

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 88

RIN 0945-AA18

Safeguarding the Rights of Conscience as Protected by Federal Statutes

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION: Final rule

SUMMARY: The Department of Health and Human Services (HHS or the Department) is issuing this final rule to partially rescind the May 21, 2019, final rule entitled, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" ("2019 Final Rule"), while leaving in effect the framework created by the February 23, 2011, final rule entitled, "Regulation for the Enforcement of Federal Health Care

Provider Conscience Protection Laws" ("2011 Final Rule"), which has been in effect continuously since March 25, 2011. Though the 2019 Final Rule never took effect, the Department also retains, with some modifications, certain provisions of the 2019 Final Rule regarding federal conscience protections, but eliminates others that are redundant or confusing, that undermine the clarity of the statutes Congress enacted to both safeguard conscience rights and protect access to health care, or because significant questions have been raised as to their legality.

DATES: This rule is effective March 11, 2024.

FOR FURTHER INFORMATION CONTACT:

Office for Civil Rights: David Christensen, Supervisory Policy Advisor, and Gabriela Weigel, Policy Advisor, HHS Office for Civil Rights, (202) 795-7830 or (800) 537-7697

(TDD), or via email at consciencerule@hhs.gov.

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 consciencerule@hhs.gov.

SUPPLEMENTARY INFORMATION:

Electronic Access

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.

Table of Contents

Contents

I. Background 900
A. Statutory Background 900
B. Regulatory Background 907
C. Litigation 910
D. The Proposed Rule 911
II. Comments on the Proposed Rule 913
A. General Comments 914
B. Comments Addressing Sections 88.1-88.4 of the Proposed Rule 916
C. Comments Addressing the Proposed Rule's Requests for Comment 941
III. Statutory Authority 971
IV. Overview and Section-by-Section Description of the Final Rule 972
V. Regulatory Impact Analysis 975
A. Introduction 975
B. Requests for Comment 976
C. Detailed Economic Analysis 981
D. Summary of Impacts 989
E. Regulatory Flexibility Analysis 990
Rule Text 993

I. Background

A. Statutory Background

Several provisions of Federal law protect the conscience rights of certain federally funded health care entities and prohibit recipients of certain Federal funds from requiring individuals and entities to participate in actions they find religiously or morally objectionable. They include the following provisions:

The Church Amendments [42 U.S.C. 300a-7]

The conscience provisions contained in 42 U.S.C. 300a-7 (collectively known as the "Church Amendments") were enacted in the 1970s in response to debates over whether receipt of Federal funds required those recipients to perform abortion or sterilization procedures. The Church Amendments

consist of five conscience provisions. The first provision, 42 U.S.C. 300a-7(b), provides that "[t]he receipt of any grant, contract, loan, or loan guarantee under [certain statutes implemented by the Department of Health and Human Services] by any individual or entity does not authorize any court or any public official or other public authority to require" (1) the individual to perform or assist in a sterilization procedure or an abortion, if it would be contrary to their religious beliefs or moral convictions; (2) the entity to make its facilities available for sterilization procedures or abortions, if the performance of sterilization procedures or abortions in the facilities is prohibited by the entity on the basis of religious beliefs or moral convictions; or (3) the entity to provide personnel for the performance or assistance in the

performance of sterilization procedures or abortions, if it would be contrary to the religious beliefs or moral convictions of such personnel.

The second provision, 42 U.S.C. 300a-7(c)(1), prohibits any entity that receives a grant, contract, loan, or loan guarantee under certain Department-implemented statutes from discriminating against any physician or other health care personnel in employment, promotion, termination of employment, or the extension of staff or other privileges because the individual "performed or assisted in the performance of a lawful sterilization procedure or abortion, because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his

religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting sterilization procedures or abortions.”

The third provision, 42 U.S.C. 300a–7(c)(2), prohibits any entity that receives a grant or contract for biomedical or behavioral research under any program administered by the Department from discriminating against any physician or other health care personnel in employment, promotion, termination of employment, or extension of staff or other privileges “because he performed or assisted in the performance of any lawful health service or research activity, because he refused to perform or assist in the performance of any such service or activity on the grounds that his performance or assistance in the performance of such service or activity would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting any such service or activity.”

The fourth provision, 42 U.S.C. 300a–7(d), provides that “[n]o individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by [the Department] if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.”

The fifth provision, 42 U.S.C. 300a–7(e), prohibits any entity that receives a grant, contract, loan, loan guarantee, or interest subsidy under certain Departmentally implemented statutes from denying admission to, or otherwise discriminating against “any applicant (including applicants for internships and residencies) for training or study because of the applicant’s reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to or consistent with the applicant’s religious beliefs or moral convictions.”

Public Health Service Act Sec. 245, The Coats-Snowe Amendment [42 U.S.C. 238n]

Enacted in 1996, section 245 of the Public Health Service Act (PHS Act) prohibits the Federal Government and any State or local governments receiving Federal financial assistance from discriminating against any health care entity on the basis that the entity (1) “refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide

referrals for such training or such abortions;” (2) refuses to make arrangements for such activities; or (3) “attends (or attended) a post-graduate physician training program, or any other program of training in the health professions, that does not (or did not) perform induced abortions or require, provide, or refer for training in the performance of induced abortions, or make arrangements for the provision of such training.” For the purposes of this protection, the statute defines “financial assistance” as including “with respect to a government program,” “governmental payments provided as reimbursement for carrying out health-related activities.” In addition, PHS Act Sec. 245 requires that, in determining whether to grant legal status to a health care entity (including a State’s determination of whether to issue a license or certificate), the federal government and any State or local governments receiving Federal financial assistance shall deem accredited any post-graduate physician training program that would be accredited, but for the reliance on an accrediting standard that, regardless of whether such standard provides exceptions or exemptions, requires an entity: (1) to perform induced abortions; or (2) to require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training.

Medicaid and Medicare

The Medicaid and Medicare statutes also include certain conscience provisions. The Balanced Budget Act of 1997, Public Law 105–33, 111 Stat. 251 (1997), provides that Medicaid managed care-managed organizations and Medicare Advantage plans are not required to provide, reimburse for, or cover a counseling or referral service if the organization or plan objects to the service on moral or religious grounds. *See id.* 40011852(j)(3)(B), 111 Stat. at 295 (codified at 42 U.S.C. 1395w–22(j)(3)(B)) (Medicare Advantage); *id.* § 4704(b)(3)(B), 111 Stat. at 496–97 (codified at 42 U.S.C. 1396u–2(b)(3)(B)) (Medicaid). The organization or plan must, however, provide sufficient notice of its moral or religious objections to prospective enrollees. 42 U.S.C. 1395w–22(j)(3)(B)(ii) (Medicare Advantage), 1396u–2(b)(3)(B)(ii) (Medicaid managed care).

These Medicare and Medicaid statutes also contain conscience provisions related to the performance of advanced directives. *See* 42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406(2). Additionally, they contain provisions related to religious nonmedical health care providers and their patients. *See* 42

U.S.C. 1320a–1(h), 1320c–11, 1395i–5, 1395x(e), 1395x(y)(1), 1396a(a) and 1397j–1(b). For example, Congress prohibited States from excluding Religious Nonmedical Health Care Institutions (RNHCIs) from licensure through implementation of State definitions of “nursing home” and “nursing home administrator,” 42 U.S.C. 1396g(e), and Congress exempted RNHCIs from certain Medicaid requirements for medical criteria and standards. 42 U.S.C. 1396a(a) (exempting RNHCIs from 42 U.S.C. 1396a(a)(9)(A), 1396a(a)(31), 1396a(a)(33), and 1396b(i)(4)). Additionally, section 6703(a) of the Elder Justice Act of 2009 (Pub. L. 111–148, 124 Stat. 119) provides that Elder Justice and Social Services Block Grant programs may not interfere with or abridge an elder person’s “right to practice his or her religion through reliance on prayer alone for healing,” when the preference for such reliance is contemporaneously expressed, previously set forth in a living will or similar document, or unambiguously deduced from such person’s life history. 42 U.S.C. 1397j–1(b).

The Weldon Amendment

The Weldon Amendment, originally adopted as section 508(d) of the Labor-HHS Division (Division F) of the 2005 Consolidated Appropriations Act, Public Law 108–447, 118 Stat. 2809, 3163 (Dec. 8, 2004), has been readopted (or incorporated) in each subsequent legislative measure appropriating funds to HHS. *See, e.g.*, Consolidated Appropriations Act, 2023, Public Law 117–328, div. H, title V General Provisions, section 507(d)(1) (Dec 29, 2022).

The Weldon Amendment provides that “[n]one of the funds made available in this Act [making appropriations for the Departments of Labor, Health and Human Services, and Education] may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.” It also defines “health care entity” to include “an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.”

The Affordable Care Act

Passed in 2010, the Patient Protection and Affordable Care Act (ACA), Public Law 111–148, 124 Stat. 119 (2010) (codified at 42 U.S.C. 18001, *et seq.*), includes certain conscience provisions in sections 1553, 1303(b)(1)(A), (b)(4), and (c)(2)(A), and 1411(b)(5)(A).

Section 1553 prohibits the Federal government, any state or local government, and any health care provider that receives Federal funding under the ACA, or any health plan created under the ACA, from subjecting an individual or health care entity to discrimination on the ground that the individual or entity does not provide services for the purpose of causing or assisting in the death of any individual, including through assisted suicide, euthanasia, and mercy killing. *See* 42 U.S.C. 18113(a). Section 1553 provides that the Department’s Office for Civil Rights (“OCR”) will receive complaints of discrimination related to that section. *Id.* 18113(d).

Section 1303(b)(1)(A) provides that issuers of qualified health plans shall determine whether or not the plan provides coverage of abortion services. *Id.* 18023(b)(1)(A)(ii). Additionally, Section 1303(b)(4) states that “[n]o qualified health plan offered through an Exchange may discriminate against any health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.” *Id.* 18023(b)(4). Additionally, Section 1303(c) states that nothing in the ACA will be understood to preempt or otherwise effect State laws “regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor,” 42 U.S.C. 18023(c)(1). Section 1303(c) also states that nothing in the ACA will be understood to have any effect on Federal laws that protect conscience; that regard the willingness or refusal to provide abortion; and that regard “discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.” *Id.* 18023(c)(2). Section 1303(d) further states that “Nothing in this Act shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law,” including the Emergency Medical Treatment and Labor Act. *Id.* 18023(d).

Section 1411(b)(5)(A) addresses exemptions to the ACA’s “individual responsibility requirement.” 42 U.S.C.

18081(b)(5)(A).¹ Under this section, the Department may grant exemptions based on hardship (which the Department has stated includes an individual’s inability to secure affordable coverage that does not provide for abortions (84 FR 23172), membership in a particular religious organization, or membership in a “health care sharing ministry”).

Federal Conscience and Anti-Discrimination Protections Applying to Global Health Programs

The Department administers certain programs under the President’s Emergency Plan for AIDS Relief (PEPFAR), to which additional conscience protections apply. Specifically, recipients of foreign assistance funds for HIV/AIDS prevention, treatment, or care authorized by section 104A of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2), 22 U.S.C. 7601–7682, or under any amendment made by the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (Pub. L. 110–293), cannot be required, as a condition of receiving such funds, (1) to “endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS,” or (2) to “endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.” 22 U.S.C. 7631(d)(1)(B). The government cannot discriminate against such recipients in the solicitation or issuance of grants, contracts, or cooperative agreements for the recipients’ refusal to do any such actions. 22 U.S.C. 7631(d)(2). In addition, recipients of foreign assistance funds under the Foreign Assistance Act of 1961 are prohibited from using those funds for performance or research respecting abortions or involuntary sterilization or to motivate or coerce any person to practice abortions or to coerce or provide any financial incentive to any person to undergo sterilization. 22 U.S.C. 2151b(f).

