with other provisions.” 84 FR 63831 (2019 NPRM). On January 12, 2021, HHS repromulgated portions of and issued amendments to the 2016 Rule. 86 FR 2257 (2021 Rule) (Jan. 12, 2021). That rule was vacated in part and remanded back to the Department<sup>2</sup> after the Department noted in litigation that it had “reviewed only a small fraction of the non-duplicative comments, did not employ a sampling methodology likely to

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<sup>1</sup> The 2016 Rule also made a technical change not set forth in the Proposed Rule, amending § 75.110(a) by removing “75.355” and adding, in its place, “75.335.”

<sup>2</sup> See Order, *Facing Foster Care et al. v. HHS*, No. 21-cv-00308 (D.D.C. June 29, 2022), ECF No. 44 (vacating “those portions of the... regulation entitled Health and Human Services Grants Regulation, 86 Fed. Reg. 2,257 (Jan. 12, 2021), that amend 45 CFR 75.101(f), 75.300(c), and 75.300(d)” and remanding to HHS). Because they were not subject to the order of vacatur, certain provisions previously adopted in the 2021 Rule remain in effect. These provisions are: 45 CFR 75.305, 75.365, 75.414, and 75.477.

produce an adequate sample of the comment received, and did not explain its use of sampling in the final rule.”<sup>3</sup>

On July 13, 2023, the Department published the NPRM associated with this rulemaking (2023 NPRM or Proposed Rule). *See* 88 FR 44750 (July 13, 2023). The Department invited comment from all interested parties. The comment period for the Proposed Rule ended on September 11, 2023, and the Department received 8,294 comments. A wide range of individuals and organizations submitted comments, including private citizens, health care workers and institutions, faith-based organizations, patient advocacy groups, civil rights organizations, and professional associations. The comments covered a variety of issues and points of view responding to the Department’s requests for comments, all of which the Department reviewed and analyzed. The overwhelming majority of comments were individual comments associated with form letter campaigns from various groups and individuals. Numerous commenters, including civil rights organizations, faith-based organizations, health organizations, legal associations, and individual commenters, supported the Proposed Rule as written. Numerous other commenters, including certain faith-based providers, legal associations, and individual commenters, expressed opposition to the Proposed Rule for a variety of reasons.

## **B. Overview of the Final Rule**

This preamble is divided into multiple sections. Section II describes changes to the regulation and contains two subparts. Subpart A sets forth general comments the Department received regarding the Proposed Rule and the responses to our request for comment on the likely impact of the Proposed Rule as compared to the 2016 Rule. Subpart B sets forth the final rule’s regulatory provisions and our responses to comments received. Subpart C discusses the Department’s comments received in Response to E.O. 13175 Tribal Consultation. Section III sets

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<sup>3</sup> Mot. to Remand with Vacatur, *Facing Foster Care et al. v. HHS*, No. 21-cv-00308 (D.D.C. June 17, 2022), ECF No. 41 (granted by Order, *Facing Foster Care et al. v. HHS*, No. 21-cv-00308 (D.D.C. June 29, 2022), ECF No. 44).

forth the Department's compliance with Executive Order 12866 and related Executive Orders on regulatory review.

Based upon comments received, the Department has made some changes to the Proposed Rule.

The Department has revised § 75.300(e) to clarify that the provision is interpretive and does not impose any new substantive obligations on entities outside the Department.

The Department has revised § 75.300(f) to also apply to grant applicants. Section 75.300(f) also is revised to provide recipients, applicants, and the public with (1) a general timetable under which the Department will acknowledge and begin to evaluate requests for assurances of religious freedom and conscience exemptions; (2) a temporary exemption during the pendency of the Department's review of such requests; (3) a list of conscience laws that may be applied to the § 75.300(f) process; (4) information about how the Department will consider these requests under the legal standards of applicable Federal religious freedom or conscience laws; (5) notice that adjudications are to be made by both ASFR and OCR; and (6) details about the administrative appeal process for applicants and recipients that receive adverse determinations.

The Department is finalizing the other provisions of the rule as proposed.

## **II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments**

### **A. General Comments**

In the 2023 NPRM, the Department sought comment on the likely impact of the Proposed Rule as compared to the 2016 Rule. The comments and our responses regarding our request, and other general comments regarding the rule, are set forth below.

*Comment:* A large city requested that HHS widely promote the protections set forth in the Proposed Rule such that grant recipients and those served by HHS programs and services are made aware that discrimination based on actual or perceived sexual orientation, gender identity, or gender expression will be prohibited. A State Department of Health expressed support for

“purposeful implementation” of the rule’s nondiscrimination protections and requested that they be diligently and efficiently enforced.

*Response:* The Department appreciates these commenters’ suggestions on promotion and implementation. This final rule clarifies that, in the identified statutes that HHS administers that prohibit discrimination on the basis of sex, HHS interprets the prohibition against discrimination on the basis of sex to include discrimination on the basis of sexual orientation, gender identity, and sex characteristics. This interpretation is consistent with *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.<sup>4</sup> And as OCR noted in the Proposed Rule, 88 FR 44753, *Bostock*’s reasoning applies with equal force to claims alleging discrimination on the basis of sex characteristics, which is inherently sex-based. When the rule is finalized, HHS intends to provide grant recipients and the public at large information about the rule and raise awareness of the protections provided by the statutes addressed in the rule, for example, through stakeholder meetings, webinars, and other outreach.

*Comment:* Numerous commenters expressed overall support for the rule, including the Proposed Rule’s reaffirmation of nondiscrimination protections and its effect on access to services and care. A coalition of 11 advocacy groups stated that, while grant programs are subject to generally applicable statutes that bar discrimination on the basis of race, color, national origin, disability, and age, the Proposed Rule would further prevent harms because of its protections against discrimination on the bases of religion and sex in grant programs. Another commenter lauded the Proposed Rule, specifically, the retention of language from the partially vacated 2021 Rule regarding Federal statutory prohibitions against discrimination and the application of Supreme Court decisions in award administration.

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<sup>4</sup> See, e.g., *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 616-17 (4th Cir. 2020), as amended (Aug. 28, 2020), *reh’g en banc denied*, 976 F. 3d 399 (4th Cir. 2020), *cert. denied*, No. 20-1163 (June 28, 2021); *Doe v. Snyder*, 28 F.4th 103, 113–14 (9th Cir. 2022); *Grabowski v. Arizona Bd. of Regents*, 69 F.4th 1110, 1113 (9th Cir. 2023).

Numerous commenters expressed support for the rule because, in their view, it would positively impact access to Federal programs and services for lesbian, gay, bisexual, transgender, queer, and intersex (LGBTQI+) people. Several commenters praised the Proposed Rule's focus on nondiscrimination protections and access to care, especially for LGBTQI+ community members amidst what commenters described as a rise in anti-LGBTQI+ discrimination and increasing barriers to health care. Some commenters stated that the Proposed Rule would help protect against discrimination based on sexual orientation and gender identity in HHS-funded health programs. Another commenter opined that the rule would help protect and support the needs of LGBTQI+ individuals by protecting them from harmful discrimination and barriers to accessing needed service.

*Response:* The Department appreciates the commenters' support. To be clear, the final rule clarifies the Department's interpretation of existing statutory provisions that prohibit discrimination based on sex within the enumerated statutes in §75.300(e). The Department offers this prospective interpretation in the interest of transparency and good governance so that the public is aware of the Department's position. *See* Attorney General's Manual on the Administrative Procedure Act 30 n.3 (1947). The Department is committed to ensuring access to its programs and compliance with all applicable Federal laws, including laws related to nondiscrimination, religious freedom, and conscience.

*Comment:* Many commenters in support of the rule included research and studies relating to the LGBTQI+ community as well as referencing their experiences with health and human services programs. Several of these commenters outlined specific concerns, including, among other things, that: LGBTQI+ individuals report "fair or poor" general physical health; are more likely than their non-LGBTQI+ peers to experience symptoms of anxiety and depression; and that a substantial percentage of LGBTQI+ people experience serious health conditions, including

those that are life-threatening.<sup>5</sup> Commenters and the studies they cited attributed these disparities to pervasive discrimination against LGBTQI+ people, lack of access to care, and lack of access to providers knowledgeable about providing services to LGBTQI+ individuals. Some commenters discussed additional barriers to quality care and supportive services. A few commenters reported that discrimination, or fear of such discrimination, is a prevalent barrier to seeking health care for members of the LGBTQI+ community.

Several commenters cited studies and reports about the experiences of transgender people specifically. They included studies about high rates of intimate partner violence and suicidality, disproportionately high rates of HIV+ diagnoses, and disparities in housing and rates of poverty among transgender people, which commenters and many of the studies attributed to pervasive stigma and discrimination against transgender people. One of these commenters stated that victims of violence who are LGBTQI+ should not have to experience discrimination in government-funded services.

Some commenters specifically addressed discrimination experienced by LGBTQI+ individuals participating in HHS programs. A coalition of 11 advocacy groups stated that LGBTQI+ people experience discrimination while accessing services under Title IV-B and IV-E of the Social Security Act (*e.g.*, family support and foster care/adoption services) and services provided to older adults under the Older Americans Act (*e.g.*, Meals on Wheels). One organization commented that state laws targeting the LGBTQI+ community have worsened disparities. A coalition of 65 advocacy groups stated that LGBTQI+ youth are often subjected to discriminatory behavior while in congregate care settings.

*Response:* The Department acknowledges that discrimination against LGBTQI+ individuals remains pervasive, especially for individuals who experience discrimination on

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<sup>5</sup> Some of studies cited by commenters did not address the whole LGBTQI+ population—for example, some studies referenced outcomes only for the “LGBT” or “LGBTQ” populations as opposed to the broader LGBTQI+ population.

multiple bases, such as gender identity and race.<sup>6</sup> The Department’s interpretation set forth in § 75.300(e) of this rule is notably limited to the scope of HHS awards and grant programs related to the statutes set forth in that section.

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. The Administration for Children and Families (ACF) has published a Proposed Rule concerning Title IV and foster care, 88 Fed. Reg. 66752 (Sept. 28, 2023); the comment period closed on November 27, 2023.

*Comment:* A commenter stated that several of these statutes protect against discrimination on the basis of religion and asserted that HHS should add additional provisions to protect religious grantees, parents, and participants.

*Response:* The Department appreciates the commenter’s suggestion but declines to add additional language to the final rule. The Department is committed to fully upholding federal laws that guarantee freedom of religion and freedom of conscience. Section 75.300(c) confirms that it is against public policy of the Department for otherwise eligible persons to be discriminated against in the administration of HHS programs, activities, projects, assistance, and services, to the extent doing so is prohibited by Federal statute. This includes laws that prohibit religious discrimination against beneficiaries, including provisions of the statutes listed in § 75.300(e) that prohibit discrimination on the basis of religion,<sup>7</sup> and other religious freedom and conscience laws.<sup>8</sup> In addition, § 75.300(f) addresses an applicant’s or recipient’s ability to avail itself of religious freedom and conscience protections, including a process by which any entity

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<sup>6</sup> See the Department’s proposed rule regarding Section 1557 of the Affordable Care Act (42 U.S.C. 18116), *Nondiscrimination in Health Programs and Activities*, 87 FR 47824, 47870 (Aug. 4, 2022).

<sup>7</sup> See, 8 U.S.C. 1522(a)(5), Authorization for programs for domestic resettlement of and assistance to refugees; 42 U.S.C. 290cc–33(a)(2), Projects for Assistance in Transition from Homelessness; 42 U.S.C. 290ff–1(e)(2), Children with Serious Emotional Disturbances; 42 U.S.C. 300w–7(a)(2), Preventive Health Services Block Grant; 42 U.S.C. 300x–57(a)(2), Substance Abuse Treatment and Prevention Block Grant and Community Mental Health Services Block Grant; 42 U.S.C. 708(a)(2), Maternal and Child Health Block Grant; 42 U.S.C. 5151(a), Disaster relief; 42 U.S.C. 9849(a), Head Start; and 42 U.S.C. 10406(c)(2)(B)(i), Family Violence Prevention and Services.

<sup>8</sup> See, e.g., U.S. Const. Amend. I; 42 U.S.C. 2000bb et seq. (RFRA); 45 CFR Part 88.3 (listing statutes).

can notify the Department of its view that it is exempt from, or entitled to a modified application of, the nondiscrimination requirements of the 13 statutes listed in § 75.300(e) due to the application of Federal religious freedom or conscience law.

*Comment:* A coalition of 11 civil rights organizations, citing *Maddonna v. United States Department of Health & Human Services*, No. 6:19-CV-3551-JD, 2023 WL 7395911 (D.S.C. Sept. 29, 2023), expressed their concerns regarding religious discrimination in government-funded services. The coalition provided examples of individuals who alleged facing religious discrimination in health and human services programs, including an agency that refused to provide a Jewish family foster-parent training and home study approval allegedly because of their religious beliefs, and a nonreligious man whom a State agency committed to various religious facilities to treat substance-use disorder, whose complaints the Department allegedly declined to investigate.<sup>9</sup>

*Response:* The Department appreciates the comments. The Department appreciates the comments. In *Maddonna*, a plaintiff sued a foster care child placement agency, along with various federal and state defendants, alleging that they had been excluded from participation in South Carolina's foster care program on the basis of their religion. The court in *Madonna* ultimately dismissed the claims against the Department. The Department is committed to protecting access to health care and human services and preventing discrimination in accordance with the Constitution and applicable Federal laws, including those involving religious discrimination.

The Department is committed to protecting access to health care and human services and preventing discrimination in accordance with applicable Federal laws, including those involving religious discrimination. As discussed above, 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

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<sup>9</sup> The coalition cited to OCR Transaction Numbers DO-21-453070 and DO-21-430481.

discrimination on the basis of sex. This list does not include Title IV-E; however, ACF has separately published a Proposed Rule concerning Title IV and foster care. 88 Fed. Reg. 66752.

*Comment:* A religious policy organization stated their view that “forcing” an alternate definition of sex would result in certain organizations no longer seeking HHS grants either because of their belief they would not qualify due to their sincerely held convictions or because of concern they would be opening themselves up to a legal battle. As an example, the commenter observed that certain States sought waivers from enforcement of the nondiscrimination requirements of the 2016 Rule, which similarly interpreted “sex” to include “sexual orientation” and “gender identity.” This organization stated its view that the 2016 Rule had worse implications for faith-based organizations than the Proposed Rule, but that the Proposed Rule was still inadequate to address religious freedom and conscience concerns.

*Response:* The Department appreciates the comment and acknowledges that waivers of enforcement were granted in connection with the 2016 Rule. The Department disagrees, however, that it is “forcing” an alternative definition of “sex.” As the Supreme Court noted in *Bostock*, nothing in its approach turned on the definition of “sex” alone, including parties’ debate over whether “sex” was limited to the notion that it only refers to distinctions between male and female. The Court therefore proceeded on the narrow assumption for argument’s sake that “sex” signifies “biological distinctions between male and female” and still reached its conclusion. *Bostock*, 590 U.S. at 655.

The Department highlights as well that this final rule allows for a religious freedom and conscience exemption process which is outlined in § 75.300(f) for applicants and recipients that have religious or conscience concerns or objections.

*Comment:* A religious policy organization advocated that HHS and the Department of Education refrain from finalization of rules that aim to interpret and apply Title IX of the Education Amendments of 1972 until courts are able to resolve the outstanding challenges

involving *Bostock* based on what they view as overlap of underlying provisions within these rulemakings.

*Response:* This rule does not interpret or apply Title IX, as it solely addresses the statutes referenced in § 75.300(e). To the extent the rules raise similar questions, or would benefit from consistency in certain areas, those concerns have been identified and addressed through interagency review processes prior to the rule’s finalization.

*Comment:* A religious legal advocacy organization stated that HHS should disclose the process by which it reviewed comments, including the methodology and estimates used to review and respond to comments, in light of HHS’s identified failure in 2020 to appropriately review comments and disclose the process used for that review, *citing* Motion for Remand with Vacatur, *Facing Foster Care in Alaska v. U.S. Health & Human Services*, No. 1:21-cv-00308 (D.D.C. June 17, 2022), ECF No. 41 (*granted by Order*, (D.D.C. June 29, 2022), ECF No. 44).

*Response:* The Department appreciates the commenter’s suggestion. We received over 8,000 submissions during the public comment period. OCR has reviewed all non-duplicative comments it received. Under the relevant legal standards and the Administrative Procedure Act (APA), OCR has identified, considered, and responded to all the significant issues raised by commenters. OCR staff’s ability to read, consider, and respond to comments on this rule were not hampered by time or funding constraints.

## **B. Comments Regarding Provisions of the Proposed Rule**

### **1. Section 75.300(c)**

In the 2023 NPRM, the Department proposed to repromulgate § 75.300(c) from the 2021 Rule with a slight edit to reference “HHS programs, activities, projects, assistance, and services” as opposed to just “HHS programs and services.” This edited provision reads: “It is a public policy requirement of HHS that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs,

activities, projects, assistance, and services, to the extent doing so is prohibited by federal statute.”

The comments and our responses regarding § 75.300(c) are set forth below.

*Comment:* Some commenters expressed general support for § 75.300(c). One commenter expressed support for the provision as explicitly aligning Federal regulations with the Supreme Court decisions in *United States v. Windsor*, 570 U.S. 744 (2013), *Obergefell v. Hodges*, 576 U.S. 644 (2015), and *Bostock*, 590 U.S. 644. Another commenter concluded that this section would help prevent what the commenter viewed as the harm caused by approaches similar to those allegedly caused by the 2019 waiver sent by ACF to South Carolina approving the state’s waiver request from the nondiscrimination requirements in paragraph (c). *See* 88 FR 44750, 44752.<sup>10</sup>

*Response:* While this rule’s text does not cite *Windsor* or *Obergefell*, the Department follows all Supreme Court precedent as noted in § 75.300(d) and appreciates the commenters’ support for the section. HHS is committed to respecting all applicable Federal laws and relevant precedent.

*Comment:* A group of commenters proposed removing § 75.300(c) altogether since § 75.300(a) makes it unnecessary for HHS to declare something contrary to “public policy” if it already contravenes Federal statute. The commenter further stated that if the Department removes § 75.300(c), it can also remove § 75.101(f), which clarifies the inapplicability of § 75.300(c) to the Temporary Assistance for Needy Families Program (Title IV–A of the Social Security Act, 42 U.S.C. 601–619) (TANF).

*Response:* The Department thanks commenters for the suggestions but, other than not adding language from former § 75.101(f), declines to accept the recommendations. The

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<sup>10</sup> For the original correspondence, *See Letter from Joo Yean Chang to Governor Henry McMaster* (Nov. 18, 2021),: <https://www.acf.hhs.gov/sites/default/files/documents/withdrawal-of-exception-from-part-75.300-south-carolina-11-18-2021.pdf>; *Letter from Joo Yean Chang to Governor Henry McMaster* (Nov. 18, 2021), <https://governor.sc.gov/sites/governor/files/Documents/newsroom/HHS%20Response%20Letter%20to%20McMaster.pdf>.

Department maintains that the final rule language best articulates HHS's position, provides additional regulatory clarity to the public and regulated community, and furthers the efficient and equitable administration of HHS grants. The Proposed Rule stated that the Department is proposing not to reinstate former § 75.101(f). 88 FR 44753. This final rule likewise is not reinstating former § 75.101(f).

*Comment:* Some commenters recommended that HHS use additional statutory authorities to establish regulatory nondiscrimination requirements across key programs and clarify interactions with other civil rights laws.

*Response:* The Department declines to add additional statutory authorities as described. The Department acknowledges the importance of accounting for simultaneous discrimination on multiple or overlapping prohibited bases, and the regulation at § 75.300(c) includes a broad nondiscrimination prohibition that is grounded in the range of prohibitions provided by Federal statute.” The Department is committed to ensuring consistent enforcement of these protections.

### **Summary of Regulatory Changes to § 75.300(c)**

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing § 75.300(c) as proposed, without modification.

### **2. Section 75.300(d)**

In the 2023 NPRM, the Department proposed to repropromulgate § 75.300(d) from the partially vacated 2021 Rule. It provided, “HHS will follow all applicable Supreme Court decisions in administering its award programs.”

The comments and our responses regarding § 75.300(d) are set forth below.

*Comment:* Some commenters opposed § 75.300(d), reasoning that it would be “unnecessary” and “pernicious” to state that HHS must follow the decisions of the Supreme Court. The commenters recommended that HHS remove this section from the Proposed Rule and

instead explain how it will apply past court decisions to new disputes with grant recipients raising different but related questions or apply Federal circuit court decisions.

*Response:* The Department appreciates the commenters' views, but declines their recommendation. The Department is required to comply with Supreme Court precedent; Section 75.300(d) reflects that.

### **Summary of Regulatory Changes to § 75.300(d)**

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing § 75.300(d) as proposed, without modification.

### **3. Section 75.300(e)**

In the 2023 NPRM, the Department proposed to add § 75.300(e), which clarifies that, in the identified statutes that HHS administers that prohibit discrimination on the basis of sex, HHS interprets the prohibition against discrimination on the basis of sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity. This interpretation is consistent with *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.<sup>11</sup> Proposed § 75.300(e) referenced 13 statutes HHS administers that prohibit discrimination on the basis of sex.<sup>12</sup>

The Department also sought comment on: (1) whether the Department administers other statutes prohibiting sex discrimination that are not set forth in proposed § 75.300(e) or whether the Department should include language or guidance in § 75.300(e) to cover current or future

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<sup>11</sup> See, e.g., *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 616-17 (4th Cir. 2020), as amended (Aug. 28, 2020), *reh'g en banc denied*, 976 F. 3d 399 (4th Cir. 2020), *cert. denied*, No. 20-1163 (June 28, 2021); *Doe v. Snyder*, 28 F.4th 103, 113–14 (9th Cir. 2022); *Grabowski v. Arizona Bd. of Regents*, 69 F.4th 1110, 1113 (9th Cir. 2023).

<sup>12</sup> 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. 9849. Head Start; 42 U.S.C. 9918. Community Services Block Grant Program; 42 U.S.C. 10406. Family Violence Prevention and Services.

laws that prohibit sex discrimination that are not set forth above; and (2) whether there is anything about any of the statutes referenced in proposed § 75.300(e), such as their language, legislative history, or purpose, that would provide a legal basis for distinguishing them from *Bostock*'s interpretation of Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e *et seq.*), that sex discrimination includes discrimination on the basis of sexual orientation and gender identity.

The comments and our responses regarding § 75.300(e) are set forth below.

*Comment:* Many commenters expressed strong support for proposed § 75.300(e) because it highlights existing statutory nondiscrimination provisions and expressly codifies a critical interpretation of discrimination on the basis of sex. Many commenters opined that § 75.300(e) is both consistent with the Supreme Court's ruling in *Bostock* and an appropriate application of the decision. One legal institute that focuses on sexual orientation and gender identity issues expressed support for § 75.300(e), stating that it has been longstanding practice to look to Title VII case law to interpret analogous provisions in other nondiscrimination laws, and that there is no language in any of the 13 statutes that suggests that HHS or the courts should not look to Title VII case law.

*Response:* The Department agrees that the final rule is consistent with *Bostock* and that Title VII case law is relevant to the analysis of the statutes listed in § 75.300(e).

*Comment:* Many commenters recommended that HHS expressly codify the prohibition of discrimination on the basis of sex characteristics, including intersex traits, in the regulatory text of § 75.300(e).

*Response:* As the Department explained in the NPRM, the Department agrees that sex discrimination covers discrimination on the basis of sex stereotypes, which can include stereotypes regarding sex characteristics and intersex traits, consistent with longstanding Supreme Court precedent. 88 FR 44750, n.11 (July 13, 2023) *see Price Waterhouse v. Hopkins*, 490 U.S. 228, 251 (1989). Moreover, like gender identity and sexual orientation, intersex traits

are “inextricably bound up with” sex, *Bostock*, 590 U.S. at 660-661, and “cannot be stated without referencing sex,” *Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 608 (4th Cir. 2020) (quoting *Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1051 (7th Cir. 2017)). Further, interpreting sex discrimination prohibitions to encompass discrimination based on sex characteristics is consistent with applicable statutory text and existing interpretations by HHS and other agencies.<sup>13</sup> The Department agrees that the final rule protects against discrimination based on sex characteristics, but does not believe it is necessary to specify this in regulatory text.

*Comment:* A commenter requested that HHS further expand § 75.300(e) to explicitly include “gender expression” and provided a revised version of the paragraph including language stating that discrimination is prohibited based on “actual or perceived” status.

*Response:* The final rule clarifies the Department’s interpretation of nondiscrimination protections on the basis of sex in certain programs and is consistent with current law. The Department agrees that sex discrimination covers discrimination on the basis of sex stereotypes, which can include stereotypes regarding gender expression, as well as discrimination against an individual based on perceived status. The Department does not believe it is necessary to specify this in regulatory text.

*Comment:* A coalition of patient advocacy groups argued that the nondiscrimination requirements in the final rule should address both Department-wide and program-specific statutory prohibitions on sex discrimination, including references to health programs and activities covered by Section 1557 of the Affordable Care Act (42 U.S.C. 18116). A different coalition of advocacy groups urged HHS to exercise the general rulemaking authority under Section 1102(a) of the Social Security Act, 42 U.S.C. 1302(a), to promulgate nondiscrimination

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<sup>13</sup> See, e.g., Notice of Proposed Rulemaking, *Nondiscrimination in Health Programs and Activities*, 87 FR 47824 (August 4, 2022); Notice of Proposed Rulemaking, *Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance*, 87 FR 41390 (July 12, 2022); U.S. Dept. of Justice, Title IX Legal Manual, <https://www.justice.gov/crt/title-ix#:~:text=The%20reasoning%20in,assigned%20at%20birth.%E2%80%9D> .

protections, including those that would address Titles IV-B and IV-E as well as the provision of child welfare services. The commenters reasoned that the broadest and most widely applicable nondiscrimination protections would minimize discrimination against vulnerable populations and other barriers to program access. One commenter recommended that HHS ensure all current and future statutes prohibiting sex discrimination are encompassed by the present rulemaking to ensure that the proposed rule's nondiscrimination requirements cover all HHS-funded programs and services.

*Response:* The Department appreciates commenters' request that this rule address Department-wide and program-specific statutory prohibitions on sex discrimination. However, as noted in the Proposed Rule, the Department identified the statutes listed in proposed § 75.300(e) because they contain specific prohibitions on sex discrimination included within program statutes, and none contain any indicia suggesting they should be construed differently than Title VII. 88 FR 44754. This was to ground the Proposed Rule's interpretation in existing statutory authority.

The Department has rulemaking authority under Section 1102(a) of the Social Security Act, 42 U.S.C. 1302(a), but declines at this time to add substantive provisions to what is otherwise an interpretive rule. In addition, the Department is unable to anticipate the way future statutes prohibiting sex discrimination may be drafted or edited, and therefore declines to include reference to such future statutes in this final rule. The Department therefore has determined at this time additional changes are not necessary.

*Comment:* Numerous commenters, including two separate coalitions of advocacy groups, requested that additional statutes be considered for inclusion in § 75.300(e). Specifically, these commenters asked that HHS consider four statutes in this rulemaking: (1) Title IX; (2) Section 1557; (3) Section 632 of the Community Economic Development Act of 1981, 42 U.S.C. 9821 (CEDA); and (4) the Violence Against Women Act, 34 U.S.C. 12291 (VAWA).

*Response:* The Department appreciates comments responding to our request regarding other statutes prohibiting sex discrimination that the Department administers. The Department is addressing Section 1557, which prohibits discrimination on the basis of sex in certain health programs and activities, under a separate rulemaking.<sup>14</sup> The Department also has a separate regulation that addresses the nondiscrimination provisions of Title IX.<sup>15</sup> The Department therefore declines to address those statutes' nondiscrimination provisions in this rule.

The Department agrees that CEDA could potentially warrant inclusion in § 75.300(e) because it authorizes Department programs and services, it prohibits sex discrimination,<sup>16</sup> and there is nothing in the text, history, or case law that suggests it should be interpreted differently than *Bostock*. However, the CED program has not been funded or active since 1998, as its funding stream authorization was repealed.<sup>17</sup> Accordingly, the Department will not add CEDA to the statutes listed in § 75.300(e) at this time.

As for VAWA, the statute itself expressly prohibits discrimination on the basis of sexual orientation and gender identity.<sup>18</sup> Therefore, VAWA's protections based on sexual orientation and gender identity apply to all HHS VAWA programs and grants operated, and the statute's inclusion in this rule is unnecessary.

*Comment:* A national campaign of form comments expressed concern that the Proposed Rule's prohibition against grant recipients discriminating on the basis of sex "sidesteps" State legislatures.

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<sup>14</sup> 87 FR 47824 (Aug. 4, 2022).

<sup>15</sup> 45 CFR part 86.

<sup>16</sup> See CEDA, 42 U.S.C. 9821(a) ("The Secretary shall not provide financial assistance for any program, project, or activity under this subchapter unless the grant or contract with respect thereto specifically provides that no person with responsibilities in the operation thereof will discriminate with respect to any such program, project, or activity because of . . . sex . . . .") and (b) ("No person in the United States shall on the ground of sex be excluded from participation in, be denied the benefits of, be subjected to discrimination under, or be denied employment in connection with any program or activity receiving assistance under this subchapter.").