Exemptions From Compulsory Medical Screening, Examination, Diagnosis, or Treatment

Additional provisions relating to conscience have also been the subject of previous HHS rulemaking. These include provisions related to mental

health treatment, hearing screening programs, vaccination programs, occupational illness testing, and compulsory health care services generally. First, under the Public Health Service Act, certain suicide prevention programs are not to be construed to require “suicide assessment, early intervention, or treatment services for youth” if their parents or legal guardians have religious or moral objections to such services. 42 U.S.C. 290bb–36(f); section 3(c) of the Garrett Lee Smith Memorial Act (Pub. L. 108–355, 118 Stat. 1404, reauthorized by Pub. L. 114–255 at sec. 9008). Second, authority to issue certain grants through the Health Resources and Services Administration (HRSA), Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH) may not be construed to preempt or prohibit State laws which do not require hearing loss screening for newborn, infants or young children whose parents object to such screening based on religious beliefs. 42 U.S.C. 280g–1(d). Third, in providing pediatric vaccines funded by Federal medical assistance programs, providers must comply with any State laws relating to any religious or other exemptions. 42 U.S.C. 1396s(c)(2)(B)(ii). Fourth, the provisions of the Occupational Safety and Health Act of 1970 are not to be construed to “authorize or require medical examination, immunization, or treatment for those who object thereto on religious grounds, except where such is necessary for the protection of the health or safety of others.” 29 U.S.C. 669(a)(5). Fifth, certain State and local child abuse prevention and treatment programs funded by HHS are not to be construed as creating a Federal requirement that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of that parent or legal guardian, 42 U.S.C. 5106i(a), and Medicaid and CHIP programs are not to be construed to require a State to compel a person to undergo medical screenings, examination, diagnosis, treatment, health care or services if a person objects on religious grounds, with limited exceptions, 42 U.S.C. 1396(f). Additionally, the Child Abuse Prevention and Treatment Act (CAPTA) specifies that it does not require (though it also does not prevent) a State finding of child abuse or neglect in cases in which a parent or legal guardian relies solely or partially upon spiritual means rather than medical treatment, in accordance with religious beliefs. 42 U.S.C. 5106i(a)(2).

¹ In 2017 Congress effectively eliminated the penalty for noncompliance by reducing it to zero. *See* Tax Cuts and Jobs Act of 2017, Public Law 115–97, 11081, 131 Stat. 2092 (codified in 26 U.S.C. 5000A(c)).

B. Regulatory Background

No statute requires the promulgation of rules to implement the conscience provisions outlined above. On August 26, 2008, however, the Department exercised its discretion and issued a proposed rule entitled “Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law” (73 FR 50274) (2008 Final Rule) to address the conscience provisions in effect at that time. In the preamble to the 2008 Final Rule, the Department concluded that regulations were necessary in order to:

1. Educate the public and health care providers on the obligations imposed, and protections afforded, by Federal law;
2. Work with state and local governments and other recipients of funds from the Department to ensure compliance with the nondiscrimination requirements embodied in the Federal health care provider conscience protection statutes;
3. When such compliance efforts prove unsuccessful, enforce these nondiscrimination laws through the various Department mechanisms, to ensure that Department funds do not support coercive or discriminatory practices, or policies in violation of Federal law; and
4. Otherwise take an active role in promoting open communication within the health care industry, and between providers and patients, fostering a more inclusive, tolerant environment in the health care industry than may currently exist.

“Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law,” 73 FR 78072, 78074.

The rule went into effect on January 20, 2009, except for a certification requirement that never took effect, as it was subject to the information collection approval process under the Paperwork Reduction Act, which was never completed.

On March 10, 2009, the Department proposed rescinding, in its entirety, the 2008 Final Rule, and sought public comment to determine whether or not to rescind the 2008 Final Rule in part or in its entirety (74 FR 10207). On February 23, 2011, the Department issued a final rule entitled “Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws” (2011 Final Rule) (76 FR 9968). Concluding that parts of the 2008 Final Rule were unclear and potentially overbroad in scope, the 2011 Final Rule rescinded much of the 2008 Final Rule, including provisions defining certain terms used in one or more of the conscience provisions and requiring entities that received Department funds,

both as recipients and subrecipients, to provide a written certificate of compliance with the 2008 Final Rule. The 2011 Final Rule retained a provision designating OCR to receive and coordinate the handling of complaints of violations of the three conscience provisions that were the subject of the 2008 Final Rule: the Church Amendments, the Weldon Amendment, and the Coats-Snowe Amendment.

On January 26, 2018, the Department issued a new proposed rule entitled “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority” (83 FR 3880) (2018 proposed rule). Citing a desire to “enhance the awareness and enforcement of Federal health care conscience and associated nondiscrimination laws, to further conscience and religious freedom, and to protect the rights of individuals and entities to abstain from certain activities related to health care services without discrimination or retaliation,” the 2018 proposed rule proposed reinstating several rescinded provisions of the 2008 Final Rule, while also expanding upon that rule in a number of respects. Among other things, the 2018 proposed rule added a number of additional statutes and a detailed provision that would apply to alleged violations of any of the statutes covered by the rule.

In response to the 2018 proposed rule, the Department received over 242,000 comments from a wide variety of individuals and organizations, health care providers, faith-based organizations, patient advocacy groups, professional organizations, universities and research institutions, consumer organizations, and State and Federal agencies and representatives. Comments dealt with a range of issues surrounding the proposed rule, including the Department’s authority to issue the rule, the need for the rule, what kinds of workers would be protected by the proposed rule, the rule’s relationship to Title VII of the Civil Rights Act and other statutes and protections, what services are covered by the rule, whether the regulation might be used to discriminate against patients, how the rule would affect access to care, legal arguments, and the cost impacts and public health consequences of the rule.

On May 21, 2019, the Department issued a final rule (84 FR 23170) (2019 Final Rule). The Department concluded that the withdrawal of the 2008 Final Rule had created confusion about the various conscience provisions, citing what the Department determined was a significant increase in complaints alleging violations of a conscience provision that it had received since

November 2016. The Department consequently reinstated the 2008 Final Rule while revising and expanding on its provisions, including by (1) adding additional statutory provisions to the rule’s enforcement scheme; (2) adopting definitions of various statutory terms; (3) imposing assurance and certification requirements; (4) reaffirming OCR’s enforcement authority; (5) imposing record-keeping and cooperation requirements; (6) establishing enforcement provisions and penalties; and (7) adopting a voluntary notice provision.

C. Litigation

Following issuance of the 2019 Final Rule, a number of States, localities, and non-governmental parties filed lawsuits challenging the rule in the Southern District of New York, the Northern District of California, the Eastern District of Washington, and the District of Maryland. Before the rule took effect, the New York, California, and Washington district courts granted summary judgment to the respective plaintiffs and vacated the rule in its entirety nationwide. *See Washington v. Azar*, 426 F. Supp. 3d 704 (E.D. Wash. 2019), *appeal pending*, No. 20–35044 (9th Cir.); *San Francisco v. Azar*, 411 F. Supp. 3d 1001 (N.D. Cal. 2019), *appeal pending*, Nos. 20–15398 et al. (9th Cir.); *New York v. HHS*, 414 F. Supp. 3d 475 (S.D.N.Y. 2019), *appeal dismissed without prejudice*, Nos. 19–4254 et al. (2d Cir.).

The courts’ rationales for vacating the 2019 Final Rule were not identical, but each concluded that the rule was defective in a number of respects. One or more courts held that the 2019 Final Rule: (i) exceeded the Department’s authority; (ii) was inconsistent in certain respects with the conscience statutes or other statutes, including the Emergency Medical Treatment & Labor Act (EMTALA) and Title VII of the Civil Rights Act; (iii) was arbitrary and capricious in its evaluation of the record, its treatment of the Department’s conclusions underlying the 2011 Final Rule and reliance interests of funding recipients, and its consideration of certain issues relating to access to care and medical ethics raised by commenters; (iv) contained a particular definitional provision that was not promulgated in compliance with the notice-and-comment requirements of the Administrative Procedure Act (APA); and (v) had penalties for non-compliance with conscience provisions that violated the separation of powers and the Spending Clause.

Because the 2019 Final Rule never took effect: (1) HHS has been

continuously operating under the 2011 Final Rule; (2) HHS currently accepts, investigates, and processes complaints under the framework created by the 2011 Final Rule; (3) There are no significant reliance interests stemming from the 2019 Final Rule; (4) No person or entity could have therefore reasonably relied on the 2019 Final Rule's provisions; and (5) Health care providers or individuals have continuously and reasonably relied on the 2011 Final Rule because it has remained operational throughout.

D. The Proposed Rule

On January 5, 2023, the Department issued a notice of proposed rulemaking entitled, "Safeguarding the Rights of Conscience as Protected by Federal Statutes." 88 FR 820 (2023 proposed rule). The Department proposed to partially rescind the 2019 Final Rule entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," 84 FR 23170 (May 21, 2019) by: (1) leaving in effect the framework created by the 2011 Final Rule (76 FR 9968) and (2) retaining, with some modifications, certain provisions of the 2019 Final Rule. The Department solicited public comment to aid in its proposed rulemaking, specifically seeking comments addressing the following:

1. Information, including specific examples where feasible, addressing the scope and nature of the problems giving rise to the need for rulemaking, and whether those problems could be addressed by different regulations than those adopted in 2019 or by sub-regulatory guidance;

2. Information, including specific examples where feasible, supporting or refuting allegations that the 2019 Final Rule hindered, or would hinder, access to information and health care services, particularly sexual and reproductive health care and other preventive services;

3. Information, including specific examples where feasible, regarding complaints of discrimination on the basis that an individual or health care entity did not provide services for the purpose of causing or assisting in the death of any individual, including through assisted suicide, euthanasia, and mercy killing, as described in section 1553 of the ACA, and comments on whether additional regulations under this authority are necessary;

4. Information, including specific examples where feasible, regarding complaints of discrimination by a qualified health plan under the ACA on the basis that a health care provider or facility refused to provide, pay for,

cover, or refer for abortions, as described in section 1303 of the ACA and comments on whether additional regulations under this authority are necessary;

5. Information, including specific examples where feasible, from health care providers regarding alleged violations of the conscience provisions provided for in the Medicaid and Medicare statutes, including the provisions codified at 42 U.S.C. 1320a-1(h), 1320c-11, 1395i-5, 1395w-22(j)(3), 1395x(e), 1395x(y)(1), 1395cc(f), 1396a(a), 1396a(w)(3), 1396u-2(b)(3), 1397j-1(b), and 14406(2) and comments on whether additional regulations under these authorities are necessary;

6. Information, including specific examples where feasible, regarding alleged violations of any of the other authorities that appeared in the 2019 Final Rule but not the 2011 Final Rule;

7. Comment on whether the 2019 Final Rule provided sufficient clarity to minimize the potential for harm resulting from any ambiguity and confusion that may exist because of the rule, and whether any statutory terms require additional clarification;

8. Comment on whether the provisions added by the 2019 Final Rule are necessary, collectively or with respect to individual provisions, to serve the statutes' or the rule's objectives, including with regard to whether the Department accurately evaluated the need for additional regulation in the 2019 Final Rule, and whether those provisions should be modified, or whether the rule's objectives may also be accomplished through alternative means, such as outreach and education;

9. Comment on the proposal to retain a voluntary notice provision, including comments on whether such notice should be mandatory, and what a model notice should include; and

10. Comment on the proposal to retain portions of the 2019 Final Rule's enforcement provisions in the proposed § 88.2.

II. Comments on the Proposed Rule

The Department received more than 48,000 comments addressing the 2023 proposed rule. 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, professional associations, state and local government and elected officials, and members of Congress. These comments covered a variety of issues and points of view responding to the Department's requests for

comments, and the Department reviewed and analyzed all of the comments. Most commenters supported the Department's proposed rule. The overwhelming majority of comments were individual comments associated with form letter campaigns from various groups and individuals.