<sup>17</sup> See Community Opportunities, Accountability, and Training and Educational Services Act of 1998, PL 105-285, sec. 202(b)(1) ("(1) SOURCE OF FUNDS.—Section 614 of the Community Economic Development Act of 1981 (42 U.S.C. 9803) is repealed.").

<sup>18</sup> 42 U.S.C. 12291(13)(a).

*Response:* The final rule simply states how the Department will apply precedent and existing obligations and does not implicate federalism concerns. The statutes identified in § 75.300(e) have long contained prohibitions against discrimination on the basis of sex. And the Supreme Court’s decision in *Bostock*, not this final rule, determined that Title VII’s prohibition on sex discrimination necessarily included a prohibition on discrimination on the basis of sexual orientation and gender identity. This rule, in turn, applies *Bostock*’s reasoning with respect to the statutes enumerated in § 75.300(e). As explained in the Proposed Rule, none of the 13 statutes referenced in § 75.300(e) contain any indicia—such as statute-specific definitions, or any other criteria—to suggest that the statutes’ general prohibitions on sex discrimination should be construed differently than Title VII’s sex discrimination prohibition. *See* 88 Fed. Reg. at 44754. This rule, therefore, makes clear that the Department interprets the identified statutes’ prohibitions on sex discrimination to include prohibitions on sexual orientation and gender identity discrimination. The rule does not dictate, however, the outcomes in particular matters and it does not direct the outcome of any complaint of discrimination asserted under the identified statutes.

*Comment:* Some commenters opined that HHS lacks the authority to finalize the Proposed Rule under 5 U.S.C. 301, sometimes referred to as the “Housekeeping Statute.” One commenter stated that HHS should not insert “significant changes” into an ASFR regulation because the Housekeeping Statute authorizes the regulation of the operation of HHS—not actors outside the HHS Secretary’s authority. Another commenter stated that the 2016 Rule was not constitutionally or statutorily authorized, and urged HHS to rescind the 2016 Rule, arguing that although the Housekeeping Statute authorizes the heads of agencies to regulate “the government of [their] department” and to “regulate [their] own affairs,” it does not mention protected classes or allow HHS to regulate externally.

*Response:* The Department recognizes that the Housekeeping Statute is “a grant of authority to the agency to regulate its own affairs . . . authorizing what the [Administrative

Procedure Act] terms ‘rules of agency organization, procedure or practice’ as opposed to ‘substantive rules.’” *Chrysler Corp. v. Brown*, 441 U.S. 281, 309–10 (1979). The Department’s clarification in this final rule with regard to the meaning of discrimination on the basis of sex is consistent with the Department’s authority under 5 U.S.C. 301 to regulate its own affairs in how it interprets existing statutes that already contain such prohibitions and is consistent with Supreme Court jurisprudence. For the avoidance of doubt, the Department has added language to § 75.300(e) clarifying that the provision is interpretive and does not impose any substantive obligations on entities outside the Department. In other words, § 75.300(e) expresses the Department’s current interpretation of the 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).

*Comment:* Several commenters asked HHS to remove § 75.300(e), asserting that the Department relied upon a misinterpretation of *Bostock* and that the Department otherwise does not have the authority to “redefine” the term “sex.” Relying on § 75.300(c)’s explanation that discrimination in HHS programs is prohibited “to the extent doing so is prohibited by federal law,” one commenter asserted that § 75.300(c) is inconsistent with the relevant statutes because the statutes and legislative history do not mention sexual orientation or gender identity. Some commenters expressed opposition to HHS’s interpretation of *Bostock* in the Proposed Rule and suggested that *Bostock*’s holding is actually about the specific meaning of the “because of” language of Title VII, specific to employment. In their view, that “because of” language is not contained in other statutes; accordingly, they argue, *Bostock* does not apply to those statutes and is limited to Title VII only.

Several commenters opined that the statutes listed in proposed § 75.300(e) lack a textual basis for HHS to “redefine” sex to include gender identity or sexual orientation. Prohibitions against sex discrimination, in the commenters’ view, should refer to a “binary, biological” definition. Other commenters flagged examples of statutes that specifically refer to one sex

including: the Refugee Resettlement Programs, 8 U.S.C. 1522(a)(1)(A); the Title VII Health Workforce Programs, 42 U.S.C. 295m(i); the definition in the Maternal and Child Health Block Grant statute of an eligible family, 42 U.S.C. 711(l)(2)(a); and the Head Start program. *See* 42 U.S.C. 9840(a)(5)(A)(iii) & (d)(3), 9840a(c)(1) & (i)(2)(G), 9852b(d)(2)(C). Commenters also argued that 42 U.S.C. 10406 of the Family Violence Prevention and Services Act (FVPSA) be removed from the list of programs in the final rule’s § 75.300(e) because, in their view, the word “sex” in the context of that statute is used in the statute.”

*Response:* The Department appreciates the comments but disagrees with the commenters’ views. *Bostock* and ensuing case law provide a compelling reason to interpret other similar statutory provisions which use the same or similar nondiscrimination language as Title VII’s prohibition against sex discrimination to include discrimination based on sexual orientation and gender identity, absent indicia to the contrary.

Further, given the similarity in nondiscrimination language between Title VII and Title IX, many Federal courts that have addressed the issue have interpreted Title IX consistent with *Bostock*’s reasoning.<sup>19</sup> Additionally, there is a significant amount of case law, pre-and post-*Bostock*, that affirms protections on the basis of either sexual orientation or gender identity, or both, pursuant to a variety of other statutes that prohibit discrimination on the basis of “sex.”<sup>20</sup>

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<sup>19</sup> See e.g., *Grabowski v. Arizona Bd. of Regents*, 69 F.4th 1110, 1116 (9th Cir. 2023); *Doe v. Snyder*, 28 F.4th 103, 113–14 (9th Cir. 2022); *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 616 (4th Cir. 2020); cf. *Adams v. School Bd. of St. Johns Cnty*, 57 F.4th 791, 811–15 (11th Cir. 2022) (en banc).

<sup>20</sup> See, e.g., *Whitaker By Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034 (7th Cir. 2017) (Title IX); *Smith v. Cty. of Salem, Ohio*, 378 F.3d 566 (6th Cir. 2004) (Title VII); *Rosa v. Park W. Bank & Trust Co.*, 214 F.3d 213 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schroer v. Billington*, 577 F. Supp. 2d 293 (D.D.C. 2008) (Title VII); *Boyden v. Conlin*, 341 F. Supp. 3d 979 (W.D. Wis. 2018) (Section 1557 and Title VII); *Flack v. Wis. Dep’t of Health Servs.*, 395 F. Supp. 3d 1001, 1014 (W.D. Wis. 2019) (Section 1557 and Equal Protection Clause); *Prescott v. Rady Children’s Hosp. San Diego*, 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017) (Section 1557); *Tovar v. Essential Health*, 342 F. Supp. 3d 947, 957 (D. Minn. 2018) (Section 1557). See also *Doe v. Snyder*, 28 F.4th 103, 113–14 (9th Cir. 2022); *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 616 (4th Cir. 2020), as amended (Aug. 28, 2020), cert. denied, 141 S. Ct. 2878 (Mem) (2020); *Kadel v. Folwell*, No. 1:19-cv-00272, 2022 WL 2106270, at \*28–\*29 (M.D.N.C. June 10, 2022); *Scott v. St. Louis Univ. Hosp.*, No. 4:21-cv-01270-AGF, 2022 WL 1211092, at \*6 (E.D. Mo. Apr. 25, 2022); C.P. by & through *Pritchard v. Blue Cross Blue Shield of Ill.*, No. 3:20-cv-06145-RJB, 2021 WL 1758896, at \*4 (W.D. Wash. May 4, 2021); *Koenke v. Saint Joseph’s Univ.*, No. CV 19-4731, 2021 WL 757778, at \*2 (E.D. Pa. Jan. 8, 2021); *Doe v. Univ. of Scranton*, No. 3:19-cv-01486, 2020 WL 5993766, at \*11 n.61 (M.D. Pa. Oct. 9, 2020); *Maxon v. Seminary*, No. 2:19-cv-9969, 2020 WL 6305460 (C.D. Cal. Oct. 7, 2020); *B.P.J. v. W. Va. State Bd. of Educ.*, No. 2:21-cv-00316, 2021 WL 3081883, at \*7 (S.D.W. Va. July 21, 2021); *Clark Cnty. Sch. Dist. v. Bryan*, 478 P.3d 344, 354 (Nev. 2020). At least one court has held that it would

As noted in the Proposed Rule, none of the listed statutes in the rule contain any indicia—such as statute-specific definitions, case law, or any other criteria—to suggest that these prohibitions on sex discrimination should be construed differently than how the Supreme Court construed Title VII’s sex discrimination prohibition in *Bostock*. The language prohibiting sex discrimination in statutes listed in § 75.300(e) is substantially similar to Title VII’s sex discrimination prohibition, and so the Department interprets them similarly. In addition, while these laws may have exceptions or other provisions that affect how they apply to particular facts and circumstances, that does not change the fact that their general prohibition on “sex discrimination” should be understood consistent with the reasoning of *Bostock*. *See Bostock*, 590 U.S. at 681 (“Whether other policies and practices might or might not qualify as unlawful discrimination or find justifications under other provisions of Title VII are questions for future cases, not these.”).

Additionally, the Department disagrees that *Bostock*’s holding was only about the term “because of.” Indeed, in *Bostock* itself, the Court used both “on the basis of” and “because of” throughout the decision to describe the unlawful discrimination at issue. *See, e.g., Bostock*, 590 U.S. at 654 (“on the basis of sex.”); *id.* at 658 (“because of sex”). As noted in the Proposed Rule, the 13 listed statutes contain minor variations in the language used to prohibit sex discrimination, sometimes within the same statute, but the Department does not believe any of the variations can be reasonably understood to distinguish the various statutes from *Bostock*’s reasoning. *See* 88 Fed. Reg. 44754.<sup>21</sup>

With regard to the commenters’ providing statutes that explicitly reference women and men to support the argument that sex should be limited to a “binary, biological” understanding,

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be a misapplication of *Bostock* to interpret the definition of “sex discrimination” under Section 1557 and Title IX to include gender identity and sexual orientation. *Neese v. Becerra*, No. 2:21-CV-163-Z, 2022 WL 16902425 (N.D. Tex. Nov. 10, 2022). The Department appealed that decision to the U.S. Court of Appeals for the Fifth Circuit and oral argument was held on January 8, 2024. The Department is not applying the challenged interpretation to members of the *Neese* class pending the appeal.

<sup>21</sup> Nevertheless, 42 U.S.C. 9849(a) actually uses the phrase “because of.” *See* 42 U.S.C. 9849(a) (“The Secretary shall not provide financial assistance for any program, project, or activity under this subchapter unless the grant or contract with respect thereto specifically provides that no person with responsibilities in the operation thereof will discriminate with respect to any such program, project, or activity *because of* race, creed, color, national origin, sex, political affiliation, or beliefs.”) (emphasis added).

we find this unconvincing. As the Supreme Court noted in *Bostock*, nothing in its approach turned on the parties' debate over whether "sex" was limited to the notion that it only refers to distinctions between male and female, and so the Court proceeded on the narrow assumption for argument's sake that "sex" signifies "biological distinctions between male and female." *Bostock*, 590 U.S. at 655. Nonetheless the Court held that the plain language of the statute included discrimination based on sexual orientation and gender identity. Finally, with regard to the FVPSA, 42 U.S.C. 10406(c)(2)(B)(i) explains that entities may "take[e] into consideration that individual's sex in those certain instances" such as "bona fide occupational qualifications" or "programmatic factors." The Department will apply the FVPSA faithfully, including this provision.

*Comment:* A group of commenters expressed their view that the Proposed Rule constitutes a "unilateral inflation" of power by the Department that invokes the "major questions doctrine" and requires Congressional approval. *West Virginia v. Environmental Protection Agency*, 142 S. Ct. 2587 (2022) and *Biden v. Nebraska*, 143 S. Ct. 2355 (2023). The group expressed concerns about the scope of the types of providers the rule would impact. The group also asserted that the Department is claiming to interpret Title VII through the Proposed Rule, despite Title VII being enforced by the Equal Employment Opportunity Commission (EEOC). One commenter argued that HHS's responsibility to comply with Supreme Court decisions includes following the major questions doctrine and upholding universal religious freedom rights.

*Response:* The Department appreciates the commenters' concerns but disagrees that this rule is beyond the Department's authority or that it is interpreting Title VII in lieu of the EEOC. The Department recognizes that, under the major questions doctrine, explicit Congressional authorization is required in "extraordinary cases" when the "history and breadth of the authority that [the agency] has asserted" and the "economic and political significance" of that assertion provide a "reason to hesitate before concluding that Congress" meant to confer such authority.

*W. Virginia v. Env’t Prot. Agency*, 597 U.S. 697, 721 (2022) (quoting *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000)). A majority of major-question cases apply to agency action that has not been clearly authorized by the text of the statute.

Here, § 75.300(e) is interpretive of the 13 statutes listed, each of which authorize programs administered by the Department. In *Bostock*, the Court interpreted language contained in—and at the heart of—the Title VII statute. 590 U.S. at 659 (observing that from “the ordinary public meaning of the statute’s language at the time of the law’s adoption, a straightforward rule emerges: [a]n employer violates Title VII when it intentionally fires an individual employee based in part on sex”). The Court states that “it is impossible to discriminate” against a person based on sexual orientation or gender identity “without discriminating against that individual based on sex.” *Id.*

Because HHS is interpreting language nearly identical to that interpreted in *Bostock*, the major questions doctrine does not apply to HHS’s interpretation of the statutes identified in this rule. The Department therefore disagrees with the commenters who opined that this rule represents agency action in violation of *Biden v. Nebraska*, 143 S. Ct. 2355 (2023) or *W. Virginia v. Env’t Prot. Agency*, 597 U.S. 697 (2022). To the contrary, HHS is relying upon all relevant statutory text and applicable case law in this interpretive rule. However, for clarity, the Department has revised § 75.300(e) in this final rule to make clear that this provision is interpretive and does not impose substantive obligations on entities outside the Department.

*Comment:* A group of commenters argued that § 75.300(e) would compel faith-based organizations in receipt of HHS funding to violate their religious identity and tenets. Another group of commenters opined that if a program required a religious organization to provide referrals for care that violate the religious organization’s ethical standards, it would discriminate against religious providers and would be inconsistent with *Trinity Lutheran Church of Columbia v. Comer*, 582 U.S. 449 (2017). A group of religious organizations recommended that, absent § 75.300(e)’s removal, § 75.300(f) should be altered to explicitly state that incidental harms to

third parties cannot curtail a request for religious exemption if the government action at issue is a burden on the claimant’s religion. Two organizations stated that challenges could arise in shelters for unaccompanied migrant children (UC) and unaccompanied refugee minors (URMs) to accommodate gender-nonconforming individuals.

One commenter asserted that the Proposed Rule would require religious organizations to place UCs and URM s with same-sex couples as foster parents because that program is funded in part by grants issued under 8 U.S.C. 1522, 45 CFR part 400, authorization for programs for domestic resettlement of and assistance to refugees, and cited *Marouf v. Azar*, No. 18-cv-00378 (D.D.C. Jul. 7, 2023). More generally, several commenters argued that the rule would force faith-based providers to provide procedures with which they disagree due to religious beliefs, and raised constitutional issues, alleging that the Proposed Rule would result in disparate impact on religious entities in violation of the Equal Protection Clause.

*Response:* The Department disagrees that this rule discriminates against religious entities in violation of the Equal Protection Clause. Rather, this final rule clarifies HHS’s interpretation of discrimination based on sex in the listed statutes, consistent with Federal law. Furthermore, §75.300(f) provides a new administrative process not previously provided for in either the 2016 Rule or the partially vacated 2021 Rule.<sup>22</sup> Under § 75.300(f), the Department will address any request for an assurance of a religious freedom- or conscience-based exemption on a case-by-case basis. This new process is designed to ensure that protections are appropriately applied and that recipients have the opportunity to request assurance of exemptions consistent with their religious tenets. The process set forth in § 75.300(f) clarifies legal obligations, demonstrates the Department’s concerted effort to approach its enforcement responsibilities under Federal antidiscrimination laws while respecting applicable Federal religious freedom and conscience laws, and maintains transparency about the Department’s enforcement mechanisms.

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<sup>22</sup> The religious freedom and conscience exemption process here complements the exemption process set forth in Section 1557 (§ 92.301), and the Department’s 2024 Conscience Rule, *Safeguarding the Rights of Conscience as Protected by Federal Statutes*, 89 FR 2078 (2024).

With regard to the consideration of third-party harms<sup>23</sup> raised by commenters, the Religious Freedom Restoration Act of 1993 (RFRA), 42 U.S.C. 2000bb *et seq.*, provides that the Federal government may not substantially burden a person’s exercise of religion unless it can demonstrate that the “application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.” 42 U.S.C. 2000bb-1(b). In determining whether the government action is the least restrictive means of furthering a compelling governmental interest, the Department will take into consideration any harms to third parties that may result from providing an exemption under RFRA.

In response to commenters’ concerns regarding the application of this rule to religious providers in the context of UCs, URM<sup>s</sup>, and foster care because of this rule’s application to 8 U.S.C. 1522, the Department notes that 8 U.S.C. 1522 applies only to URM<sup>s</sup> and not UCs or foster care. Additionally, the Department notes the process at § 75.300(f) is available to religious providers to request an assurance of an exemption from the application of the nondiscrimination requirements addressed in this rule to their programs under applicable Federal religious freedom and conscience laws.

*Comment:* Some commenters stated that, in their view, the Proposed Rule would affect women’s access to services where an entity has been required, based on this rule, to expand its services to include a new population on top of the population they already serve. Some commenters discussed their belief that the rule would require specific programs to expand the services provided, alleging that programs like Head Start and the Community Mental Health and Maternal/Child Health Block Grants would be required to affirm LGBTQI+ children, which would require providing correspondingly affirming health care.

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<sup>23</sup> See *Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005) (In addressing religious accommodation requests, “courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries.”).

*Response:* The Department appreciates these comments, but they do not accurately characterize requirements related to women, children, and health care. The final rule clarifies HHS's interpretation of discrimination based on sex in the listed statutes, consistent with Federal law. The Department is not setting standards of care for the practice of medicine in this rule, nor is it requiring providers to provide any specific services.

*Comment:* Numerous commenters raised concerns that the Proposed Rule affects parental rights related to curricula taught to children and decisions about medical care.

*Response:* The Department appreciates the fundamental role that parents play in raising their children. The final rule clarifies HHS's interpretation of discrimination based on sex in the listed statutes, consistent with Federal law. The rule does not set standards for parental involvement and nothing in this rule derogates parental rights. The rule also does not opine on the authority of parents to choose when and how to educate their children about certain matters, or to choose when and what health care to provide their children.

*Comment:* A commenter expressed concern that the Proposed Rule does not clarify the extent of its nondiscrimination requirements, nor does it adequately establish what services recipients must provide or how they must operate under the Proposed Rule.

*Response:* The Department appreciates these comments. The Department is committed to working with recipients to ensure compliance with their particular programs' nondiscrimination requirements. The Department disagrees that the rule's approach would leave applicants with uncertainty about their antidiscrimination obligations. As discussed above, the concept that discrimination on the basis of sex includes discrimination on the basis of sexual orientation and gender identity is not new, and there exists a wide body of case law on its application in numerous circumstances. This rule memorializes the Department's interpretation as applied to 13

statutes. Indeed, many Federal courts have long interpreted Title VII’s prohibition on sex-based discrimination to encompass discrimination based on gender identity.<sup>24</sup>

It is true, however, that the *Bostock* Court noted it did not address the issue of how “doctrines protecting religious liberty interact with Title VII,” leaving those questions “for future cases. . .”<sup>25</sup> The Department will apply the law on these issues as it develops.

*Comment:* A few commenters expressed concern that HHS grant recipients would now be required, in their view, to use participants’ preferred pronouns or adopt, according to these commenters, a “false” view of sex with which individuals may disagree, potentially burdening their speech and expressive association.

*Response:* This rule does not require grant recipients to adopt any particular views, and neither requires nor authorizes the restriction of any rights protected by the First Amendment or any other Constitutional provision. To reiterate, § 75.300(e) does not impose any substantive requirements on entities outside the Department. Rather, the final rule clarifies HHS’s interpretation of discrimination based on sex in the listed statutes and interprets those statutes’ prohibitions consistent with Federal law. This regulation neither addresses specific conduct constituting discrimination under any particular statute nor dictates any of the outcomes of any claim of discrimination. Whether discrimination has occurred is a fact-specific inquiry.<sup>26</sup>

*Comment:* Several commenters discussed that at least five of the statutes referenced in § 75.300(e) prohibit sex discrimination by incorporating prohibitions in Title IX, which the

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<sup>24</sup> See, e.g., *Barnes v. City of Cincinnati*, 401 F.3d 729, 738 (6th Cir. 2005); *Schroer v. Billington*, 577 F. Supp. 2d 293, 308 (D.D.C. 2008); *Roberts v. Clark Cnty. Sch. Dist.*, 215 F. Supp. 3d 1001, 1014 (D. Nev. 2016).

<sup>25</sup> On this matter, the *Bostock* Court said that how doctrines protecting religious liberty -- including Title VII’s religious exemption, the First Amendment’s religion clauses, and the Religious Freedom Restoration Act -- interact with Title VII “are questions for future cases . . .” 590 U.S. 644, 682 (2020).

<sup>26</sup> For example, according to guidance from the U.S. Equal Employment Opportunity Commission (EEOC), “although accidental misuse of a transgender employee’s name and pronouns does not violate Title VII, intentionally and repeatedly using the wrong name and pronouns to refer to a transgender employee could contribute to an unlawful hostile work environment.” EEOC, *Sexual Orientation and Gender Identity (SOGI) Discrimination*, <https://www.eeoc.gov/sexual-orientation-and-gender-identity-sogi-discrimination>.

commenters state provide for broad carveouts and exceptions for religious entities. 42 U.S.C. 290cc-33(a)(1), 300w-7(a)(1), 300x-57(a)(1), 708(a)(1), 10406(c)(2)(A).

*Response:* While each of the five statutes referenced by commenters mentions Title IX in a rule of construction, they also each contain a separate, standalone prohibition against discrimination on the basis of sex. 42 U.S.C. 290cc-33(a)(2), 300w-7(a)(2), 300x-57(a)(2), 708(a)(2), 10406(c)(2)(B)(i). These provisions are not reliant on Title IX. They are separate authorities that prohibit sex discrimination outright, and the Department disagrees that the statutory exemptions and exceptions from Title IX should be read into them.

The final rule has no effect on a covered entity's<sup>27</sup> or applicant's ability to maintain, seek, claim, or assert a religious exemption under Title IX. The Department remains committed to applying Title IX's religious exception for the education programs and activities of entities controlled by religious organizations under Title IX. And applicants or recipients that do not have an education program or activity that qualifies under the Title IX religious exception are able to claim assurances of a religious freedom exemption to the requirements of this regulation under this final rule's new administrative process outlined in § 75.300(f). Nothing in this rule invalidates or limits the existing rights, remedies, procedures, or legal standards available under Federal religious freedom and conscience laws.

*Comment:* Some organizations raised issues with compliance and the impact of instituting nondiscrimination requirements related to sexual orientation and gender identity in educational settings, particularly as applied to sex-segregated facilities or programs. Other commenters stated that the *Bostock* decision did not create a presumption that sex nondiscrimination statutes prohibit sexual orientation and gender identity discrimination in the context of single-sex spaces.

*Response:* The final rule clarifies HHS's interpretation of discrimination based on sex in the listed statutes, consistent with Federal law. To the extent warranted, the Department will

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<sup>27</sup> Here, as in the NPRM, *e.g.*, 88 FR 44758, “covered entity” is used interchangeably with “recipient,” and is distinct from any defined terms in other rules, including “covered entity” as defined in Section 1557.

provide guidance for grantees with questions about compliance with their nondiscrimination obligations. And if program recipients have a religious freedom or conscience objection to the nondiscrimination obligations addressed in this rule, the Department has set forth an administrative process at § 75.300(f). Accordingly, the Department declines to make additional revisions in response to these comments.

*Comment:* Two commenters asserted that the statutes in the Proposed Rule are exercises of Congress's Spending Clause authority and therefore are subject to the *Pennhurst* "clear statement rule," which provides that Congress cannot impose conditions on the grant of Federal funding without providing a clear statement as to what these conditions would entail.

*Response:* In *Pennhurst State School and Hospital v. Halderman*, the Supreme Court held that "if Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously . . . , enabl[ing] the States to exercise their choice knowingly, cognizant of the consequences of their participation." 451 U.S. 1, 17 (1981). In *Bostock*, the Supreme Court relied on the plain meaning of Title VII to hold that discrimination because of sex includes discrimination because of sexual orientation and gender identity. HHS is relying on the same plain meaning of the 13 statutes listed in § 75.300(e). As noted in the Proposed Rule, the statutes listed in proposed § 75.300(e) were identified because they contain prohibitions on sex discrimination similar to that in Title VII; none contain any indicia suggesting they should be construed differently than Title VII; and the Department is unaware of any reported case law with regard to these statutes that requires a contrary construction. 88 FR 44754. Indeed, since *Bostock*, three Federal courts of appeal have held that the plain language of statutes such as Title IX's prohibition on sex discrimination must be read similarly to Title VII's prohibition.<sup>28</sup> Thus, like Title VII, these 13 statutes unambiguously prohibit recipients from discriminating on the

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<sup>28</sup> See *A.C. by M.C. v. Metro. Sch. Dist. of Martinsville*, 75 F.4th 760, 769 (7th Cir. 2023); *Grabowski v. Arizona Bd. of Regents*, 69 F.4th 1110, 1116-17 (9th Cir. 2023); *Doe v. Snyder*, 28 F.4th 103, 113-14 (9th Cir. 2022); *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 616 (4th Cir. 2020), as amended (Aug. 28, 2020), cert. denied, 141 S. Ct. 2878 (Mem.) (2020).

basis of sexual orientation or gender identity. The Department's interpretation in this final rule therefore does not affect the States' knowing choice in accepting Federal funds here. Recipients of Federal funds in the relevant grant programs are clearly on notice that they must comply with the antidiscrimination provisions of the 13 listed statutes. Even if one accepted the argument that the "application of [the condition] might be unclear in [some] contexts," that would not render the condition unenforceable under the Spending Clause. *Bennett v. Ky. Dep't of Educ.*, 470 U.S. 656, 665-66, 673 (1985). Unlike *Pennhurst*, in which the Federal law at issue was unclear as to whether the states incurred any obligations at all by accepting Federal funds, the 13 listed statutes clearly condition receipt of funds on complying with the statutes' prohibition on sex discrimination. *See* 8 U.S.C. 1522; 42 U.S.C. 290cc-33; 42 U.S.C. 290ff-1; 42 U.S.C. 295m; 42 U.S.C. 296g; 42 U.S.C. 300w-7; 42 U.S.C. 300x-57; 42 U.S.C. 708; 42 U.S.C. 5151; 42 U.S.C. 8625; 42 U.S.C. 9849; 42 U.S.C. 9918; 42 U.S.C. 10406.

#### **Summary of Regulatory Changes to § 75.300(e)**

For the reasons set forth in the Proposed Rule and considering the comments received, we are adding text to § 75.300(e) that states the provision is interpretive and does not impose any substantive obligations on entities outside the Department.

#### **4. Section 75.300(f)**

In the 2023 NPRM, the Department proposed to add § 75.300(f)(1), which provided that a recipient may, at any time, raise with the Department the recipient's belief that the application of a specific nondiscrimination provision or provisions addressed in this regulation as applied to the recipient would violate Federal religious freedom protections.

Section 75.300(f)(2) proposed that once the awarding agency, working jointly with ASFR or OCR (in the course of investigating a civil rights complaint or compliance review), receives a notification from a recipient seeking a religious exemption, the awarding agency, working jointly with either ASFR or OCR, would promptly consider the recipient's view that they are entitled to an exemption in responding to any complaints, or determining whether to proceed with any

investigation or enforcement activity regarding that recipient's compliance with the relevant nondiscrimination provisions, or in responding to a claim raised by the recipient in the first instance, in legal consultation with the Office of the General Counsel. Any relevant ongoing investigation or enforcement activity regarding the recipient would be held in abeyance until a determination has been made.

Section 75.300(f)(3) proposed that, in determining whether a recipient is wholly or partially exempt from the application of the specific provision or provisions raised in its notification, the awarding agency, working jointly with ASFR or OCR, in consultation with the Office of the General Counsel, must assess whether there is a sufficient, concrete factual basis for making a determination and apply the applicable legal standards of the religious freedom statute at issue.

Section 75.300(f)(3) also proposed that, upon making a determination regarding whether a particular recipient is exempt from—or subject to a modified requirement under—a specific provision addressed in this part, the awarding agency, working with ASFR or OCR, will communicate that determination to the recipient in writing, noting that that determination does not otherwise limit the application of any other Federal law to the recipient.

Section 75.300(f)(4) proposed that the awarding agency, working jointly with ASFR and OCR, may determine at any time whether a recipient is wholly or partially exempt from certain provisions addressed in this part under Federal religious freedom laws, either after a complaint is made against the recipient or when the recipient seeks an exemption before any complaint is filed (provided the Department has a sufficient, concrete factual basis for determining whether the recipient is entitled to an exemption).