Numerous commenters, including civil rights organizations, health organizations, legal associations, and individual commenters, supported the proposed rule as written, while some commenters, including some faith-based organizations, supported the proposed rule as an improvement over the 2011 Final Rule. Some others supportive of the proposed rule, including certain legal associations, faith-based organizations, and individual commenters, requested the Department incorporate additional provisions from the 2019 Final Rule that were not at issue in the litigation over that rule. Still other commenters said they generally supported the proposal to rescind the 2019 Final Rule.

Commenters also expressed opposition to the proposed rule for a variety of reasons. Numerous commenters, including some non-profits, legal organizations, faith-based organizations, and individuals opposed this rule because they would like the Department to retain the 2019 Final Rule. Other commenters, including a professional health care organization, a legal organization, and a local Department of Health, opposed the proposed rule on the grounds that they would like the Department to return to the 2011 Final Rule completely. Numerous commenters said they believed that the proposed rule would remove conscience protections, undermine the diversity of views in health care, and cause health care professionals to exit the profession.

The Department thanks commenters for sharing their views on the proposed rule. Because the 2019 Final Rule never went into effect, the 2011 Final Rule has been in effect since its enactment. This final rule builds on the 2011 Final Rule and does not remove provisions from it. The Department therefore disagrees that employees would decide to leave the workforce in response to this final rule. The Department responds in greater detail in the following sections to comments requesting additions to the proposed rule text and other comments raising specific points of support for or opposition to this rule.

This final rule responds to comments as follows. Subpart A addresses comments expressing concern over access to care; Subpart B addresses comments received on specific sections

of the proposed rule; and Subpart C addresses comments in response to the Department's requests for comments in the proposed rule.

A. General Comments

Concerns Over Access to Care

Comment: The Department received numerous comments that raised concerns over access to health care generally. For example, commenters, including reproductive health organizations and major professional health care associations, discussed the negative impact that refusals of care have on people of certain genders, sexes, ages, or races, and individuals with disabilities. The commenters further explained that these refusals exist against the backdrop of barriers many patients already face, especially among Black, Indigenous, and other people of color. These disparities are heightened for individuals living in rural areas, religious minorities, and people with disabilities. Some commenters said that conscience-based refusals to provide certain forms of health care block access to such care and endanger patient's lives. Many reproductive health organizations, individuals and other commenters, discussed the impact on reproductive health care after *Dobbs vs. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), and the confusion for providers and patients that they contended that decision caused, especially in states that have banned, or attempted to ban, abortion. Commenters gave various examples of pregnant women being denied medical treatment for miscarriage management and sterilization procedures. Others were denied, or delayed in obtaining, medications, including emergency contraception. Many commenters, including reproductive health groups, reported that women were forced to wait extended periods or travel across state lines to obtain health care.

Others said conscience-based refusals to provide certain kinds of care have negatively impacted the LGBTQI+ community, especially older LGBTQI+ adults. Many of these commenters also cited what they said were specific examples of such denials of care that constituted discrimination against LGBTQI+ individuals, including patients being shamed by doctors for taking pre-exposure prophylaxis (PrEP) medication; denials of gender-affirming care at hospitals; denials of emergency room care; refusals to provide prescription refills for gender dysphoria medication by pharmacists; and refusals of requests from persons with HIV to

process lab specimens. Also, a professional health care organization urged the Department to ensure that its efforts to protect conscience not further reduce availability of abortion care, especially in areas where providers retain the ability under state law to provide those services. The organization recommended that while HHS permits individual providers to abide by their conscience, providers should do so in a way that is consistent with patients' immediate needs.

Response: The Department thanks commenters for sharing this information. The Department is committed to protecting access to health care and protecting conscience rights as set forth in Federal statutes.² OCR works to advance access to health care by enforcing federal civil rights laws, the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules, the Patient Safety Act and Rule, and Federal health care conscience statutes, which together protect fundamental rights of nondiscrimination, health information privacy, and conscience. The Federal health care conscience protection statutes represent Congress' attempt to strike a careful balance between maintaining access to health care on the one hand and honoring religious beliefs and moral convictions on the other.³ Some doctors, nurses, and hospitals, for example, object for religious or moral reasons to providing or referring for abortions or assisted suicide, among other procedures. Respecting such objections honors liberty and human dignity. Patients also have rights and health needs, sometimes urgent ones. The Department will continue to respect the balance Congress struck, work to ensure individuals understand their conscience rights, and enforce the law.

B. Comments Addressing §§ 88.1–88.4 of the Proposed Rule

1. Comments Addressing § 88.1

General Support and Opposition

Comment: Numerous commenters including some non-profit, legal, and faith-based organizations, supported the inclusion of the statutory authorities contained in § 88.1 of the 2019 Final Rule, and that are maintained in the proposed rule, because their inclusion provides clarity and awareness of the various conscience protections and ensures all federal conscience

protections follow one clear and transparent process.

Response: The Department appreciates the commenters' views. We will finalize and include in this final rule all the authorities providing for conscience protections that were contained in the 2019 Final Rule.

Comment: Two reproductive health groups stated that the proposed rule properly relies on HHS's Housekeeping Authority under 5 U.S.C. 301 to create internal processes and guidelines "rather than impose substantial burdens on those regulated by the Church, Coats-Snowe, and Weldon Amendments, which HHS lacks the authority to do." Another commenter argued that the Department's interpretation of the Federal conscience statutes is not entitled to deference given that "nothing in the Church, Coats-Snowe, and Weldon Amendments suggest that HHS is 'charged with administering' them." Other individual commenters noted that the 2019 Final Rule was justified under the Housekeeping Authority. Two commenters suggested that, in order to be consistent in noting the limited nature of the Housekeeping Authority for this rule, the Department must rescind other rules that exceed the bounds of that authority.

Response: The Department thanks the commenters for their views on the scope of the Department's authority, including under the Housekeeping Authority. The Department agrees that it is authorized under its Housekeeping Authority, 5 U.S.C. 301, to establish internal processes for handling complaints raised under the conscience statutes. HHS is obligated to ensure compliance with these statutes because they apply to certain HHS programs and specific funding streams that HHS is expressly charged with administering.⁴ Finally, whether any HHS rules outside of the context of the rulemakings for the Federal conscience statutes should be rescinded as beyond the Housekeeping Authority is beyond the scope of this rulemaking.

Comment: Some commenters, including professional health care

⁴ For example, 42 U.S.C. 300a–7(b) regards the receipt of Public Health Service Act funds which are administered by HHS agencies such as the Substance Abuse and Mental Health Services Administration (SAMHSA), the Agency for Healthcare Research and Quality (AHRQ), and the National Institutes of Health (NIH); 42 U.S.C. 280g–1(d) regards funds for hearing screening which are awarded through the Health Resources and Services Administration (HRSA); 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B) are rules of construction expressly applying to Medicare Advantage and Medicaid Managed Care Organizations which the Department oversees through the Centers for Medicare and Medicaid Services (CMS).

² See "Nondiscrimination in Health Programs and Activities," 87 FR 47824 (Aug. 4, 2022).

³ See lengthier discussion of this principle on pages 40–41, below.

organizations and a local governmental entity, expressed opposition to the inclusion of statutes in the 2019 Final Rule that were not in the 2011 Final Rule.⁵ The commenters argued: (1) HHS does not adequately justify why it is necessary to reference these statutes; (2) including these statutes will have negative consequences, such as undermining patients' access to medical care and information, imposing barriers to physicians' and health care institutions' ability to provide treatment, legitimizing discrimination against underserved and vulnerable patients, especially as regards abortion and gender-affirming care, and creating confusion and uncertainty among physicians, other health care professionals, and health care institutions about their legal and ethical obligations to treat patients; (3) HHS has not demonstrated that the public lacks awareness about these statutes; and (4) no influx of relevant complaints justifies the inclusion of the statutes. Another commenter noted that many of the conscience provisions have not been traditionally overseen by OCR, meaning they do not share the well-developed body of legal guidance applicable to civil rights complaints and it is therefore unclear which, if any, of the traditional safeguards for civil rights complainants, such as anti-retaliation protection, are available to complainants that refuse to engage in certain activities due to their religious or moral beliefs. Another commenter suggested HHS should not frame the statutes as conscience statutes and instead "accurately describe the scope of possible exemptions, including both religious and secular exemptions" or remove certain provisions from the rule. For example, 42 U.S.C. 18081 covers individuals seeking an exemption "as an Indian, or as an individual eligible for a hardship exemption"; 22 U.S.C. 7631 prevents aid from being provided with a condition that the recipient "endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS"; 29 U.S.C. 669 prevents that chapter from being "deemed to

authorize or require medical examination."

Response: The Department appreciates the concerns raised by commenters. First, the Department notes that this rule clarifies the Department's processes for handling the Federal health care conscience statutes. Second, the Department agrees that access to health care is a significant concern, especially for patients with urgent health care needs or marginalized populations whose care is facing restrictions across the country. As stated in the proposed rule, the Federal health care conscience protection statutes represent Congress' attempt to strike a careful balance. The Department is obligated to ensure compliance with the Federal conscience statutes set forth in this rule and is committed to doing so. At the same time, the Department, through OCR, also enforces civil rights laws that prohibit recipients of HHS federal financial assistance from discriminating on the basis of race, color, national origin, disability, age, sex, and religion in the provision of health care services. In addition to exhibiting the Department's commitment to patient access to care, this guidance is an example of OCR's role in coordinating compliance across various authorities. As explained in the proposed rule, retaining these provisions as part of the rule, and maintaining OCR as the centralized HHS office tasked with receiving and investigating complaints under these provisions, is consistent with OCR's existing role and delegations and will aid the public by: (1) increasing awareness of the rights protected by the various statutes, and (2) providing clear direction on where to file complaints alleging violations of those rights, even where the public is already aware of these authorities. Rather than requiring an affected party to determine which HHS component was responsible for the stream of funding connected to a potential problem, and how to raise their concerns, the rule creates a single intake point for anyone who believes their federally protected conscience rights may have been violated in the context of HHS programs. The Department disagrees that it should not retain the additional conscience statutes from the 2019 Final Rule in this final rule.

In addition, the Department disagrees that 42 U.S.C. 18081, 22 U.S.C. 7631(d), and 29 U.S.C. 669(a)(5) are unrelated to conscience and do not belong in this rule. As with each of the other Federal health care conscience statutes, each of the provisions referenced by the commenter provides exemptions for or

prohibits discrimination based on an individual or entity's religious or moral (or other) objection to a health care method or service. First, as noted in the proposed rule, 42 U.S.C. 18081(b)(5)(A) addresses exemptions to the ACA's "individual responsibility requirement."⁶ Under this section, the Department may grant exemptions based on hardship, which the Department has stated includes an individual's inability to secure affordable coverage that does not provide for abortions (84 FR 23172), membership in a particular religious organization, or membership in a "health care sharing ministry." Second, the provisions at 22 U.S.C. 7631(d) state that a faith-based organization or other organization is not required in order to receive such assistance to "endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS;" or "endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection." Finally, the relevant provision at 29 U.S.C. 669(a)(5) clarifies that nothing in that chapter will be deemed to "authorize or require medical examination, immunization, or treatment for those who object thereto on religious grounds." The text of these statutes makes it clear that these provisions relate to protections for conscience, and so the Department declines to remove them from this rule.

Comment: Some commenters, including a health care organization, requested that the Department ensure the conscience statutes are properly enforced even in the context of enforcing other recent proposed HHS regulations, such as the Section 1557 notice of proposed rulemaking, 87 FR 47824, so that there is not an increase in instances where religious adherents are required to engage in conduct that violates their religious beliefs. These commenters suggested that the Department clarify how they planned to enforce the conscience statutes in light of these other regulations.

Response: The final rule will maintain the general framework that OCR has been employing since 2011—enforcing the listed conscience statutes on a case-by-case basis, which respects the balance Congress sought to achieve through these statutes. The Section 1557 proposed rule is beyond the scope of this rulemaking. We note, however, that the proposed rule for Section 1557, for

⁶ In 2017 Congress effectively eliminated the penalty for noncompliance by being reducing it to zero. See Tax Cuts and Jobs Act of 2017, Public Law 115–97, 11081, 131 Stat. 2092 (codified in 26 U.S.C. 5000A(c)).