The comments and our responses regarding § 75.300(f) are set forth below.

*Comment:* A commenter expressed support for § 75.300(f) because it calls for written notification to a grantee explaining the “scope, applicable issues, duration, and all other relevant terms of any [granted] exemption.” The commenter reasoned that such a notification would

minimize potential risks to LGBTQI+ individuals by restricting grantees from taking action beyond what a granted exemption allows. The commenter also asked, however, that the Department codify a requirement that this written notification be made available to the public as well as the grantee. One commenter said any determination letters from OCR granting an exemption should be made public within 10 days by posting on the Department's website.

*Response:* The Department thanks the commenters. The Department declines to revise § 75.300(f) to require publication of exemptions granted under this provision, consistent with Title IX regulations that do not impose a similar notification requirement for exemptions granted consistent with that statute or its implementing regulations.<sup>29</sup> The Department notes that nothing in this rule prevents applicants or recipients from independently disclosing any such exemptions they have received to the general public or individuals participating or seeking to participate in their programs, and we encourage applicants or recipients to do so. We recognize that individuals are not always aware that the recipients of Federal funding that administer the programs in which they participate may have religious freedom- or conscience-based exemptions, and the Department remains committed to working with recipients, applicants, and the public to improve transparency, clarity, and access to HHS funded programs and activities through implementation of this rule. HHS is also subject to FOIA, and information may be released to a requestor or made available for public inspection consistent with the agency's obligations under that statute and its implementing regulations.

*Comment:* A commenter expressed concern with the notification procedure in proposed § 75.300(f), because the process, in their view, would not function as a substitute for automatic exemptions authorized under the Constitution, RFRA, Title IX, and other statutes. Some commenters expressed concern that § 75.300(f) offers recipients no assurance in the form of either substance or process. Some commenters said that the exemption process in § 75.300(f) may discourage otherwise eligible entities from applying for or receiving certain Federal grant

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<sup>29</sup> See e.g., 45 CFR 86.12; see also 85 FR 59916, 59951-2 (September 23, 2020) (Dep't of Educ. rulemaking).

funds because the process is unclear, unpredictable, and unreliable. One commenter opined that the existence of § 75.300(f) demonstrates that the rule is rewriting the underlying terms of grants in a way that will have substantial impacts on recipients.

A commenter expressed concern that the Department's view is that RFRA requires no affirmative agency compliance or enforcement beyond what a court orders. The commenter cited to a November 2021 Federal Register notice that withdrew a prior Delegation of Authority, which had centralized authority for implementation and compliance of RFRA within the Department with OCR. *See* 86 FR 67067 (Nov. 24, 2021) (withdrawing 83 Fed. Reg. 2804 (Jan. 19, 2018)). The commenter continued that with this understanding, the Proposed Rule would result in religious providers having to undergo extensive enforcement proceedings and litigation to resolve their religious freedom concerns.

A commenter asked that the Department establish some objective criteria for a religious safe harbor because proposed § 75.300(f) provides little guidance on how Federal religious freedom laws would be applied. Another commenter similarly stated that additional clarity is needed because at least three of the 13 statutes in the Proposed Rule require applicants to make affirmative representations about their compliance with the relevant law's nondiscrimination provisions, namely 42 U.S.C. 295m; 42 U.S.C. 296g; and 42 U.S.C. 9849.

*Response:* The Department disagrees with commenters that it views RFRA as requiring no agency compliance. The new § 75.300(f) administrative process demonstrates the Department's concerted effort to balance its enforcement responsibilities under Federal antidiscrimination laws while respecting applicable Federal religious freedom and conscience laws, including RFRA. Section 75.300(f) provides an administrative process, not provided for in either the 2016 Rule or the partially vacated 2021 Rule, under which grant applicants and recipients may either rely on the protections of Federal religious freedom or conscience law or seek assurance of an exemption directly from the Department under such laws.

Section 75.300(f) sets forth a detailed administrative process to submit exemption assurance requests, and the standards governing the relevant Federal religious freedom and conscience laws speak for themselves. To provide added predictability to grant applicants and recipients, they are afforded an automatic, temporary exemption under §75.300(f)(2) until the Department adjudicates their request. For additional clarity, the Department is adding the following clause to § 75.300(f)(2), which states that a temporary exemption will take effect upon the submission of the request. The exemption shall be limited to the particular application of the specific provision(s) identified in the notification to the Department. The exemption includes conduct that occurred during the pendency of any administrative investigation and enforcement that is covered by the temporary exemption.

Finally, the Department disagrees that the inclusion of § 75.300(f) indicates any grant terms are being rewritten. The Department's inclusion of § 75.300(f) ensures that the Department consistently applies both *Bostock* and other relevant case law and complies with its obligations under applicable Federal religious freedom and conscience law.

*Comment:* Some comments raised concerns regarding privacy protections for organizations seeking an exemption under § 75.300(f), and others cited the need for more privacy protections for such organizations. A commenter speculated that, without such protections, such religious organizations may become targets of individuals with anti-religious animus.

*Response:* The Department will apply all applicable privacy laws in handling the information it receives from entities regarding requests for exemptions, will not target or retaliate against an entity that seeks an exemption under § 75.300(f), and will handle according to the applicable provisions of the of the Privacy Act of 1974. As noted above, the Department does not require publication of exemptions granted to applicants or recipients under this provision, though applicants or recipients may independently and voluntarily disclose any such exemptions they have received the public and participating or seeking to participate in their

programs. As noted above, HHS is subject to the FOIA; thus, information may be requested pursuant to that statute.

*Comment:* Some commenters stated that § 75.300(f) does not explain what happens if a request for an exemption is submitted, but the factual record is not fully developed when the Department makes its assessment per § 75.300(f)(3). These commenters also expressed concern that § 75.300(f)(3) does not explain what facts would assist in HHS's assessment.

A group of commenters opined that § 75.300(f) should be clarified by citing the proposition that, under RFRA, the Government must show “application of the burden to the person is in furtherance of a compelling governmental interest.”

Another group of commenters requested that the Department include in the text of the regulation a requirement that it conduct an Establishment Clause analysis of any proposed exemptions. They stated that such an analysis is a constitutionally required step that previous Administrations have omitted and that the Establishment Clause commands that “an accommodation must be measured so that it does not override other significant interests,” “impose unjustified burdens on other[s],” or have a “detrimental effect on any third party.”

*Cutter v. Wilkinson*, 544 U.S. 709, 720, 722, 726 (2005); *see also Thornton v. Caldor*, 472 U.S. 703, 709–10 (1985); *Burwell v. Hobby Lobby Stores*, 573 U.S. 682 (2014); *Texas Monthly v. Bullock*, 489 U.S. 1, 18 n.8 (1989) (Brennan, J., plurality op.).).

A coalition of legal advocacy groups and religious groups recommended that the Department expressly adopt a case-by-case approach to granting exemptions under the final rule, reasoning that issuance of blanket exemptions or exemptions for hypothetical burdens should be minimized.

*Response:* As stated above, the Department will follow all relevant legal authorities, including Supreme Court precedent, in administering § 75.300(f) and the final rule. The Department affirms, consistent with the preamble of the Proposed Rule, that it will evaluate each situation on a case-by-case basis to determine whether a recipient—or, as of this final rule,

applicant—is wholly exempt from the application of, or entitled to a modification of the application of, certain provisions addressed in this part, under an applicable Federal religious freedom or conscience law. When HHS makes a case-by-case determination, this refers to the evaluation of the exemption request as a whole—which may be requesting assurance of an exemption from a category of services. An entity will not be required to submit an exemption assurance request for each time it seeks to offer a service if an exemption already applies. Such a case-by-case analysis also mitigates concerns that the Department will always evaluate the facts in a particular direction and negatively affect third parties as raised in the comment. In making such determinations, the Department will faithfully apply the legal standards set forth in the particular Federal religious freedom or conscience law at issue. The Department declines the commenter’s recommendation to articulate the legal standards in RFRA in the regulatory text of § 75.300(f) as unnecessary.

However, to address commenters’ concerns, the Department has revised § 75.300(f)(1) to state that a recipient or applicant may rely on applicable Federal religious freedom and conscience protections. In other words, a recipient or applicant is not required to seek an exemption assurance from the Department, although it may do so if it wishes. Revised § 75.300(f)(1) also states that, where such protections apply, the application of a particular provision(s) of the statute at issue to the specific contexts, procedures, or services at hand shall not be required. When a recipient acts based upon its good faith reliance that it is exempt from providing a particular service due to the application of relevant religious freedom and conscience protections (e.g., RFRA), even if the recipient had not affirmatively sought a written exemption assurance under § 75.300(f)(2), HHS will not seek backward-looking relief against that recipient. But if the Department determines, after an investigation, that the recipient does not satisfy the legal requirements for an exception, it will seek forward-looking relief as appropriate under the facts.

If the applicant or recipient wishes to receive an assurance from the Department regarding an exemption under any applicable religious freedom and conscience laws, it may do so under § 75.300(f)(2) either prior to, or during the course of, an investigation.

It is important to note that Federal religious freedom and conscience laws often differ in significant ways, and the facts that would assist the Department in its assessment of such claims would be consistent with the applicable legal authorities set forth in this revision to § 75.300(f)(2). For example conscience laws frequently are tied to federal funding, while RFRA provides that the Federal government may not substantially burden a person's exercise of religion unless it can demonstrate that the “application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.” 42 U.S.C. 2000bb-1(b). In determining whether the government action is the least restrictive means of furthering a compelling governmental interest, the Department will take into consideration any harms to third parties that may result from providing an exemption under RFRA. The Department will apply the RFRA standard in determining whether and to what extent an applicant or recipient is exempt from the application of any provision addressed in this final rule under that law. The Department will consider the harms that an applicant or recipient's request for an assurance of an exemption may have on third parties if and when that harm is relevant when considering whether to grant an assurance under a particular Federal religious freedom or conscience law.

Given this framework for addressing third party harms, the Department notes that it remains committed to fully complying with the First Amendment, including the Free Exercise and Establishment Clause, but declines to add language relating to third party harms to the final rule.

However, for the sake of additional clarity, the Department is revising proposed § 75.300(f)(1), now § 75.300(f)(2), to explain that at any time, a grant applicant or recipient may notify the HHS awarding agency, ASFR, or OCR that it views itself as exempt from, or requires

modified application of, certain provisions addressed in this rule because of the application of the Church, Coats-Snowe, and Weldon Amendments, the generally applicable requirements of the RFRA, the First Amendment, and other applicable Federal laws.

*Comment:* A coalition of legal advocacy groups and religious groups requested that HHS require that an awarding agency work with both ASFR and OCR in reviewing, considering, and deciding whether to grant a religious exemption or modification to the provisions of the relevant statute.

*Response:* The Department thanks commenters for the request and agrees that the awarding agency should work with both ASFR and OCR in reviewing, considering, and deciding requests for assurances of exemption. Accordingly, the Department is revising § 75.300(f) to replace “or” with “and” as the conjunction between ASFR and OCR where relevant in § 75.300(f).

*Comment:* Several commenters stated that the Department should explicitly state that the notification procedure in § 75.300(f) is optional and clarify that a recipient will not be prejudiced if they do not seek an exemption under this provision.

Additionally, a couple of commenters requested that the Department clarify in § 75.300(f) who will make the final determination on religious freedom- or conscience-based exemption requests and clarify on what basis the determination is to be made.

*Response:* The Department appreciates the commenters’ concerns and suggestions. To start, when a recipient acts based upon its good faith reliance that it is exempt from providing a particular service due to the application of relevant religious freedom and conscience protections (e.g., RFRA), even if the recipient had not affirmatively sought a written exemption under § 75.300(f)(2), the Department will not seek backward-looking relief against that recipient. Nothing in § 75.300(f) *requires* a grant applicant or recipient to seek an exemption under this process prior to an investigation, though they *may* do so if they so choose. Nor will an applicant or recipient be prejudiced if they do not seek an exemption under this provision; recipients may

make exemption requests during an investigation or administrative enforcement proceedings as well.

In addition, the Department is adding § 75.300(f)(5) to the final rule to state that if an applicant or recipient receives an adverse determination of its exemption request, the entity may appeal the Department’s determination under 45 CFR Part 81. Section 75.300(f)(5) also provides the temporary exemption provided to the applicant or recipient expires upon a final decision under 45 CFR Part 81. The Department is also adding § 75.300(f)(6) to the final rule, which explains that a determination of an exemption is not final for purposes of judicial review until after a final determination under 45 CFR Part 81. This mirrors the process for appeals in the Section 1557 Final Rule.<sup>30</sup>

Finally, it is the awarding agency, working jointly with ASFR and OCR, in legal consultation with the Office of the General Counsel, that will make the final determination on whether to grant the request, and will do so consistent with applicable Federal law. Applicants or recipients who have been denied an exemption under § 75.300(f) may raise their request before an administrative hearing examiner from the Department, as provided for under 45 CFR part 81. The temporary exemption would run through consideration of the administrative appeal.

*Comment:* A group of commenters suggested that § 75.300(f) expressly mention the “church autonomy doctrine” as a basis for an exemption.

*Response:* Section 75.300(f) provides for exemptions based on applicable Federal religious freedom and conscience laws, including the First Amendment. Given that the church autonomy doctrine is rooted in the religion clauses of the First Amendment,<sup>31</sup> its inclusion here is implied and it need not be explicitly mentioned in the regulatory text.

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<sup>30</sup> See Section 1557 § 92.302(g).

<sup>31</sup> See, e.g., *Belya v. Kapral*, 45 F. 4th 621, 628 (2d Cir. 2022) (“We use the term ‘church autonomy doctrine’ to refer generally to the First Amendment’s prohibition of civil court interference in religious disputes.”); see also *Our Lady of Guadalupe Sch. v. Morrissey-Berru*, 140 S. Ct. 2049, 2061 (2020) (describing “the general principle of church autonomy” as religious organizations’ “independence in matters of faith and doctrine and in closely linked matters of internal government”).

*Comment:* A couple of commenters expressed concern that the Proposed Rule's religious exemption provisions at § 75.300(f) would be duplicative of the provisions put forth in HHS's recent rulemaking on Section 1557 of the Affordable Care Act.

*Response:* The Department appreciates the comment and views the similarities in the processes in both this rule and the Proposed Rule with the Section 1557 rulemaking<sup>32</sup> as appropriate to the extent that RFRA and the other Federal religious freedom and conscience statutes would function similarly in this context as in Section 1557. However, the entities that receive grants from the Department may or may not be subject to Section 1557 by virtue of not being or operating health programs or activities, and thus, it is necessary for both rules to contain religious exemption provisions.