⁵ The statutes added by the 2019 Final Rule and retained in this final rule are: 42 U.S.C. 18113; 42 U.S.C. 14406(1); 26 U.S.C. 5000A; 42 U.S.C. 18081; 42 U.S.C. 18023(b)(1)(A) and (b)(4); 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B); 42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406(2); 22 U.S.C. 7631(d); 22 U.S.C. 2151b(f), see, e.g., the Consolidated Appropriations Act, 2019, Public Law 116–6, Div. F, sec. 7018 (the "Helms, Biden, 1978, and 1985 Amendments"); 42 U.S.C. 1396f and 5106i(a); 42 U.S.C. 280g–1(d); 29 U.S.C. 669(a)(5); 42 U.S.C. 1396s(c)(2)(B)(ii); 42 U.S.C. 290bb–36(f); 42 U.S.C. 1320a–1(h), 1320c–11, 1395i–5, 1395x(e), 1395x(y)(1), 1396a(a), and 1397j–1(b)). 84 FR 23170, 23170 (May 2019).

example, contains its own religious and conscience exemption process at proposed § 92.302 for how to raise such claims in the context of that rulemaking, 87 FR 47885–47886.

Requests for Technical Changes

Comment: Some commenters, including members of Congress, stated § 88.1's list of citations is incomplete without additional context like that provided in the 2019 Final Rule, making it harder for covered entities to have a full understanding of the implications of the law and how they will be applied and enforced. These commenters suggest that the rule “should include the full list of laws with their applicability, requirements, and prohibitions explained, as included in the 2019 rule at 88.3.” A commenter argued it would be unlawful for HHS not to retain language from § 88.1 of the 2019 Final Rule, given this rule's purpose of protecting conscience rights and preventing non-discrimination.

Response: The Department thanks the commenters for their views. We have added explanatory text to the preamble of this final rule to elaborate on the full list of the laws included in this final rule. However, we are finalizing this rule without the additional information drawn from § 88.3 of the 2019 Final Rule because, in the Department's view, that explanatory language is not necessary to accomplish the goal of this section, namely clarifying which conscience statutes OCR enforces. We have added the full list of the laws covered by this final rule in the model notice. Additionally, the Department maintains information about the Federal conscience statutes on OCR's website, and has included a link to this web page in the model notice text in Appendix A of this final rule.⁷ Moreover, a purpose provision similar to § 88.1 of the 2019 Final Rule is unnecessary given the procedural nature of this final rule. We note in this regard that the court in *New York v. U.S. Dep't of Health & Human Servs.*, 414 F. Supp. 3d 475, 513–14, 523 (S.D.N.Y. 2019), cited language used in the purpose provision of § 88.1 of the 2019 Final Rule in support of its view that that rule was substantive.

Comment: Two commenters requested that the Department correct an error in the preamble of the proposed rule that improperly paraphrased a provision of Section 1303 of the ACA, 42 U.S.C. 18023. The commenters pointed out that, when paraphrasing one provision

of Section 1303 of the ACA, 42 U.S.C. 18023(c)(1), the language in the proposed rule did not mirror the language of the statute because the NPRM stated the provision discussed preemption of state laws about conscience, rather than lack of preemption of certain state laws about abortion.

Response: OCR has made the noted corrections. Section 1303(c)(1) states that “Nothing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor.” 42 U.S.C. 18203(c)(1). The preamble of the final rule uses that language.

Comment: A commenter suggested that § 88.1 should explicitly state that the Department's goal is to balance the interests of providers and patients. Another commenter argued that the freedom of conscience and religion should not be extended to facilities or institutions, such as hospital systems or universities, but only to individual providers.

Response: The Department maintains that Congress sought to balance provider and patient rights through a variety of statutes and, as we noted in the proposed rule, the Department respects that balance. The Department declines to make changes to the final rule recommended by the commenter but discusses the issue of balancing these rights in greater detail in response to other comments *infra* at pages 42–43. Finally, regarding facilities or institutions, the Department will refer to each individual conscience statute in determining whether a particular statute applies to a particular entity.

Comment: Noting that some of the statutory provisions do not apply to only health care providers, a commenter suggested changing the collective reference to the statutory authorities in § 88.1 and throughout the rule from “health care provider conscience protection statutes” to “health care conscience statutory protections.”

Response: The Department agrees with the commenter's concern. For example, 42 U.S.C. 280g–1(d) protects parents of newborns, infants, and young children who object to hearing screenings based on religious beliefs. Likewise, 29 U.S.C. 669(a)(5) protects employees who object to “medical examination, immunization, or treatment . . . on religious grounds.” The Department will revise this provision in the final rule to refer to the

statutes as the “Federal health care conscience protection statutes.”

Comment: A commenter requested that reference be made to 42 U.S.C. 1395x(ss) within the reference to “certain Medicare and Medicaid provisions” in the list of statutory authorities in § 88.1.

Response: OCR has been delegated multiple authorities that relate to protecting Religious Nonmedical Health Care Institutions (RNHCIs), five of which reference 42 U.S.C. 1395x(ss)(1), which defines RNHCIs. Section 1395x(ss)(1) contains the definition of RNHCIs, Section 1395x(ss)(2) covers accreditation of RNHCIs, and Section 1395x(ss)(3) contains a conscience provision that restricts the Secretary from requiring patients of RNHCIs to undergo certain medical services, such as medical screenings and treatment, against their religious beliefs, or from requiring RNHCIs and their personnel from undergoing medical supervision, regulation, or control, against their religious beliefs. Section 1395x(ss) was not delegated to OCR in the 2018 proposed rule's Delegations of Authority.⁸ The Department declines to include 1395x(ss) in this final rule but is taking this comment under consideration outside this rulemaking process.

2. Comments Addressing § 88.2

Requests for Clarification

Comment: Many commenters, including legal organizations and reproductive health groups, asked OCR to clarify that its enforcement authority is limited to existing provisions—such as those in the proposed rule and HHS's Uniform Administrative Requirements (UAR)—and clarify that it is not creating new mechanisms under this provision. Many commenters asked for clarification regarding the terms “relevant funding” and “appropriate action,” as well as the scope of the terms regarding violations of the proposed rule. Specifically, some commenters urged HHS to clarify that “appropriate action” relates to the enforcement tools of existing regulations (such as the UAR) and suggested establishing a limiting principle for “relevant funding” so that it cannot include all the funds available to an entity.

One commenter expressed support for the proposed rule because they believed it removed the authority to initiate compliance reviews, make enforcement referrals to the Department of Justice,

⁷ See U.S. Dep't of Health and Human Servs., Off. for Civil Rights, *Conscience and Religious Nondiscrimination*, <https://www.hhs.gov/conscience/conscience-protections/index.html>.

⁸ “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority,” 83 FR 3880, 3901 (Jan. 26, 2018).

and claw back relevant funding. The commenter argued that these enforcement tools went beyond the existing regulations for enforcement that should be used when handling and investigating complaints. Another commenter indicated that in their view, proposed § 88.2(a)(4) in conjunction with proposed § 88.2(d) removes OCR's ability to undertake involuntary enforcement measures. The commenter approved of this perceived change and what they understood in the proposed rule to be a clarification that enforcement will be a voluntary process with flexibility for recipients to work with OCR to correct any findings of violations of the proposed rule. Other commenters asked the Department to modify the proposed rule to clarify that the scope of OCR's authority is limited to seeking voluntary resolution of complaints. Other commenters stated that the Department should not wait for a complaint in order to ensure compliance with the conscience statutes, and so should include the authority to initiate compliance reviews.

Additional commenters argued that OCR should release formal findings of fact in any investigation before reconciliation is attempted and that the rule should state that complainants should be informed of other possible avenues for seeking relief when their complaint is resolved.

Response: The Department thanks commenters for their views. As noted in the proposed rule, 45 FR 820, 825, the Department decided to retain certain provisions of the 2019 Final Rule with modifications and not to retain others in order to address various concerns, including concerns raised in litigation regarding the lawfulness of certain provisions of the 2019 Final Rule. The Department clarifies, however, that, where authorized by the funding at issue, OCR may initiate compliance reviews when it determines to do so in its enforcement discretion and may refer items to the Department of Justice for appropriate proceedings. Additionally, the provisions included under this rule maintain the authority to seek voluntary compliance. Specifically, the rule provides that matters of noncompliance will, when possible, be resolved using informal means. This does not preclude the Department from using relevant enforcement regulations, including, when necessary, formal means of achieving compliance. These existing enforcement regulations could include, for example, the Department's authority under the Uniform Administrative Requirements, Cost Principles, and Audit Requirements For HHS Awards (UAR; 45 CFR part 75). We also note

that "relevant funding" as referenced in § 88.2(c) of the proposed rule is defined by the terms of the Federal conscience statutes. The Department makes several changes to the rule text to clarify its authority. The Department is adding reference to OCR's authority to initiate compliance reviews in § 88.2(a)(2) and a new § 88.2(c). The Department also notes OCR's authority in § 88.2(a)(7) to coordinate additional remedial action as the Department determines to be both necessary and allowed by applicable law and regulation. Additionally, the Department is adding a new paragraph (3) to proposed § 88.2(d), now § 88.2(g) in this final rule, to specify that where a matter is not able to be resolved by informal means, OCR will coordinate with the relevant Departmental component to (1) utilize enforcement regulations, such as those existing applicable to grants, contracts, or other programs and services, or (2) withhold funding as authorized and relevant under the statutes listed in § 88.1. Finally, the Department is also adding in § 88.2(a)(8) a reference to, and a new paragraph in § 88.2(g)(4) regarding, OCR's ability to refer enforcement items to the Department of Justice.

Comment: Many commenters, including some non-profits, elected officials, and legal organizations, suggested that the provisions in proposed § 88.2 are not strong enough. Specifically, commenters were concerned that this rule does not include certain enforcement provisions from the 2019 Final Rule and were concerned with the statement that matters "will be resolved by informal means whenever possible." Some asked the Department to define "informal means" and explain how that will deter future violations of the conscience statutes or prevent retaliation. One commenter stated that HHS should incorporate a formal resolution process in the rule in order to ensure conscience rights are not treated differently than other civil rights. Two commenters stated that the proposed rule was at risk of being unlawful because the Department failed to explain its rationale for not maintaining a formal resolution process similar to the 2019 Final Rule or because the rule was removing additional protections for conscience rights. Another commenter stated that the lack of effective and reasonable enforcement mechanisms would be an obstacle to ensuring compliance with the law.

Several commenters stated that the proposed rule's removal of enforcement provisions from the 2019 Final Rule, including the requirement that HHS respond to and resolve conscience

complaints, demonstrates clear anti-religious and anti-conscience bias and treats conscience rights as "less-than" or demonstrates "overt hostility on the part of the administration to both conscience rights and to religious liberty of health care professionals." Many commenters raised the Department's investigation of the University of Vermont Medical Center, the California Department of Managed Health Care, and other recent decisions by the Department as examples of the need for additional provisions to ensure the final rule is adequate for consistently enforcing the Federal health care conscience statutes. Another commenter argued that the enforcement provisions retained in the proposed rule lacked an articulable standard against which any investigation will be conducted. The commenter stated that providers will be uncertain with respect to complaint investigations in this area, but that such uncertainty is preferable to over-regulating in the form of attempting to define violations without sufficiently stated guidance. Other commenters also claimed that the proposed rule will make it harder for any further discrimination claims to be filed, investigated, and remedied.

Commenters made various additional requests, including for the rule to contain more rigorous enforcement protections, the explanatory provisions and enforcement mechanisms from the 2019 Final Rule, and clear protections against retaliation.