*Comment:* A group of commenters stated that the financial exemption provided by 45 CFR 75.102(b) should also apply to those with religious objections to the operation of proposed § 75.300(e). The commenters asserted that the Proposed Rule acknowledged the secular exemption in 45 CFR 75.102 but sought to discourage its application based on historical use. 88 FR 44755 n.26. The commenters stated that it would violate the Free Exercise Clause to make exemptions available for secular reasons under 45 CFR 75.102(b) but not have similar exemptions available for religious reasons unless strict scrutiny is satisfied, citing both *Fulton v. Philadelphia*, 141 S. Ct. 1868 (2021), and *Tandon v. Newsom*, 141 S. Ct. 1294 (2021) (per curiam), for this proposition.

*Response:* The Department disagrees with commenters' claim. Unlike the government regulations at issue in *Fulton* and *Tandon*, under § 75.300(f), entities have numerous avenues to seek religious exemptions, including an assurance of exemption under the Church, Coats-Snowe, and Weldon Amendments, the generally applicable requirements of the RFRA, the First Amendment, and other applicable Federal laws. The Department therefore declines to apply 45 CFR 75.102(b), which has historically been used to address requests for financial and

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<sup>32</sup> 87 FR 47824 (Aug. 4, 2022).

administrative exemptions, to provide exemptions. Instead, the Department directs recipients and applicants with religious objections to the process laid out under § 75.300(f).

*Comment:* A group of commenters stated that they approved of the fact that § 75.300(f) could be invoked even if there is no active complaint pending against the recipient. The group further stated that the Department should also provide prospective recipients of grants from the Department a procedure whereby they could seek a preclearance exemption. Relatedly, the commenter urged the Department to ensure that nothing in the electronic grant application process would require a religious applicant to affirm nondiscriminatory conduct in a manner that would be at odds with RFRA or the First Amendment.

*Response:* As we stated in the NPRM, the Department is fully committed to respecting religious freedom laws, including RFRA and the First Amendment, when applying the nondiscrimination requirements addressed in this rule. The final rule allows for a religious exemption process in § 75.300(f). Further, because the nondiscrimination provisions being interpreted by this rule to apply based on receipt of certain Federal funds, we decline to allow for a general preclearance process, not associated with a specific funding application, from prospective grantees. However, an applicant may submit a request for assurance of an exemption concurrently with its grant proposal, which will be reviewed on a case-by-case basis. Neither the submission nor adjudication of a grant applicant's or recipient's request for assurance of a religious exemption will have any bearing on the awarding agency's determination of award unless the organization has made clear that the exemption is necessary to its participation and HHS has determined that it would deny the request.

### **Summary of Regulatory Changes to § 75.300(f)**

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 75.300(f), with the following modifications.

We are adding a new § 75.300(f)(1) to provide notice that an applicant or recipient may rely on Federal protections for religious freedom and conscience. We are revising proposed

§ 75.300(f)(1), now § 75.300(f)(2), to state that applicants, in addition to recipients, are allowed to submit requests for assurances of exemption, to provide a non-exhaustive list of conscience laws that may be applied to the § 75.300(f) process, and to notify recipients, applicants, and the public about the type of information the notification must include. We are also revising proposed § 75.300(f)(2), now § 75.300(f)(3), to provide a temporary exemption during the pendency of the Department's review of the request and a general timetable under which the Department will acknowledge and begin to evaluate requests for assurances of exemption; proposed § 75.300(f)(3), now § 75.300(f)(4), to provide that the awarding agency, ASFR, or OCR will inform the applicant or recipient in writing of the determination regarding the assurance of exemption request and that any such determination does not otherwise limit the application of any other provision of the relevant statute to the applicant or recipient or to other contexts, procedures, or services; and proposed § 75.300(f)(4), now § 75.300(f)(5), to provide details about the administrative appeal process for recipients and applicants receiving adverse determinations. Finally, in a new subparagraph § 75.300(f)(6), the Department notes that for purposes of judicial review, determinations made under § 75.300(f) are not final until after a final decision under 45 CFR Part 81.

### **5. Section 75.300(g)**

*Comment:* One commenter stated that, in their view, the proposed severability clause in § 75.300(g) makes clear that HHS will not apply any RFRA ruling beyond the parties protected in a case to similarly situated entities. The commenter viewed the proposed rule as therefore forcing objecting religious providers to each undergo years of enforcement proceedings followed by years of litigation.

*Response:* Section 75.300(g) ensures that, even if a court were to strike down some provision of this final rule, other portions of this rule not found to be unlawful would remain in effect. Contrary to the comment, § 75.300(g) states that any provision held to be invalid or unenforceable as applied to any person or circumstance, will not affect the application of the

provision to other persons *not* similarly situated or to other, *dissimilar* circumstances. The language of § 75.300(g) is standard in severability clauses and indicates here that the provisions of this rule are able to operate independently of each other.

### **Summary of Regulatory Changes to § 75.300(g)**

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provision as proposed in § 75.300(g).

### **C. Comments Received in Response to E.O. 13175 Tribal Consultation**

The Department conducted a Tribal Consultation on December 19, 2023, with 27 participants. The Department received 10 comments from tribal entities following the consultation.

*Comment:* Several Federally recognized Indian Tribes asked the Department to clarify that Tribal health programs exclusively benefiting American Indian and Alaska Native (AI/AN) people do not violate the discrimination provisions in the proposed § 75.300(c). The tribes said that § 75.300(c) should include an exemption modeled after Title VI's implementing regulation at 45 CFR 80.3(d), which states that for Indian Health and Cuban Refugee Services, it will not be considered discrimination if an individual is excluded from benefits because those benefits are limited by Federal law to individuals of a particular race, color, or national origin.

*Response:* The Department recognizes the unique relationship between the United States and Federally recognized tribal entities.<sup>33</sup> The regulation at 45 CFR 80.3(d) provides that an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law—such as the Indian Health Service—to individuals of a different race, color, or national origin. Because of the unique relationship between the United States and Federally recognized tribal entities, Federal government preferences based on an individual's membership or eligibility in a Federally recognized tribal entity are political classifications and

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<sup>33</sup> Indian Entities Recognized by and Eligible to Receive Services from the United States Bureau of Indian Affairs, 8 FR 2112 (Jan. 12, 2023).

are not race-based.<sup>34</sup> Preferences based upon the unique relationship between the United States and Federally recognized tribal entities are distinct from the forms of discrimination prohibited by Federal civil rights laws, which aim to protect all individuals on the basis of race, color, or national origin (including AI/AN individuals, regardless of political affiliation).<sup>35</sup> The Department respects this unique relationship and the resulting benefits that are conferred by the Federal government on the basis of political classification, which remain distinct from racial classification and therefore distinct from race nondiscrimination prohibitions referenced in § 75.300(c). It is unnecessary, however, to change the regulatory text of § 75.300(c) to reflect that ongoing commitment, and the Department declines to do so here.

*Comment:* One commenter from a Federally recognized Indian tribe requested clarity on whether the rule impacts Indian Health Service (IHS) Compact funding and if the IHS Compact funding stream is included in the list of statutes under § 75.300(e).

*Response:* The IHS Compact funding stream under Title IV of the Indian Self-Determination Education Assistance Act (ISDEAA) (25 U.S.C. 5381 *et seq.*; 42 CFR 137 *et seq.*) is not included in the list of 13 statutes in § 75.300(e). Regarding grants related to the 13 statutes listed in § 75.300(e), the Department notes that Tribes and Tribal organizations that compact with IHS to assume full funding and control over IHS Programs, Services, Functions and Activities (PSFA) can “add” statutorily mandated grants to their funding agreement once those grants have been awarded. *See* 42 CFR 137.60. However, the statutes listed in § 75.300(e) are not grants that can be added to a Tribe’s ISDEAA funding agreement with IHS.

### **III. Executive Order 12866 and Related Executive Orders on Regulatory Review**

#### **A. Executive Order 12866 Determination**

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<sup>34</sup> *See Morton v. Mancari*, 417 U.S. 535, 553 & n.24 (1974).

<sup>35</sup> *See Morton v. Mancari*, 417 U.S. 535, 550 (1974) (“[a] provision aimed at furthering Indian self-government by according an employment preference within the [Bureau of Indian Affairs] for qualified members of the governed group can readily co-exist with a general rule prohibiting employment discrimination on the basis of race.”).

The Department has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Small Business Regulatory Enforcement Fairness Act of 1995 (also known as the Congressional Review Act, 5 U.S.C. 801 et seq.), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) (UMRA). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The final rule states that: (1) grant recipients may not discriminate to the extent prohibited by Federal statute; and (2) HHS complies with applicable Supreme Court decisions. The rule likewise clarifies the Department’s interpretation of nondiscrimination protections on the basis of sex in 13 statutes consistent with Supreme Court precedent. This rulemaking has been determined to be significant for the purposes of E.O. 12866 as amended by E.O. 14094 and, therefore, has been accordingly reviewed by the OMB. Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 et seq.), OMB’s Office of Information and Regulatory Affairs has determined that this final rule does not meet the criteria set forth in 5 U.S.C. 804(2). The UMRA (section 202(a)) requires HHS to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. The final rule would not result in an expenditure in any year that meets or exceeds this amount.

#### *1. Public Comments*

The Department requested comment on the analysis of the impact of the Proposed Rule on small entities, and the assumptions that underlie that analysis. The Department received public comments on the likely impacts of the Proposed Rule, including its likely impacts as compared to the 2016 Rule. Below is a summary of the comments received and our response:

*Comment:* HHS received comments discussing the need for additional economic analysis of the effect of the Proposed Rule in addition to Information Collection Requests (ICRs) and other information gathering methods before the rule is enacted, including requests for information, regional roundtables, task forces, regulatory reviews of each grant statute, or a survey of all the relevant populations.

A number of commenters expressed concerns that familiarization costs and the effects on religious entities were not adequately captured and requested that these costs be considered as well as the impact overall it would have on the health care system.

Another commenter urged HHS to perform a family policy assessment in addition to stating its policy of reading and responding to comments.

*Response:* For the analysis of the final rule, HHS has included legal and other familiarization costs and has expanded the RIA to include costs specifically associated with assurance of religious freedom and conscience exemptions requests. Taking those into consideration, the Department concludes that the final rule would result in annualized costs over a five-year time horizon of approximately \$4.0 million or \$3.8 million annualized, discounted at 7 percent and 3 percent respectively.

Through the analysis, the Department has determined that the additional costs associated with the final rule will not have a significant impact on organizations' ability to administer the grants they receive, and therefore will not put additional strain on their ability to operate effectively.

The Department received no additional evidence or data from commenters about changes in the number or composition of grantees since the 2016 Rule.

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires Federal agencies to determine whether a policy or regulation may negatively affect family well-being. If the agency determines a policy or regulation negatively affects family well-being, then the agency must prepare an impact assessment addressing seven criteria specified in the law. HHS maintains that it is not necessary to prepare a family policymaking assessment (see Pub. L. 105–277) for this rule, because it will not have a negative impact on the autonomy or integrity of the family as an institution, or family well-being within the meaning of the legislation.

The Department considers the opportunity for grant recipients and applicants to raise recipient-specific and applicant-specific concerns to be a benefit of the final rule. For the purposes of the RIA, we do not attribute any litigation costs to the final rule.

## *2. Summary of Costs and Benefits*

This analysis quantifies several categories of costs to covered entities and to the Department under the final rule. Specifically, the Department quantifies costs associated with covered entities becoming familiar with the rule provisions and making a determination of applicability as well as costs associated with drafting and submitting assurance of exemption requests. HHS also quantifies the anticipated costs to adjudicate the assurance of exemption requests from covered entities. Our analysis addresses the uncertainty in quantifying the number of entities that will submit exemption requests. For the primary estimate, the Department reports cost estimates of approximately \$16.47 million using a 7 percent discount rate, and a cost estimate of approximately \$17.41 million using a 3 percent discount rate. All cost estimates are in 2022 dollars. The Department concludes that the final rule would result in annualized costs over a five-year time horizon of approximately \$4.0 million or \$3.8 million, discounted at 7 percent and 3 percent respectively. In addition to these quantified cost estimates, the main analysis includes a discussion of the potential unquantified benefits associated with the rule.

Table 1 below shows the estimated annualized costs of the final rule.

**Table 1: Annualized Costs of the Final Rule (\$Millions, 2022 dollars)**

Primary Estimate	Low Estimate	High Estimate	Year Dollars	Discount Rate (percent)	Period Covered
\$4.02	\$2.91	\$5.67	2022	7%	2024-2028
\$3.80	\$2.75	\$5.34	2022	3%	2024-2028

### *3. Baseline*

To quantify the costs associated with this rule, the Department has attempted to estimate whether the number and composition of recipients changed in response to the prior two rulemakings and how those costs will impact this rule. The 2016 Rule has never been enforced; the Department issued the Notice of Nonenforcement in 2019; and the 2021 Rule never went into effect. Because of this, HHS does not have any data with regard to whether the number and composition of recipients changed in response to prior rulemakings, as there was no change in the enforcement of these rules which would impact those grants. However, the Department understands that its recipients generally fall into one of the following three categories in how they have been impacted by the prior two rulemakings.

The first category includes recipients that adopted the nondiscrimination practices prior to the 2016 Rule, whether voluntarily or as a result of State and/or local law. Their observance of nondiscrimination requirements is not the result of the 2016 Rule and thus, these recipients are not impacted by this rule. The second category includes recipients that had not adopted nondiscrimination practices prior to the 2016 Rule, but that complied since the 2016 Rule, including after the 2019 Notice of Nonenforcement was issued and until now. However, because the 2016 Rule did not contain any procedural enforcement mechanisms such as an assurance of compliance or adoption of a grievance process, it is difficult to quantify the costs, if any, incurred by this second category of recipients. These recipients would likely continue to follow such nondiscrimination practices voluntarily or because of new or newly enforced State and/or local laws, given that they could have declined to comply with the 2016 Rule requirements after the 2019 Notice of Nonenforcement issued, and yet have continued to comply with those

requirements notwithstanding that notice. Thus, these recipients are similarly situated to the first category of recipients insofar as they are not impacted by whether or not the 2016 Rule is in effect. The third category includes recipients that had not followed, and continue to not follow, the 2016 Rule. However, their practice was likely not impacted by the 2016 Rule, as the rule was not enforced. In 2019, the Department issued the Notice of Nonenforcement which applied to all recipients covered by the 2016 Rule, which is still in effect to date. As such, these recipients could not have relied upon the relevant provisions of the 2021 Rule, either, since that rule was partially vacated and never went into effect. Since this final rule removes the 2016 Rule's requirements, and adds a religious and conscience exemption process, the Department expects that these grantees will continue their current practice.