Response: OCR works to achieve voluntary compliance with all the authorities it is delegated to enforce and has found this to be an effective means of ensuring compliance. This includes OCR's approach to enforcement of the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules, to the extent practicable and consistent with law,⁹ and Title VI.¹⁰ The Department's approach to the Federal conscience statutes is consistent with this approach. OCR further notes that applying a single "articulable standard," as requested by a commenter, may not be appropriate given the breadth and variety of conscience statutes OCR is delegated to enforce. Rather than provide a one-size-fits-all standard, OCR will investigate complaints based on the relevant statute at issue. This rule

⁹ See 45 CFR 160.304.

¹⁰ See 28 CFR 42.411 ("Effective enforcement of title VI requires that agencies take prompt action to achieve *voluntary* compliance in all instances in which noncompliance is found." (emphasis added)). Many of the other authorities OCR enforces, such as Title IX, Section 1557, Section 504, and the Age Discrimination Act, contain identical requirements.

clarifies that OCR is the central office to receive and handle complaints related to the conscience statutes and will coordinate complaints with partner agencies as appropriate on a case-by-case basis. This approach creates a more efficient and powerful method for ensuring compliance with the various statutes.

Further, the Department is making several additions to the rule text, similar to procedures contained in the 2019 Final Rule, in response to comments. As discussed in response to other comments, the Department is adding reference to OCR's authority to initiate compliance reviews in § 88.2(a) and a new § 88.2(c). The Department also notes OCR's authority in § 88.2(a)(7) to coordinate other remedial action as the Department deems appropriate and necessary and as allowed by law and applicable regulation. The Department is adding a new paragraph (3) to proposed § 88.2(d), now § 88.2(g) in this final rule, to specify that where a matter is not able to be resolved by informal means, OCR will coordinate and consult with the relevant Departmental component to either utilize enforcement regulations, such as those that existing applicable to grants, contracts, or other programs and services, or withhold funding as authorized and relevant under the statutes listed under § 88.1. Finally, the Department notes its authority in § 88.2(a)(8) to make enforcement referrals to the Department of Justice, and is adding a new paragraph (4) to proposed § 88.2(d), now § 88.2(g) in this final rule, to specify that OCR may, in coordination with the Office of the General Counsel, refer a matter that cannot be resolved informally to the Department of Justice to enforce the Federal health care conscience protection statutes as authorized by law.

The Department takes seriously its obligations to comply with the Federal health care conscience protection statutes and has taken numerous actions to defend religious freedom rights, including by supporting the right to exercise faith freely. For example, the Department is participating in the National Strategy to Counter Anti-Semitism, including by providing ongoing OCR trainings on antidiscrimination laws, including the Federal health care conscience statutes, to medical students nationwide and holding listening sessions with chaplains on religious discrimination in healthcare settings.¹¹ As part of this

same initiative, OCR recently released a bulletin on countering antisemitism which explains that, depending on the factual context, Title VI of the Civil Rights Act of 1964 and Section 1557 of the Affordable Care Act may prohibit discrimination against individuals who are or are perceived to be Jewish, Christian, Muslim, Sikh, Hindu, Buddhist, or of another religion, if the discrimination is based on their ancestry or ethnic characteristics.¹² Also, the Department, through the longstanding operation of the HHS Center for Faith-Based and Neighborhood Partnerships, continues efforts to build and support partnerships with faith-based and community organizations in order to better serve individuals, families and communities in need.¹³ The Department's regulations state that faith-based organizations are eligible, on the same basis as any other organization, to participate in agency programs and services.¹⁴

Comment: One commenter requested that the Department specifically clarify OCR's process for handling complaints and the potential involvement of state health agencies as mentioned in proposed § 88.2(b). Other commenters requested OCR limit the extent to which OCR is permitted to rely on state agencies due to concerns about state laws and policies related to abortion and gender-affirming care potentially interfering with an accurate evaluation of the complaint under applicable federal law, especially where the state health departments involved have a record of hostility towards those seeking reproductive health care and gender-affirming care. They requested that OCR implement protections for the information gathered in the investigative process and clarify which state agencies may provide assistance, whether these agencies will make recommendations regarding resolution of the investigation, and when OCR will engage in independent fact finding.

Antisemitism (May 25, 2023), <https://www.whitehouse.gov/briefing-room/statements-releases/2023/05/25/fact-sheet-biden-harris-administration-releases-first-ever-u-s-national-strategy-to-counter-antisemitism/>.

¹² See Bulletin, U.S. Dep't of Health and Human Servs., Off. for Civil Rights, Fact Sheet: Protecting Patients and Recipients of Human Services from Discrimination Based on Actual or Perceived Shared Ancestry or Ethnic Characteristics (Sept. 28, 2023), <https://www.hhs.gov/civil-rights/for-individuals/special-topics/shared-ancestry-or-ethnic-characteristics-discrimination/index.html>.

¹³ See Off. of Intergovernmental and External Affairs, Ctr. for Faith-based and Neighborhood Partnerships (Partnership Center) Homepage, (updated as of September 21, 2023), <https://www.hhs.gov/about/agencies/iea/partnerships/index.html>.

¹⁴ 45 CFR part 87.

Another commenter suggested that HHS work to implement privacy protections ensuring state agencies cannot weaponize any collected information against any patients.

Response: Where appropriate, OCR may coordinate the handling of complaints related to the Federal conscience statutes with State agencies. However, authority for making determinations about the Department's or another entity's compliance with the Federal conscience statutes as it relates to HHS programs and funding ultimately rests with the Department, which will consider all relevant facts and use its independent judgment in making its determination.

Comment: Some commenters noted that the proposed rule does not obligate OCR to evaluate every complaint or assure the public of the prompt, transparent, thorough, and reasonable handling of complaints, which undercuts the effectiveness of the proposed rule. In addition, some commenters said the rule should be modified to "permit OCR to adopt a negative inference against an investigated entity for any factual question to which the entity fails to respond." A couple of commenters questioned whether OCR was truly an independent factfinder without conflicts of interests and argued that more enforcement or compliance tools are needed to demonstrate independence.

Response: The Department agrees with the commenters' recommendation on the prompt handling of complaints and has determined to retain, at proposed § 88.2(b), now § 88.2(d) of this final rule, text from § 88.7(d) of the 2019 Final Rule stating that "OCR shall make a prompt investigation" of conscience complaints. Additionally, OCR reviews all complaints it receives and takes into consideration a covered entity's response to questions and data requests to assess if a violation has taken place, or technical assistance can help the entity comply with the law. To clarify this, the Department is finalizing this final rule with the addition of a new § 88.2(e) that notes that, OCR may adopt a negative inference if, absent good cause, an entity that is subject to the Federal health care conscience protection statutes fails to respond to a request for information or to a data or document request within a reasonable timeframe. As noted in the proposed rule, the Department remains committed to educating patients, providers, and other covered entities about their rights and obligations under the conscience statutes and using its independent judgment to ensure compliance.

¹¹ See Press Release, The White House, Fact Sheet: Biden-Harris Administration Releases First-Ever U.S. National Strategy to Counter

Comment: One commenter recommended that to reduce confusion, the Department should use different forms to collect information on violations of the proposed rule than those used to collect civil rights complaints because conscience claims are legally distinct from civil rights complaints and will likely require different data and information during intake.

Response: The Department thanks the commenter for their suggestion. However, OCR's intake forms are beyond the scope of this rulemaking.

Comment: Some commenters requested that the rule state that complainants may be represented by legal counsel.

Response: OCR's website states that a complaint may be filed on behalf of someone else.¹⁵ We agree that legal counsel may file a complaint on behalf of their client and represent their client throughout the complaint investigation process. The Department is finalizing this final rule with the addition of a new § 88.2(b) which explains that any entity or individual may file a complaint with OCR alleging a potential violation of Federal health care conscience protection statutes, and the entity or individual filing does not have to be the entity or individual whose rights have been violated.

Interpretation of Federal Health Care Conscience Statutes

Comment: Numerous commenters provided their views on the proper interpretation of the Federal health care conscience statutes with many requesting substantive guidance in the final rule on how OCR will interpret and apply the various statutes included in § 88.1. Two commenters stated that even if the Department lacks authority to issue substantive regulations interpreting any or all of the Federal health care conscience statutes, it cannot pretend that it will not engage in some interpretation of the meaning of those statutes in the course of its enforcement efforts. The commenters argued that therefore, the proposed rule should set out, for internal administrative purposes, and in at least general terms, principles governing how the Department will interpret the federal health care conscience statutes in relation to other laws. In the absence of definitions, the commenters argued that such a provision would provide some guidance to covered entities about how

the Department understands the statutes subject to the proposed rule.

Response: We appreciate these comments. The Department is committed to applying the relevant conscience statutes on a case-by-case basis, which respects the balance Congress sought to achieve through these statutes.¹⁶ The Department appreciates the recommendation to issue additional guidance outside of this rulemaking and takes these comments under advisement, but it does not agree that there is a need for additional language as to the Department's interpretation of the statutes in this rule at this time given the Department's intended case-by-case approach to enforcing the conscience statutes. The Department consequently declines to add language interpreting the provisions of the conscience statutes to the rule text as it is unnecessary to include such information to clarify OCR's processes by which it enforces these statutes or to enforce the conscience statutes on a case-by-case basis. Additionally, this final rule encompasses a variety of statutes such that certain "general principles," may not apply to all the statutes contained in this rulemaking.

Comment: Many commenters, including some faith-based organizations, legal organizations, and non-profits, stated the federal conscience rights should not be balanced against other competing interests and that HHS was not delegated authority to balance these interests, especially as against access to abortion. These commenters also expressed concern that a balancing test could result in different levels of protection for different providers based on factors like their geographic location or otherwise result in the arbitrary handling of conscience complaints. Another commenter said it was confusing to speak about a balance between the federal health care conscience statutes and other interests, as the proposed rule did, noting that the conscience statutes set forth absolute protections. The commenter went on to say that the courts that vacated the 2019 rule incorrectly held that the rule's broad construction of the federal health care statutes unlawfully displaced Title VII's application to employment-related religious exercise claims in the health care setting.

Another commenter also emphasized that conscience statutes "are themselves a subset of nondiscrimination law." At the same time, this commenter stressed that it agreed "that patients' autonomy

and religious moral convictions must be respected" too.

Response: As noted in the proposed rule, the Federal health care conscience protection statutes represent Congress' attempt to strike a careful balance between the rights of both providers and patients, and the Department intends to respect that balance. This statement reflects the balance Congress struck, not the legal requirements specific to each conscience statute set forth in this rule. Each of those conscience statutes contain particular legal requirements that must be met in order for them to apply to any given set of facts, and any determination regarding their application will be made based upon each statute.

The Department wishes to affirm that conscience statutes are a subset of nondiscrimination law and to clarify that it understands that the text of the conscience statutes themselves generally does not contain balancing tests. At the same time, these statutes co-exist with others protecting rights of access to health care. As it did in the preamble to the 2011 final rule, the Department continues to affirm that health care entities must comply with the long-established requirements of statutes governing Departmental programs. These statutes strike a careful balance between the rights of patients to access needed health care, and the conscience rights of health care providers. Many of the conscience laws in this rule and the other federal statutes have operated side by side, often for many decades. As the 2011 Final Rule stated, "repeals by implication are disfavored and laws are meant to be read in harmony." The Department will continue to enforce all the laws it has been charged with administering. At the same time, entities must continue to comply with their Title X, Section 330, EMTALA, Medicaid obligations and the federal health care provider conscience protection statutes.¹⁷

The Department will bear these points in mind in its investigation of any complaints it may receive.

Comment: Many commenters, including professional health care associations and reproductive health groups, stated that the government should ensure that patients' access to care is a top priority and should be appropriately balanced with the needs of health care providers. Another commenter stated that it is important to ensure an exhaustive good faith effort is made to connect patients with care.

Response: The Department thanks commenters for raising these concerns

¹⁵ See, e.g., U.S. Dep't of Health and Human Servs., Off. for Civil Rights, *Complaint Portal Assistant*, <https://ocrportal.hhs.gov/ocr/smartscreen/main.jsf>.

¹⁶ See lengthier discussion of this principle on pages 40–41, below.

¹⁷ 76 FR 9968, 9973–74 (2011).

and agrees that patients' access to care is a top priority. Protecting the rights of conscience, as directed by Congress in federal statutes, is also a top priority, which the Department is committed to safeguarding as well. As noted elsewhere, the Department will handle complaints related to conscience on a case-by-case basis which respects the balance Congress sought to achieve through these statutes.

Comment: One commenter requested that HHS focus its resources on civil rights complaints rather than conscience complaints because, compared to civil rights complaints, violations of conscience rights occur less frequently and rarely result in adverse medical outcomes for the provider. The commenter said that patients who encounter denial of care may be unable to find a suitable provider if they face a denial of care and may suffer adverse health consequences or death due to the denial. On the other hand, the commenter said providers seeking to deny care or that were prevented from denying care are unlikely to face the medical complications or death that can result from denial of care.

Response: OCR reviews all the complaints it receives and will continue to do so for each of the authorities it is delegated to enforce.

Comment: One commenter recommended that HHS include a provision that states no one served by HHS programs will be denied medically indicated care and impose a penalty for institutions and providers that deny necessary services under the "pretext" of religious freedom. The commenter noted, however, that HHS should restore the enforcement provisions from the 2019 Final Rule to avoid making providers feel they must choose between their religion and livelihood and facing retaliation.

Response: The Department thanks the commenter for sharing its views. As discussed in response to other comments, the Department is adding provisions to this final rule similar to some of the enforcement provisions of the 2019 Final Rule. These include: reference to OCR's authority to initiate compliance reviews in § 88.2(a) and a new § 88.2(c); noting OCR's authority in § 88.2(a)(7) to "coordinate other appropriate remedial action as the Department deems necessary and as allowed by law and applicable regulation"; new paragraphs (3) and (4) to proposed § 88.2(d), now § 88.2(g) in this final rule, to specify formal means of enforcement, which may include the withholding of funds and referrals to the Department of Justice.

Comment: One commenter recommended requiring that providers, grantees, and other entities subject to the proposed rule ensure patients are able to obtain care, including by being made aware of the treatments and procedures a provider refuses to provide, informed of alternative providers, and referred to alternative providers when failing to do so would harm the patient.

Response: The Department agrees that patients should be able to make informed choices about which providers to seek care from, access care broadly, and receive the best care possible. This final rule clarifies OCR's existing authority and process for handling complaints under the conscience statutes. Adding a substantive provision in line with the commenter's request is beyond the scope of this rulemaking. The Department notes, however, that patients will also benefit from awareness of the Federal conscience statutes generated by entities posting a voluntary notice as outlined in this final rule.

Comment: Several commenters, including professional health care organizations and a think tank, addressed the importance of having sufficient enforcement provisions in the proposed rule because courts have held that conscience statutes do not contain or imply a private right of action, meaning the government has the central role in enforcing Federal conscience laws and protecting providers from discrimination.

Response: The Department agrees with commenters regarding the importance of the Department's role with respect to the Federal conscience statutes. As stated in the proposed rule, 45 FR 820, 826, the Department remains committed to educating patients, providers, and other covered entities about their rights and obligations under the conscience statutes and remains committed to ensuring compliance. As mentioned in response to other comments, this rule is being finalized with additional provisions from the 2019 Final Rule as well as all the authorities that the proposed rule previously incorporated from the 2019 Final Rule to allow for consistent and effective enforcement of the Federal conscience statutes. We believe that this rule simplifies, and therefore strengthens, the Department's approach to ensuring compliance with the underlying statutes. It provides clarity to providers and patients about where and how they may register their concerns. And it provides the Department the ability to apply the specific legal standards and

enforcement mechanisms that correspond to the statute at issue. This, in turn, allows the Department to better achieve outcomes consistent with the statutory protections Congress enacted. We also note that in the proposed rule for Section 1557, the Department provided an additional process at proposed § 92.302 for individuals to raise requests for a conscience or religious freedom exemption, 87 FR 47885–47886.

3. Comments Addressing § 88.3 General Support

Comment: Many commenters, including a national association of faith-based medical and dental providers and a national hospital association of faith-based providers, expressed support for the voluntary nature of the rule's notice provision. Additionally, a couple of commenters supported the proposed rule for allowing entities to tailor the voluntary notice to "particular circumstances and communities" and combine the notice with other notices. A couple of commenters also supported the proposed rule's inclusion of a recognition that some entities will have a conscience-based objection to posting details about alternative providers that offer services that the posting entity objects to providing. Commenters stated the proposed voluntary notice provision appropriately promotes compliance without undue burden.

Response: The Department appreciates the commenters' support. The Department includes the voluntary notice provision, including the provision recognizing that some entities will have a conscience-based objection to posting details about alternative providers in the final rule.

Requests for Changes to Rule Text

Comment: A commenter argued that the proposed rule does not incentivize entities to post a voluntary notice. This commenter suggested that certain compliance requirements from § 88.6 of the 2019 Final Rule and the provision from § 88.5 of the 2019 Final Rule, which noted that posting the voluntary notice would constitute "non-dispositive evidence of compliance" and support the Department's goal of clarifying what an entity must do to comply with the federal conscience statutes.

Response: As noted in the proposed rule, while the Department considers posting a notice to be a best practice and encourages covered entities to post the model notice included in this regulation, this alone does not satisfy the substantive obligations imposed on

a covered entity by the underlying statutes. The proposed rule and this final rule modify § 88.5 of the 2019 Final Rule to avoid implying that covered entities can substantively comply with the underlying statute by simply posting a notice because such an implication could undermine the conscience protections provided by the underlying statutes themselves, and therefore the goal of this rule. While the Department does not adopt § 88.5 of the 2019 Final Rule, the Department is finalizing § 88.3 with additional statements that the Department considers posting a notice to be a best practice “towards achieving compliance with and educating the public about the Federal health care conscience statutes” and that “OCR will consider posting a notice as a factor in any investigation or compliance review” to emphasize the importance of posting the voluntary notice.

The Department declines, however, to maintain all the compliance requirements from § 88.6 of the 2019 Final Rule. Some commenters raised concerns in response to both the 2018 Proposed Rule and the proposed rule for this rulemaking that the compliance requirements at § 88.6 were overly burdensome on covered entities, especially the record keeping requirements, and not authorized by the conscience statutes. In the Department’s view, these concerns raised by commenters warrant additional consideration. Even though the Department declines to maintain the duty to cooperate as specified in § 88.6(c) of the 2019 Final Rule, however, this final rule includes a notice to covered entities in § 88.2(e) that OCR will adopt a negative inference if, absent good cause, an entity that is subject to the Federal health care conscience protection statutes fails to respond to a request for information or to a data or document request within a reasonable timeframe. In the Department’s view, this requirement will encourage compliance without creating additional regulatory burden.

Comment: One commenter requested that HHS require that notices related to conscience exceptions also be required to comply with the Section 1557 language access and auxiliary aids and services requirements.

Response: The Department appreciates this comment. Covered entities are required to comply fully with all applicable language access requirements found in statute or regulation, regardless of whether the requirements overlap with the topics of this regulation.

Language of the Notice

Comment: Some commenters stated that the model notice should be the same as the model notice proposed in the 2019 Final Rule because it provided more clarity. Other commenters recommended more specific and clear language generally. A commenter said that, while they supported aspects of the proposed notice, such as listing the relevant statutes and dropping the implication that posting the notice would be some evidence of substantive compliance with the underlying statute, the commenter urged HHS to include in the notice a general description of the types of protections these statutes provide.

Response: The Department appreciates the commenters’ recommendations and has included the following text in the model notice text in response to commenter requests for more clarity: “You may have rights as a provider, patient, or other individual under these Federal statutes, which prohibit coercion or other discrimination on the basis of conscience in certain circumstances.” The Department also notes that § 88.3(d) states that an entity “may tailor its notice to address its particular circumstances and to more specifically address the conscience laws covered by this rule that apply to it.” Finally, the Department has included in the model notice a list of the federal health care conscience protection statutes and a link to the HHS web page where additional resources can be accessed for covered entities and the public to better understand their obligations and rights under the Federal health care conscience statutes.¹⁸

Comment: A commenter argued that the following language in proposed § 88.3(d) was improper: “where possible, and where the recipient does not have a conscience-based objection to doing so, the notice should include information about alternative providers that may offer patients services the recipient does not provide for reasons of conscience.” This commenter maintained that the language is improper because the Coats-Snowe Amendment prohibits a covered entity from requiring a physician or certain other individuals to refer patients, which may be the case where a covered employer does not object to the inclusion of information about alternative providers, but their employee physician does. Another

commenter argued that this language was “a prudent observance of the Supreme Court’s decision in *NIFLA v. Becerra*.”

Response: The Department disagrees that the challenged language is improper. The provision identified by the commenter does not require recipients to provide information about alternative providers in any notice, nor does it suggest that any recipient may require a health care provider (e.g., a doctor) to post this information in violation of their rights under applicable health care conscience protection statutes or the Constitution.

Comment: A few commenters requested additional language in the voluntary notice that would focus on protecting patients from negative impacts caused by a denial of care under the conscience statutes. These commenters suggested that the voluntary notice provision has two target audiences: employees of providers and members of the public, and so there should be two separate notice provisions for each group, and they should be posted on the health care provider’s website.

Response: The Department agrees that patients should also be the focus of the voluntary notice and notes that the text of § 88.3 addresses this concern. Section 88.3(d) states that “[w]here possible, and where the recipient does not have a conscience-based objection to doing so, the notice should include information about alternative providers that may offer patients services the recipient does not provide for reasons of conscience,” which gives entities the opportunity to include additional information for the consideration of patients about access to certain health care services. Additionally, the Department in § 88.3(d) states that an entity “may tailor its notice to address its particular circumstances and to more specifically address the conscience laws covered by this rule that apply to it.” The Department is also adding text to the voluntary notice to make clear that the Federal health care conscience statutes also provide certain conscience protections for patients. Finally, the Department notes that § 88.3(b)(1) of both the proposed rule and this final rule recommends the model notice be posted on provider’s websites, where both patients and providers may view it.

4. Comments Addressing Section 88.4

Comment: A commenter noted that the preamble to the proposed rule stated that it was repealing the severability provision, but that the provision is retained in the regulation text at § 88.4.

¹⁸ See U.S. Dep’t of Health and Human Servs., Off. for Civil Rights, *Conscience and Religious Nondiscrimination*, <https://www.hhs.gov/conscience/conscience-protections/index.html>.

Response: The Department thanks the commenter. The statement that OCR was removing the severability provision was a typographical error at 88 FR 820, 825. The error is corrected in this final rule. This rule provides meaningful tools for OCR to enforce the Federal health care conscience protection statutes. Section 88.4 ensures that portions of this rule not found to be unlawful would remain in effect even if a court were to strike down some provision of this final rule. The various complaint handling and investigating provisions at § 88.2, for instance, operate independently of each other. Likewise, the notice provision at § 88.3 can operate independently of the rest of the rule.

C. Comments Addressing the Proposed Rule's Requests for Comment

1. Information, Including Specific Examples Where Feasible, Addressing the Scope and Nature of the Problems Giving Rise to the Need for Rulemaking, and Whether Those Problems Could Be Addressed by Different Regulations Than Those Adopted in 2019 or by Sub-Regulatory Guidance

Comments Addressing the Scope and Nature of the Problems Giving Rise to the Need for Rulemaking

Comment: In support of the need for rulemaking, one legal organization provided court cases related to the Religious Freedom Restoration Act. Another individual commenter cited her own published work which suggests that nurses and nursing students are under the impression that they must set aside their conscientious views to be a nurse. Other commenters highlighted that their religious beliefs and moral convictions are what motivate them to be in the health care field and help them to relate to the spiritual needs of patients who desire a religious perspective.