#### 4. *Covered Entities*

The final rule specifically addresses the application of Federal religious freedom and conscience protections for grant applicants and recipients and states that an applicant or recipient may raise with the Department their belief that the application of a specific provision or provisions of the grants' requirements as explained in Section 75.300 as applied to the applicant or recipient violate Federal religious freedom or conscience protections. The final rule also states that an applicant or recipient may seek an assurance of exemption based upon the application of a Federal religious freedom or conscience law and the Department would assess whether there is a significant concrete factual basis prior to making any determination. To estimate the population of covered entities, the Department uses historical information on the number of grantees for HHS programs as well as data on the number of religious hospitals. Based on information in the Department's Tracking Accountability in Government Grant Spending (TAGGS) system, the Department estimates that there was a total of 144,817 grantees in 2023.<sup>36</sup> The Department

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<sup>36</sup> U.S. Dep't of Health and Human Servs. Tracking Accountability in Gov't Grants Sys. (TAGGS), *Grants by Recipient Class*, <https://taggs.hhs.gov/ReportsGrants/GrantsByRecipClass>.

acknowledges that it issues many grants on an annual basis, and many recipients receive multiple grants. There were an estimated 707 active religious hospitals as of 2020.<sup>37</sup>

The Department does not have information on the number of grantees that will seek an assurance of exemption; therefore, it acknowledges the uncertainty with the number of grantees that will submit requests for assurance of exemption under the block grant programs. Because of the uncertainty, the Department estimates a range of covered entities will be impacted by the final rule. For the low population estimate, the Department assumes all 707 religious hospitals will request assurances of religious exemptions and receive funding under the block grants. This is likely an overestimate, as most hospitals do not receive funding under the 13 statutes at issue. Nevertheless, for the primary estimate, the Department assumes that 2% of the total population of TAGGS grantees, including religious freedom requests and those made on the basis of conscience, along with all 707 religious hospitals will request exemptions. For the high population estimate, the Department assumes 5% of the total population of TAGGS grantees along with all 707 religious hospitals will request exemption requests. To estimate the number of grantees in future years of the analysis, the final rule estimates the growth rate for the population of grantees by calculating a compound annual growth rate of 6.10% for the decade from 2013 to 2023.<sup>38</sup> The grantee annual growth rate is then applied to the total number of existing grantees each year during the five-year period of analysis, beginning in 2023. To account for costs to covered entities after the final rule is promulgated, the Department assumes only new entities will incur costs associated with the rule after the first year of implementation. After the first year, new entities are considered the source of associated costs, and the same percentage of religious exemptions (2%) is applied for new entities each year. Table 2 below shows the estimated

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<sup>37</sup> Total Catholic (577) + Non-Profit Church (130), Table 5: Short-Term Acute Care Hospitals by Category: 2001-2020; Tess Solomon et al., *Bigger and Bigger The Growth of Catholic Health Systems*, <https://www.communitycatalyst.org/wp-content/uploads/2022/11/2020-Cath-Hosp-Report-2020-31.pdf>.

<sup>38</sup> The compound annual growth rate (CAGR) uses the number of grantees between 2013 – 2023 and is calculated as  $((144,817 \div 80,124) ^ (1 \div 10)) - 1 = 6.10\%$ . Grantee data is collected from HHS's Tracking and Accountability in Government Grants System (TAGGS). U.S. Dep't of Health and Human Servs. Tracking Accountability in Gov't Grants Sys. (TAGGS) *supra* note 36.

population of grantees based on the annual growth rate (6.10%), and the estimated number of new grantees per year.

**Table 2: Covered Entities**

Year	Entities + Growth	New Entities	Annual Entities (2%)	Annual Entities (5%)
	$a = n * (1 + 6.10\%) ^ (a_{yn} - a_{yn-1})$	$b_{y1} \ a_{y1}$ $b_{yn} \ a_{yn} - a_{yn-1}$	$c = b * 2\%$	$d = b * 5\%$
2024	153,647	153,647	3,780	8,389
2025	163,016	9,369	187	468
2026	172,956	9,940	199	497
2027	183,503	10,546	211	527
2028	194,692	11,189	224	559

Note: Values may not multiply due to rounding.

## B. Costs of the Final Rule

In this section, the Department discusses the incremental costs of the final rule, which excludes ongoing costs attributable to prior rulemaking. The Department identifies potential costs associated with grantees becoming familiar with this rule along with submitting exemption requests, and follows the analytic approach contained in its analysis. The Department considered additional potential sources of costs that would be attributable to the final rule and found that Parts (c)–(e) of the rule clarify for all covered grants what is already required by law; and therefore, do not constitute incremental costs associated with this final rule. Below are descriptions of the quantified costs associated with the final rule.

### *1. Familiarization*

The Department anticipates that all covered entities will incur costs to familiarize themselves with the final rule. Depending on the grantee, the task of familiarization could potentially fall to the following occupation categories: (1) lawyers (23-1011), with a \$65.26 median hourly wage; (2) general and operations managers (11-1021), with a \$47.16 median hourly wage; (3) grantee social and community service managers (11-9151), with a \$35.69 median hourly wage; (4) medical and health services managers (11-9111), with a \$50.40 median hourly wage; or (5) compliance officers (13-1041), with a \$34.47 median hourly wage. Across all grantees, the Department adopts a pre-tax hourly wage that is the average across the median

hourly wage rates for these 5 categories, or \$46.60 per hour.<sup>39</sup> To compute the value of time for on-the-job-activities, the Department adopts a fully loaded wage rate that accounts for wages, benefits, and other indirect costs of labor that is equal to 200% of the pre-tax wage rate, or \$93.20 per hour.<sup>40</sup> Accordingly, the Department estimates that it would take a typical grantee approximately 0.68 hours to become familiar with the proposed provisions.<sup>41</sup> In Year 1, there are an estimated total of 153,647 grantees.<sup>42</sup>

In Year 2 through Year 5, the Department also assumes that new grantees will incur a similar familiarization cost in the year they enter the market. To calculate the cost to covered entities to familiarize themselves with the final rule, the Department multiplies the total number of grantees per year (see Table 3) by the estimated familiarization hour burden (0.68 hours) and by the average loaded wage for the grantee's accountable individual responsible for rule familiarization (\$93.20). In Year 1, the Department estimates the cost associated with grantee rule familiarization to be approximately \$9,686,014. Over the five-year period of analysis, the total cost to covered entities associated with rule familiarization is estimated to be \$12,273,485.

**Table 3: Familiarization Costs (2022 dollars)**

<b>Year</b>	<b>New Entities</b>	<b>Hour Burden</b>	<b>Wage</b>	<b>Total Cost</b>
	<b>a</b>	<b>b</b>	<b>c</b>	<b><math>d = a \times b \times c</math></b>
2024	153,647			\$9,686,014
2025	9,369			\$590,618
2026	9,940	0.68	\$93.20	\$626,631
2027	10,546			\$664,841
2028	11,189			\$705,380
<b>Total</b>				<b>\$12,273,485</b>

Note: Values may not multiply due to rounding.

<sup>39</sup> The average hourly wage is calculated as  $(\$65.26 + \$47.16 + \$35.69 + \$50.40 + \$34.47) \div 5 = \$46.60$ .

<sup>40</sup> JENNIFER R. BAXTER ET AL., *Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices*, (June 2017), [https://aspe.hhs.gov/sites/default/files/migrated\\_legacy\\_files/176806/VOT.pdf](https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/176806/VOT.pdf).

<sup>41</sup> According to the Department, reviewers read at the average speed of approximately 200 to 250 words per minute. (source: LISA A. ROBINSON ET AL., *Guidelines for Regulatory Impact Analysis*, (2016), at 26 Table 4.1, [https://aspe.hhs.gov/sites/default/files/private/pdf/242926/HHS\\_RIAGuidance.pdf](https://aspe.hhs.gov/sites/default/files/private/pdf/242926/HHS_RIAGuidance.pdf).) For this analysis the Department estimates the hour burden associated with rule familiarization by dividing the length of the NPRM (9,659 words) by an average reading rate (238 words per minute). The familiarization hour burden is calculated as  $9,659 \div 238 \div 60 = 0.68$  hours. (Source: MARC BRYSBART, *How many words do we read per minute?*, (2019), <https://osf.io/preprints/psyarxiv/xynwg/>.)

<sup>42</sup> Year 1 grantee population is estimated as the 2023 TAGGS grantee population, plus the annual grantee growth. The Department calculates the estimated Year 1 grantee population as  $144,817 * (1 + 6.10\%) = 153,647$ . Values may not multiply due to rounding. TAGGS accessed in: October 2023.

## 2. Exemption Assurance Requests

The final rule describes a process for applicants and recipients notifying an awarding agency that they are seeking assurance of a religious freedom- or conscience-based exemption, and for HHS to promptly consider the applicant’s or recipient’s views that they are entitled to an exemption. The Department has identified costs related to covered entities submitting a request for assurance of an exemption based on Federal religious freedom and conscience laws. The Department estimates this potential cost associated with such requests as the opportunity cost of time spent by covered entities to (a) assess the need for an exemption; (b) write the exemption assurance request; and (c) submit the request. To estimate the opportunity cost of time spent drafting and submitting such requests, the Department assumes that one (1) employee will spend two (2) hours assessing the need for an exemption and three (3) hours writing and submitting the exemption assurance request for a total of five (5) hours.<sup>43</sup> The Department further assumes that legal personnel, including lawyers and legal assistants, would perform these functions. The mean hourly wage for these occupations is \$65.26 per hour for each employee, which the Department doubles to account for overhead and other costs.<sup>44</sup> To compute the value of time for on-the-job activities, the Department adopts a fully loaded wage rate that accounts for wages benefits and other indirect costs of labor that is equal to 200% of the pre-tax wage rate or a fully loaded wage of \$130.52.<sup>45</sup> The Department calculates the cost per exemption assurance request for covered entities as the hour burden to determine applicability as well as drafting and submitting the exemption assurance request (5 hours) multiplied by the loaded wage for legal personnel

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<sup>43</sup> Based on internal OCR estimates.

<sup>44</sup> U.S. Bureau of Labor Statistics, *Occupational Employment and Wages, May 2022, 23-1011 Lawyers*. <https://www.bls.gov/oes/current/oes231011.htm>.

<sup>45</sup> JENNIFER R. BAXTER ET AL., *Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices*, (June 2017), [https://aspe.hhs.gov/sites/default/files/migrated\\_legacy\\_files/176806/VOT.pdf](https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/176806/VOT.pdf).

involved in the request process (\$130.52). The total cost per covered entity to draft and submit such a request is estimated to be \$652.60.<sup>46</sup>

Our cost estimate reflects a wide range of uncertainty in the number of exemption assurance requests the Department will receive. In the primary scenario, OCR adopts a central estimate of the number of such requests of 2 percent of all covered entities plus all 707 religious hospitals, which is estimated to be 3,780 requests in Year 1, covering all areas addressed under the statute and regulations.<sup>47</sup> In Year 1, the primary estimate of the total number of anticipated grantees seeking exemption assurance requests (3,780) is multiplied by the cost per request (\$652.60) for a total cost of \$2,466,794, with the range of estimates between \$461,388 and \$5,474,903 using the low and high population estimates respectively. In Years 2 through 5, the Department assumes that 2 percent of all new grantees will submit an exemption assurance request in the year they enter the market. Over the five-year period of analysis, the Department estimates that the primary estimate of total costs associated with covered entities drafting and submitting such requests to be \$3,002,508, with the range of estimates between \$461,388 and \$6,814,187 using the low and high population estimates respectively.

In conjunction with covered entities drafting and submitting exemption assurance requests, the Department will incur costs associated with adjudicating such requests received from covered entities. The awarding agency, working jointly with ASFR and OCR, and in legal consultation with the Office of the General Counsel, will be responsible for reviewing the request and making a determination of applicability as well as suitability for the exemption. The Department assumes that personnel involved in adjudicating these requests received from covered entities will be a single (1) Step 1 GS-14 employee with a loaded wage of \$126.86 per hour.<sup>48</sup> The Department also assumes it takes five hours to complete the review and adjudicate

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<sup>46</sup> Total costs per exemption request are calculated as \$130.52 x 5 hours = \$652.60 per exemption request.

<sup>47</sup> Total exemption requests calculated as 707 + (153,647 x .02) = 3,780 exemption requests.

<sup>48</sup> U.S. Off. of Pers. Mgmt., *Salary Table 2023-DCB, For the Locality Pay Area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA*, (Jan. 2023), [https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB\\_h.pdf](https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB_h.pdf). The loaded wage for GS-14 Step 1 personnel is calculated as \$63.43 x 200% = \$126.86.

exemption assurance requests.<sup>49</sup> To calculate the costs associated with the adjudication of such requests, the Department multiplies the estimated number of requests received per year by the hour burden to adjudicate the request (5 hours) and by the loaded wage for the reviewer (\$126.86). In Year 1, the primary estimate of costs associated with adjudicating exemption assurance requests is estimated to be \$2,397,621, with a range of estimates between \$448,450 and \$5,321,378 using the low and high population estimates respectively. In Years 2 through 5, the Department anticipates it will receive exemption assurance requests from new covered entities that will require the same adjudication process. Over the five-year period of analysis, the primary estimate of total costs to HHS associated with adjudicating such requests received from covered entities is estimated to be \$2,918,312, with a range of estimates between \$448,450 and \$6,623,105 using the low and high population estimates respectively.

To estimate the total cost of the exemption assurance request provision, the Department sums the estimated total costs for covered entities to draft and submit such a request with the estimated total costs to adjudicate it. In Year 1, the primary estimate of total costs associated with exemption assurance requests are estimated to be \$4,864,415, with a range of estimates between \$909,838 and \$10,796,281 using the low and high population estimates respectively. Over the five-year period of analysis, the primary estimate of total costs associated with such requests are estimated to be \$5,920,820, with a range of estimates between \$909,838 and \$13,437,292 using the low and high population estimates respectively.

*Table 4* below shows the estimated total costs associated with exemption assurance requests using the low, primary, and high population range.

**Table 4: Exemption Assurance Requests with Population Sensitivity (2022 dollars)**

<b>Year</b>	<b>Low</b>		<b>Primary</b>		<b>High</b>	
	<b>Entities</b>	<b>Total Cost</b>	<b>Entities</b>	<b>Total Cost</b>	<b>Entities</b>	<b>Total Cost</b>
2024	707	\$909,838	3,780	\$4,864,415	8,389	\$10,796,281

<sup>49</sup> Based on internal OCR estimates.

2025	0	\$0	187	\$241,136	468	\$602,839
2026	0	\$0	199	\$255,839	497	\$639,598
2027	0	\$0	211	\$271,439	527	\$678,598
2028	0	\$0	224	\$287,991	559	\$719,977
Total	707	\$909,838	4,601	\$5,920,820	10,442	\$13,437,292

### *3. Total Quantified Costs*

In the first year under the final rule for the primary population estimate, these costs include \$9.69 million in familiarization and \$4.86 million for covered entities to submit and review exemption assurance requests and HHS to adjudicate the requests for a total cost of \$14.55 million. Both familiarization and these requests have costs associated with the number of new grantees in the market and submitting the requests. Total costs for the final rule are estimated to be \$18.19 undiscounted and \$17.41 or \$16.47 when discounting at the 3 percent and 7 percent respectively. Table 5 below presents the total annual costs anticipated under the final rule for which cost estimates have been developed.

**Table 5: Estimate of Total Annual Costs (\$ Millions, 2022 dollars)**

Year	Familiarization	Exemption Requests	Undiscounted Total Costs	3% Discounted Costs	7% Discounted Costs
2024	\$9.69	\$4.86	\$14.55	\$14.13	\$13.60
2025	\$0.59	\$0.24	\$0.83	\$0.78	\$0.73
2026	\$0.63	\$0.26	\$0.88	\$0.81	\$0.72
2027	\$0.66	\$0.27	\$0.94	\$0.83	\$0.71
2028	\$0.71	\$0.29	\$0.99	\$0.86	\$0.71
<b>Total Cost Annualized</b>	<b>\$12.27</b>	<b>\$5.92</b>	<b>\$18.19</b>	<b>\$17.41</b>	<b>\$16.47</b>
				<b>\$3.80</b>	<b>\$4.02</b>

### *4. Discussion of Benefits*

The benefits of the rule help ensure that HHS grants programs will be administered fairly and consistently with Supreme Court precedent. Section 75.300(c) makes compliance simpler and more predictable for Federal grant recipients. Likewise, § 75.300(d) notes that HHS will comply with Supreme Court decisions, which also simplifies compliance for Federal grant recipients. Section 75.300(e) clarifies that the Department interprets the prohibition of

discrimination on the basis of sex in 13 listed statutes to include discrimination based on sexual orientation and gender identity, consistent with *Bostock v. Clayton County*, 590 U.S. 644 (2020), which provides additional clarity to the public regarding the Department's interpretation and helps facilitate the efficient and equitable administration of HHS grants. Finally, § 75.300(f) states that the Department will comply with all Federal religious freedom and conscience laws, including RFRA and the First Amendment, which will assist the Department in fulfilling that commitment by providing the opportunity for recipients and applicants to raise concerns with HHS and for those concerns to be evaluated on a case-by-case basis. The Department notes that there are other non-quantifiable benefits associated with this rule, such as protecting conscience rights; the free exercise of religion and moral convictions; allowing for more diverse and inclusive health care and service providers and professionals; improving provider-patient/recipient-beneficiary relationships that facilitate improved quality of care and services; and increased equity, fairness, nondiscrimination, and access to care and services. These benefits for the fair and nondiscriminatory enforcement of the programs covered by this rule are not quantified.

#### *5. Comparison of Costs and Benefits*

In summary, the Department expects the benefits of clarity will simplify compliance and ensure fair and nondiscriminatory administration of covered programs under this rule. Costs associated with implementing this administrative change include costs for some covered entities who may seek an exemption.

### **C. Analysis of Regulatory Alternatives to the Final Rule**

The Department carefully considered several alternatives but rejected them for the reasons explained below. Total undiscounted costs associated with the final rule are estimated to be \$18.2 million. The first alternative considered assumes HHS takes no action and makes no change from the 2016 rule; therefore, when compared to the final rule, it results in a total cost savings of \$17.4 million or \$16.5 million when using the three percent and seven percent

discount rates, respectively. HHS concluded that this first alternative would potentially lead to legal challenges, in part over the scope of the Department's authority under 5 U.S.C. 301.

The second alternative considered maintains the text of the 2016 Rule, but also promulgates a regulatory exemption for faith-based organizations as provided under proposed § 75.300(f). This alternative could address the religious exemption issues raised by the 2016 Rule's application to certain faith-based organizations that participate in, or seek to participate in, Department-funded programs or activities. As discussed earlier, total undiscounted costs for the familiarization provision are estimated to be \$12.3 million. When compared to the final rule, the second alternative results in a cost savings of \$11.7 million or \$11.1 million when using the three percent and seven percent discount rates respectively; however, the provisions of the 2016 Rule would be subject to the same legal challenges under 5 U.S.C. 301.

The third alternative considered enumerates the Department's interpretation of applicable nondiscrimination provisions and the programs as well as recipients/subrecipients to which the nondiscrimination provisions would apply, as set forth in § 75.300(e), without including a religious freedom and conscience exemption process. This results in total costs of \$12.3 million associated with only including familiarization costs, or a cost savings when compared to the preferred alternative by \$5.76 million or \$5.4 million using the three percent and seven percent discount rates, respectively. However, given the applicability of Federal religious freedom and conscience laws, a process by which such applicants and recipients can submit requests for assurance of a religious freedom- or conscience-based exemption that are evaluated on a case-by-case basis helps ensure that the Department complies with its legal obligations.

The Department has not quantified the potential benefits associated with the various policy alternatives. Table 6 reports the present value of total costs as well as annualized costs of these policy alternatives, adopting a three percent and seven percent discount rate. Table 7 reports the difference between the total cost of the alternatives compared to the provisions of the final rule, using the same accounting methods and discount rates.

**Table 6: Total Cost of Policy Alternatives Considered**

	<b>Present Value</b>	<b>Annualized</b>		
<b>Accounting method discount rate</b>	3%	7%	3%	7%
Final Rule	\$17.4	\$16.5	\$3.8	\$4.0
Alternative 1: No change from 2016 Rule	\$0	\$0	\$0	\$0
Alternative 2: 2016 Rule with religious exemption	\$5.7	\$5.4	\$1.2	\$1.3
Alternative 3: New nondiscrimination provisions without religious exemption	\$11.7	\$11.1	\$2.6	\$2.7

**Table 7: Comparison of Alternatives to Final Rule**

	<b>Present Value</b>	<b>Annualized</b>		
<b>Accounting method discount rate</b>	3%	7%	3%	7%
Alternative 1: No change from 2016 Rule	-\$17.4	-\$16.5	-\$3.8	-\$4.0
Alternative 2: 2016 Rule with religious exemption	-\$11.7	-\$11.1	-\$2.6	-\$2.7
Alternative 3: New nondiscrimination provisions without religious exemption	-\$5.7	-\$5.4	-\$1.2	-\$1.3

#### **D. Regulatory Flexibility Act—Final Small Entity Analysis**

The Department has examined the economic implications of this final rule as required by the Regulatory Flexibility Act, 5 U.S.C. 601–612 (RFA). The RFA requires an agency to describe the impact of a proposed rulemaking on small entities by providing an initial regulatory flexibility analysis unless the agency expects that the Proposed Rule will not have a significant impact on a substantial number of small entities, provides a factual basis for this determination, and proposes to certify the statement. 5 U.S.C. 603(a), 605(b). If an agency must provide a final regulatory flexibility analysis, this analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. HHS generally considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue on at least five percent of small entities. As discussed, the final rule would:

- Explain applicable Federal statutory nondiscrimination provisions.
- Provide that HHS complies with applicable Supreme Court decisions in administering its grant programs.

Affected small entities include all small entities which may apply for HHS grants; these small entities operate in a wide range of sections involved in the delivery of health and human services. Grant recipients are required to comply with applicable Federal statutory nondiscrimination provisions by operation of such laws and pursuant to 45 CFR 75.300(a); HHS is required to comply with applicable Supreme Court decisions. Thus, there would be no additional economic impact associated with §§ 75.300(c)–(e). The Department anticipates that this rulemaking would primarily serve to provide information to the public. The Department anticipates that this information will allow affected entities to better deploy resources in line with established requirements for HHS grant recipients. As a result, HHS has determined, and the Secretary proposes to certify, that this final rule, will not have a significant impact on the operations of a substantial number of small entities.

#### **E. Executive Order 13132 on Federalism**

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments or has Federalism implications. The Department has determined that this rule does not impose such costs or have any Federalism implications.

#### **F. Executive Order 12250 on Leadership and Coordination of Nondiscrimination**

Pursuant to Executive Order 12250, the Department of Justice has the responsibility to “review . . . proposed rules . . . of the Executive agencies” implementing nondiscrimination statutes that prohibit discrimination in programs and activities that receive Federal financial assistance “in order to identify those which are inadequate, unclear or unnecessarily inconsistent.” Exec. Order 12250 (reprinted at 45 Fed. Reg 72995 (Nov. 5, 1990); 28 CFR 0.51. The Department of Justice has reviewed and approved this final rule.

#### **G. Paperwork Reduction Act**

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR § 1320 appendix A.1), the Department has reviewed this rule and has determined that there are no new collections of information contained therein.

### **List of Subjects in 45 CFR Part 75**

Administrative practice and procedure, Civil Rights, Cost principles, Grant programs, Grant programs—health, Grant programs—social programs, Grants Administration, Hospitals, Nonprofit Organizations reporting and recordkeeping requirements, and State and local governments.

Dated: April 22, 2024.

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**Xavier Becerra,**

*Secretary,*

*Department of Health and Human Services.*

For the reasons set forth in the preamble, the Department revises 45 CFR part 75 to read as follows:

## **PART 75—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR HHS AWARDS**

1. The authority citation for 45 CFR part 75 continues to read as follows:

**Authority:** 5 U.S.C. 301, 2 CFR part 200.

2. Amend § 75.300 by revising paragraphs (c) and (d), and adding paragraphs (e), (f), and

(g) to read as follows:

**§ 75.300 Statutory and national policy requirements.**

\* \* \* \*

(c) It is a public policy requirement of HHS that no person otherwise eligible will be excluded from participation in, denied the benefits of, or otherwise subjected to discrimination in the administration of HHS programs, activities, projects, assistance, and services, to the extent doing so is prohibited by Federal statute.

(d) HHS will follow all applicable Supreme Court decisions in administering its award programs.

(e) In the statutes listed in paragraphs (e)(1) through (13) that HHS administers which prohibit discrimination on the basis of sex, the Department 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. This provision is interpretive and does not impose any substantive obligations on entities outside the Department. This paragraph (e) interprets the following HHS authorities that prohibit discrimination on the basis of sex:

- (1) 8 U.S.C. 1522. Authorization for programs for domestic resettlement of and assistance to refugees.
- (2) 42 U.S.C. 290cc-33. Projects for Assistance in Transition from Homelessness.
- (3) 42 U.S.C. 290ff-1. Children with Serious Emotional Disturbances.
- (4) 42 U.S.C. 295m. Title VII Health Workforce Programs.
- (5) 42 U.S.C. 296g. Nursing Workforce Development.
- (6) 42 U.S.C. 300w-7. Preventive Health Services Block Grant.
- (7) 42 U.S.C. 300x-57. Substance Use Prevention, Treatment, and Recovery Services Block Grant; Community Mental Health Services Block Grant.
- (8) 42 U.S.C. 708. Maternal and Child Health Block Grant.
- (9) 42 U.S.C. 5151. Disaster relief.
- (10) 42 U.S.C. 8625. Low Income Home Energy Assistance Program.
- (11) 42 U.S.C. 9849. Head Start.
- (12) 42 U.S.C. 9918. Community Services Block Grant Program.
- (13) 42 U.S.C. 10406. Family Violence Prevention and Services.

(f)(1) A grant applicant or recipient may rely on applicable Federal protections for religious freedom and conscience, and application of a particular provision(s) of this section to specific contexts, procedures, or services shall not be required where such protections apply.

(2) A grant applicant or recipient that seeks assurance consistent with paragraph (f)(1) of this section regarding the application of particular provision(s) of this part to specific contexts, procedures, or services may do so by submitting a notification in writing to the HHS awarding agency, the Office of the Assistant Secretary for Financial Resources (ASFR), or the Office for Civil Rights (OCR). Notification may be provided by the grant applicant or recipient at any time, including before an investigation is initiated or during the pendency of an investigation. The notification must include:

(i) The particular provision(s) of this section from which the applicant or recipient asserts they are exempt under Federal religious freedom or conscience protections;

(ii) The legal basis supporting the applicant's or recipient's exemption should include the standards governing the applicable Federal religious freedom and conscience protections, such as the provisions in the relevant statute from which the applicant or recipient is requesting an exemption; the Church, Coats-Snowe, and Weldon Amendments; the generally applicable requirements of the Religious Freedom Restoration Act (RFRA); and

(iii) The factual basis supporting the applicant's or recipient's exemption, including identification of the conflict between the applicant's or recipient's religious or conscience beliefs and the requirements of this section, which may include the specific contexts, procedures, or services that the applicant or recipient asserts will violate their religious or conscience beliefs overall or based on an individual matter related to a particular grant.

(3) A temporary exemption from administrative investigation and enforcement will take effect upon the applicant's or recipient's submission of the notification—regardless of whether the assurance is sought before or during an investigation. The temporary exemption is

limited to the application of the particular provision(s) of the relevant statute as applied to the specific contexts, procedures, or services identified in the notification to the HHS awarding agency, ASFR, or OCR.

(i) If the notification is received before an investigation is initiated, within 30 days of receiving the notification, OCR, ASFR, or the HHS awarding agency must provide the applicant or recipient with email confirmation acknowledging receipt of the notification.

The HHS awarding agency, working jointly with ASFR and OCR, will then work expeditiously to reach a determination of applicant's or recipient's notification request.

(ii) If the notification is received during the pendency of an investigation, the temporary exemption will exempt conduct as applied to the specific contexts, procedures, or services identified in the notification during the pendency of the HHS awarding agency's review and determination, working jointly with ASFR and OCR, regarding the notification request. The notification shall further serve as a defense to the relevant investigation or enforcement activity regarding the applicant or recipient until the final determination of the applicant's or recipient's exemption assurance request or the conclusion of the investigation.

(4) If the HHS awarding agency, working jointly with ASFR and OCR, makes a determination to provide assurance of the applicant's or recipient's exemption from the application of the relevant statutory provision(s) or that modified application of certain provision(s) is required, the HHS awarding agency, ASFR, or OCR, will provide the applicant or recipient the determination in writing, and if granted, the applicant or recipient will be considered exempt from OCR's administrative investigation and enforcement with regard to the application of that provision(s) as applied to the specific contexts, procedures, or services provided. The determination does not otherwise limit the application of any other provision of the relevant statute to the applicant or recipient or to other contexts, procedures, or services.

(5) An applicant or recipient subject to an adverse determination of its request for an

exemption assurance may appeal the Department's determination under the administrative procedures set forth at 45 CFR part 81. The temporary exemption provided for in paragraph (f)(3) of this section will expire upon a final decision under 45 CFR part 81.

(6) A determination under paragraph (f) of this section is not final for purposes of judicial review until after a final decision under 45 CFR part 81.

(g) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.