Response: The Department appreciates the concerns raised by the commenters regarding the need for this rulemaking. While the Department does not opine here on any of the cases raised by the commenters, the comments help illustrate that finalizing this rule will provide further clarity about OCR's enforcement authority and processes related to the Federal health care conscience statutes. The Department is committed to applying the text of the relevant conscience statutes on a case-by-case basis, which respects the balance Congress sought to achieve through these statutes, and that commitment is evidenced in part through this new rulemaking. The Department has also taken steps to

ensure that the public is aware of the protections under the conscience statutes beyond this rulemaking, including by issuing guidance on the Church Amendments.¹⁹ The Department encourages anyone who believes the Federal health care conscience statutes have been violated to file a complaint with OCR. For detailed instructions on how to file a complaint or to download a complaint form, please visit OCR's website at www.hhs.gov/ocr/complaints.

Whether the Problems Giving Rise to Rulemaking Could Be Addressed by Different Regulations or by Sub-Regulatory Guidance

Comment: A commenter proposed a new framework for evaluating conscience complaints, revolving around requiring objections to be stated in advance, increasing staffing to accommodate objections, and requiring health care entities that object to providing procedures to either (1) facilitate and pay for transferring patients to hospitals that provide procedures or (2) limit their services to patients who share their beliefs and divest facilities where there is no similar sized health care entity within a 30 minute drive that provides all needed services. Another commenter similarly commented that any exceptions based on the Church Amendments should not apply if the provider's refusal to provide care results in serious harm to the patient, and the patient could not schedule another in-network provider.

Response: The Department thanks the commenters. We decline to implement the commenters' recommendations in this final rule as they are beyond the scope of this rulemaking. The Department will adhere to the Federal health care conscience statutes and apply them on a case-by-case basis.

Comment: Given the lack of explicit enforcement mechanisms in the existing statutes, one commenter urged the Department to consider what additional regulatory language or subsequent guidance it can provide consistent with its authority to ensure that the conscience laws are fully and effectively enforced when violations of conscience rights are found.

Response: The Department thanks the commenter for recommending that the Department consider additional

regulatory language and subsequent guidance. As discussed in response to other comments, the Department is adding regulatory language to clarify the Department's and OCR's authority to enforce the Federal health care conscience statutes, including through compliance reviews (§ 88.2(a) and a new § 88.2(c)), coordinating other appropriate remedial action (§ 88.2(a)), and OCR's authority to utilize existing enforcement regulations or withhold relevant funding to the extent authorized under the Federal health care conscience statutes where a matter cannot be resolved by informal means (§ 88.2(g)(3)). The commenter did not provide any recommendations on what that guidance should include, but the Department will continue to consider whether additional guidance under the conscience statutes is warranted.

2. Information, Including Specific Examples Where Feasible, Supporting or Refuting Allegations That the 2019 Final Rule Hindered, or Would Hinder, Access to Information and Health Care Services, Particularly Sexual and Reproductive Health Care and Other Preventive Services

Comment: Some commenters, including reproductive health groups, claimed that the 2019 Final Rule generally would have had a negative effect on patients by restricting access to care and increasing denials of care. Commenters stated that barriers to health care are compounded in health systems that refuse to provide certain types of care due to religious or moral objections. These commenters said patients do not necessarily know about such limits on care. The commenters further said this occurs more often in rural areas where there are often no alternative providers, impacts those with lower incomes, and impacts pregnant women of color who disproportionately give birth at hospitals that object to abortion and contraception.

Numerous commenters, including reproductive health groups and LGBTQI+ rights groups discussed the 2019 Final Rule's potential impact on services and access to care for groups of marginalized or underserved populations, including but not limited to women, older Americans, LGBTQI+ people, people with disabilities, people living in rural areas, Black, Indigenous, and people of color, immigrants, low-income communities, people with HIV, and people with substance use disorder. Numerous commenters discussed general health disparities and heightened discrimination against LGBTQI+ individuals, including access

¹⁹ U.S. Dep't of Health and Human Servs., Off. for Civil Rights, "Guidance on Nondiscrimination Protections under the Church Amendments" (Content last reviewed Feb. 3, 2023), <https://www.hhs.gov/conscience/conscience-protections/guidance-church-amendments-protections/index.html>.

to reproductive health care and technology, that they claimed would have occurred because of the 2019 Final Rule. One commenter tied the fact that LGBTQI+ individuals already experience significant health inequities due to refusals to provide certain forms of care and stated LGBTQI+ individuals often suffer from “health care avoidance” due to facing discrimination in a number of services, including reproductive services, adoption and foster care services, childcare, homeless shelters, and transportation services—as well as physical and mental health care services. A commenter stated the 2019 Final Rule would have allowed providers to object to providing care, especially emergency services, which would disproportionately affect transgender people because of their struggle to access care. Another commenter argued the 2019 Final Rule would have harmed older adults by authorizing discrimination and increasing disparities in Medicare and Medicaid, especially for transgender older adults that would be at the mercy of Medicare Advantage plans hoping the plan contracts with providers who will not refuse them treatment. Additionally, a commenter discussed refusals to provide care that are based on religious or moral objections as particularly impactful to transgender individuals.

Numerous commenters described the types of services that they believed the 2019 Final Rule would have negatively impacted, such as contraception, end-of-life care, vaccination, pregnancy and reproductive services, counseling and behavioral health, infertility treatment, pre-exposure prophylaxis (PrEP) and HIV treatment, among others. One commenter said the 2019 Final Rule could have allowed providers to refuse cancer treatment or reproductive services for pregnant individuals. Another commenter discussed the importance of family planning under the Title X program, stating that they believed the 2019 Final Rule would have reduced access to such “sexuality education” and family planning care and would have made it difficult for Title X facilities to hire employees willing to perform core job functions. Other commenters said that by further restricting access, the 2019 Final Rule would have exacerbated existing racial and socio-economic health disparities.

A few commenters, including reproductive health organizations, noted that immigrants, ethnic minorities, and LGBTQI+ individuals faced disproportionate barriers accessing reproductive health care before the *Dobbs v. Jackson Women’s Health Organization*, 142 S. Ct. 2228 (2022),

decision and the 2019 Final Rule would have increased those barriers. One commenter stated that the 2019 Final Rule targeted people seeking reproductive health care, but even before the 2019 Final Rule, people cited religious beliefs to deny access to services such as abortion, sterilization, certain infertility treatments, and miscarriage management. A commenter stated there are serious physical and socioeconomical impacts on patients who experience discrimination when seeking abortion care, and refusals to provide such care can have profound health consequences for women. Two commenters stated that this partial rescission of the 2019 Final Rule comes at an important time in the wake of the *Dobbs* decision, as abortion services are harder to obtain.

Several commenters, including a reproductive health group, stated that the 2019 Final Rule upset the careful balance in Federal laws between patient needs and conscience rights, and that the proposed rule appropriately resets that balance. A professional health care association stated that in the balance between conscience rights and patients’ rights, patients’ rights must come first as the patient is in the more vulnerable position, meaning there is a duty to refer on the part of the objecting provider. A few commenters argued that the proposed rule is needed to ensure LGBTQI+ patients have access to care, free from discrimination. Two commenters stated that the proposed rule would minimize the frequency of refusals to provide abortions, which especially burden the most vulnerable in our society. The commenter also stated that physicians should have some discretion if they truly believe performing an abortion in certain cases would violate their duties as medical professionals, but those who would be unwilling to perform abortion under any circumstance are not well suited for reproductive health care.

Numerous commenters, including a reproductive health organization, urged the Department to eliminate the 2019 Final Rule because it would have allowed almost any worker in a health care facility, insurance plan, or hospital to delay or block patients from getting care because of who they are or the kind of care they seek, including individuals indirectly involved in the provision of health care. One commenter stated that the 2019 Final Rule would have caused massive disruptions to large provider networks because costs of compliance with the 2019 Final Rule would have been astronomical, since losing federal funding for failure to comply would

have led to the discontinuation of essential services and even closures.

One commenter stated that the 2019 Final Rule failed to account for health care providers who have moral beliefs that motivate them to treat and provide health care, especially abortion, end-of-life care, and gender-affirming care, to patients.

Response: The Department thanks commenters for sharing their views. The Department appreciates the concern that patients have full access to health care and as the proposed rule stated, 88 FR 820, 826, the Department maintains that our health care systems must effectively deliver services to all who need them in order to protect patients’ health and dignity. The Department is engaging in this rulemaking in part to address the concerns raised by commenters about the impact of the 2019 Final Rule. The Department reiterates its commitment to ensuring that patients are not discriminated against, including by being denied health care on the various bases protected under civil rights laws. In addition, the Department is committed to ensuring compliance with the conscience statutes, including those provisions under the Church Amendments that offer protections for physicians or certain other individuals in certain federally funded health, training, or research programs who have performed or assisted in the performance of, or who are willing to perform or assist in the performance of, a lawful sterilization procedure or abortion.

3. Information, Including Specific Examples Where Feasible, Regarding Complaints of Discrimination on the Basis That an Individual or Health Care Entity Did Not Provide Services for the Purpose of Causing or Assisting in the Death of Any Individual, Including Through Assisted Suicide, Euthanasia, and Mercy Killing, as Described in Section 1553 of the ACA, and Comments on Whether Additional Regulations Under This Authority Are Necessary

General Support for Conscience Protections

Comment: Some commenters requested that conscience protections for assisted suicide be strengthened due to a recent rise in conscience objections. Some commenters referenced various examples, including cases and state laws from Vermont, Maine, California, and New Mexico and stated that since state laws protect conscience rights to a lesser degree than Section 1553, the Department must ensure compliance with Section 1553 to protect the

conscience rights of those providers who object to taking human life.

Response: The Department appreciates commenters providing their views regarding conscience rights related to assisted suicide. The Department remains committed to educating patients, providers, and other covered entities about their rights and obligations under the conscience statutes and remains committed to ensuring compliance, including with Section 1553 of the Affordable Care Act.

Comment: A commenter noted that assisted suicide or medical aid in dying is not necessary, life-preserving, or lifesaving, so there should be no issue with permitting health care entities to refuse to perform such services for moral or religious objections. A commenter stated that conscientious objections are from the perspective of the objector, meaning it is immaterial how a state defines the “practice” of assisted suicide or whether it disagrees that abortion is a procedure that takes the life of a separate, unique, human being.

Response: Each of the conscience statutes contains particular requirements that must be met in order for them to apply to a given set of facts. The Department remains committed to faithfully applying each statute as drafted by Congress on a case-by-case basis.

Requests for Technical Changes

Comment: One end-of-life patient advocacy group raised concerns about the proposed rule using the term “assisted suicide” as opposed to “medical aid in dying,” arguing that using that term in conjunction with citing Section 1553 of the Affordable Care Act would create barriers preventing terminally ill patients from accessing their right to “medical aid in dying” in states that authorize it and consider it as distinct from assisted suicide. The commenter argued that medical aid in dying is a medical procedure in which a physician writes a prescription for medication for a mentally capable, terminally ill adult who can then decide if they want to self-administer the medication if their suffering becomes too great. The commenter contrasted that with assisted suicide, which it defined as a criminal act in which someone encourages and facilitates the self-inflicted death of an individual irrespective of their life expectancy. The commenter recommended the Department use the term “medical aid in dying” to ensure that patients are informed of the option, and to distinguish between the duty to share information about medical options

at the end of life from the act of participating in a medical procedure to which a provider objects.

Response: The Department appreciates this comment. The Department notes that the final rule includes reference to Section 1553 of the Affordable Care Act, which uses the terms “assisted suicide,” “euthanasia,” and “mercy killing.”²⁰ The Department declines, however, to incorporate additional language in the rule text regarding the definition of “assisted suicide” or the other terms in the statute as it is unnecessary to include such language to clarify OCR’s processes by which it enforces this statute or to enforce it on a case-by-case basis.

4. Information, Including Specific Examples Where Feasible, Regarding Complaints of Discrimination by a Qualified Health Plan Under the ACA on the Basis That a Health Care Provider or Facility Refused To Provide, Pay for, Cover, or Refer for Abortions, as Described in Section 1303 of the ACA and Comments on Whether Additional Regulations Under This Authority Are Necessary

Comment: The Department received a comment in response to this question, but did not receive information regarding complaints of discrimination by a qualified health plan. The commenter expressed concern that patients can either choose their employer’s insurance plan or an Affordable Care Act plan but stated that neither type of insurance plan should be allowed to deny care under the federal conscience statutes. The commenter stated that health insurance plans, and hospitals as well, are not people with rights that can be infringed.

Response: The Department thanks the commenters for sharing their views, but notes that each of the conscience statutes contains particular requirements and prohibitions that were put in place by Congress. Any determination regarding their application will be made based upon the specifics of each statute.

²⁰ “The Federal Government, and any State or local government or health care provider that receives Federal financial assistance under this Act (or under an amendment made by this Act) or any health plan created under this Act (or under an amendment made by this Act), may not subject an individual or institutional health care entity to discrimination on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.” 42 U.S.C. 18113(a).

5. Information, Including Specific Examples Where Feasible, From Health Care Providers Regarding Alleged Violations of the Conscience Provisions Provided for in the Medicaid and Medicare Statutes, Including the Provisions Codified at 42 U.S.C. 1320a–1(h), 1320c–11, 1395i–5, 1395w–22(j)(3), 1395x(e), 1395x(y)(1), 1395cc(f), 1396a(a), 1396a(w)(3), 1396u–2(b)(3), 1397j–1(b), and 14406(2) and Comments on Whether Additional Regulations Under These Authorities Are Necessary

Comment: A patient advocacy group generally discussed the importance of advance directives as a health care planning tool for end-of-life medical care. The commenter stated that the Medicare and Medicaid provisions regarding advanced directives should not be construed to allow entities and providers to fail to provide complete information to patients about end-of-life care and advance directives, pointing out that under many state laws providers may refuse to follow advance directives for religious or moral beliefs so long as the physician informs the patient and in many cases assists in the transfer to another provider who will honor the patient’s wishes.

Another commenter stated that the Department failed to articulate a sufficient reason for expanding the proposed rule to include these Medicare and Medicaid provisions. The commenter stated the proposed rule invalidates the inherent authority of advance directives by allowing providers to ignore these documents if they disagree. The commenter asserted that Section 1395cc(f) and CMS implementing regulations (See 42 CFR 489.102(a)(1)(ii) (2018); 42 CFR 418.52(a)(2) (2018)) require facilities to inform patients and residents of their rights to have completed advance directives, and that facilities should provide their patients and residents with written information about whether or not the provider objects on conscience grounds to honoring the directive. The commenter recommended that the Department require health care entities to provide accessible and prominent notice about all information the health care entity or provider refuses to offer and urged the Department to ensure patients are still timely transferred if a health care provider objects to honoring an advance directive.

Response: As the proposed rule stated, retaining the Federal conscience provisions as a part of the rule and maintaining OCR as the centralized HHS office tasked with receiving and investigating complaints under these

provisions will aid the public by increasing awareness of the rights protected by these statutes and where to file complaints alleging violations of those rights. The Department declines to include provisions beyond the text of the conscience statutes in this procedural rule as recommended by the commenter or to require entities to post information about services to which they have a conscience objection. The Department notes, however, that the voluntary notice provision of this final rule states that, where possible, and where the recipient does not have a conscience-based objection to doing so, the notice should include information about alternative providers that may offer patients services the recipient does not provide for reasons of conscience.

Comment: One commenter referenced the Department's request for comment for examples from providers about discrimination in violation of conscience provisions in the Medicaid and Medicare statutes without directly providing such examples. The commenter stated that public and private insurance should safeguard existing benefits for children and should include reproductive health and related services. The commenter urged HHS to ensure no individuals receiving care through public health insurance are denied access to care or willing providers.

Response: The Department thanks the commenter for sharing their concern. Providing such substantive provisions, however, is beyond the scope of this rulemaking.

6. Information, Including Specific Examples Where Feasible, Regarding Alleged Violations of Any of the Other Authorities That Appeared in the 2019 Final Rule But Not the 2011 Final Rule

Comment: The Department only identified one comment in response to this question. A commenter offered suggestions on "other relevant authorities" (without citation) in reference to this request for comment and urged HHS to support only organizations that advocate in favor of childhood vaccination and not to make policy changes to weaken measures to immunize health care personnel.

Response: The Department thanks the commenter for their response. This final rule clarifies OCR's existing authorities over the Federal conscience statutes in § 88.1, which includes a provision regarding pediatric vaccines (42 U.S.C. 1396s(c)(2)(B)(ii)).

7. Comment on Whether the 2019 Final Rule Provided Sufficient Clarity To Minimize the Potential for Harm Resulting From Any Ambiguity and Confusion That May Exist Because of the Rule, and Whether Any Statutory Terms Require Additional Clarification

Whether the 2019 Final Rule Provided Sufficient Clarity To Minimize the Potential for Harm

Comment: Numerous commenters, including reproductive health organizations and legal organizations, generally expressed support for the rescission of 2019 Final Rule provisions, stating that the 2019 Final Rule was confusing and redundant, unlawful, overbroad, discriminatory, and ripe for abuse. Many of these commenters also stated that rescinding the 2019 Final Rule would restore OCR's appropriate scope of enforcement. One commenter stated that the proposed rule reflected the appropriate balance between providing reasonable accommodations for providers who cannot perform certain services in good conscience and obligations to patients and providing the care they need—a balance that hospitals already have vast experience in addressing.

Two commenters stated that for many major medical providers, including their own, the threat of loss of federal funding is a threat to the facilities' existence, meaning the 2019 Final Rule would have skewed health systems against patient care and in favor of refusals to provide certain services based on religious or moral objections. Three commenters stated that the 2019 Final Rule would have aggravated health disparities, contrary to the mission of HHS and OCR. One commenter expressed their support for the proposed rule because it declined to retain the provisions in the 2019 Final Rule that appeared to give OCR the authority to withhold federal financial assistance and suspend award activities based on "threatened violations" alone, without first allowing for the completion of an informal resolution process. A couple of commenters stated that they support the proposed rule for removing onerous reporting requirements that the 2019 Final Rule would have imposed.

Other commenters discussed physicians' duties to patients, with one commenter asking that the Department clarify that the Federal government's stance is that providers cannot refuse to serve patients due to personal beliefs. Another commenter supported the proposed rule out of concern that the 2019 Final Rule would have negatively impacted the field of pediatrics and the

care and well-being of children in particular.

Many commenters, including legal organizations and reproductive health organizations, argued that the sweeping language of the 2019 Final Rule definitions exceeded statutory and constitutional authority by abandoning the long-standing balancing framework under Title VII of the Civil Rights Act of 1964 or violating the Establishment Clause, especially the definitions of "referral/refer" and "assist in the performance." Many of these commenters said the 2019 Final Rule definitions would have allowed providers to violate principles of medical ethics and informed consent by refraining from informing patients about treatment options that they find objectionable and referring the patient to another provider, even in an emergency. These commenters said that this would have weakened the integrity of key HHS programs and the quality of U.S. health care by disregarding evidence-based standards of care. One legal organization asserted that the 2019 Rule's definition of "discrimination" contrasted with prior case law regarding the Weldon and Coats-Snowe Amendments and the reasonableness of accommodations. Several commenters, including state attorneys general, a legal organization, and a reproductive health organization, argued that the definition of "health care entity" in the 2019 Rule would have exceeded the reach of the Weldon and Coats-Snowe Amendments by including dozens of new entities under their protection, such as employers that provide health benefits, pharmacists, and medical laboratories. One of these commenters elaborated that in the Coats-Snowe Amendment, Congress chose to focus on a select group of individuals involved in the abortion training context in its definition of "health care entity," and cited to contemporary statements by Senator Coats that the statute was meant to "simply address the question of training for induced abortions."²¹ The commenter likewise cited floor statements by Representative Weldon to show that the Weldon Amendment was meant to apply to a limited group of entities. Additional commenters argued the 2019 Final Rule would have made it exceedingly difficult for health care providers to interview, hire, or respond to accommodation requests, and to continue to provide essential services to their patients since the rule would have, in their view, impermissibly broadened the right to object based on conscience

²¹ 142 Cong. Rec. 5,158 (1996) (statement of Sen. Coats).

to virtually any other person in the health care setting.

Response: The Department thanks the commenters for sharing their views on the 2019 Rule. As stated in the proposed rule, the Federal health care conscience protection statutes represent Congress' attempt to strike a careful balance, which the Department will respect. Some doctors, nurses, and hospitals, for example, object for religious or moral reasons to providing or referring for abortions or assisted suicide, among other procedures. Respecting such objections honors liberty and human dignity. It also redounds to the benefit of the medical profession. Patients also have autonomy, rights, and moral and religious convictions. And they have health needs, sometimes urgent ones. Our health care systems must effectively deliver services to all who need them in order to protect patients' health and dignity. The Department maintains that this final rule appropriately addresses the concerns raised by commenters and three separate district courts about the 2019 Final Rule, and in particular, its definitions, and allows the Department to faithfully apply each statute on a case-by-case basis.

Whether Any Statutory Terms Require Additional Clarification

Comment: Several commenters, including local governments, legal organizations, and others, generally expressed opposition to the rescission of the definitions that appeared at § 88.2 of the 2019 Final Rule on the grounds that those definitions provide more clarity regarding conscience protection statutes, that some of the definitions were not redundant, unlawful, or unnecessary, and that the definitions would ensure adequate enforcement and prevent arbitrary determinations by OCR. One commenter stated that the Department has failed to provide an adequate justification for why the removal of all definitions improves the application or interpretation of laws regarding conscience protections, while another commenter requested that the Department replace the allegedly confusing definitions of the rule with new definitions. A few commenters said that the 2019 Final Rule's definitions upheld the balance between conscience protection and patient rights and appropriately reflected the breadth of the underlying statutes.

Response: The Department thanks the commenters for sharing their concerns regarding the 2019 Final Rule's definitions and clarifying certain statutory terms. The Department is declining to include certain portions of the 2019 Final Rule, including the

definitions mentioned by commenters, because questions have been raised as to their clarity and legality, including whether they undermine the balance Congress struck between safeguarding conscience rights and protecting access to health care. In response to the 2018 Proposed Rule, the Department received numerous comments about the clarity and scope of the proposed definitions. *See*, 84 FR 23170, 23186–23204 (May 21, 2019). While the Department finalized the definitions in the 2019 Final Rule with changes to address these concerns, the district court for the Southern District of New York found that the 2019 Final Rule's definitions of “discrimination,” “assist in the performance,” “referral,” and “health care entity,” in the court's view, impermissibly broaden the conscience statutes beyond the balance struck by Congress. *New York*, 414 F. Supp. 3d at 523. The district court for the Northern District of California similarly found that the 2019 Final Rule, including the definitions and enforcement provisions, were not “mere housekeeping.” *San Francisco*, 411 F. Supp. 3d at 1023. In the court's view, the “expansive definitions,” which departed from the federal statutes, coupled with the termination of all HHS funding as a consequence of noncompliance, rendered the rule “undoubtedly substantive.” *Id.* In response to the proposed rule, the Department received comments again raising concerns about the clarity and scope of the 2019 Final Rule's definitions. Taken together, the Department determined that the questions raised about the definitions in the 2019 Final Rule by commenters and the courts warrant additional careful consideration. Finally, as noted elsewhere, the Department declines to add language interpreting the provisions of the conscience statutes to the rule text as it is unnecessary to include such language to clarify OCR's processes by which it enforces these statutes or to enforce them on a case-by-case basis.²²

²² The Department notes that the model notice text includes a link to the HHS web page where additional resources can be accessed for covered entities and the public to better understand their obligations and rights under the Federal health care conscience statutes. *See* U.S. Dep't of Health and Human Servs., Off. for Civil Rights, *Conscience and Religious Nondiscrimination*, <https://www.hhs.gov/conscience/conscience-protections/index.html>. As noted elsewhere in this preamble, the Department agrees it is important to ensure the public is aware of the Federal conscience statutes and remains committed to educating patients, providers, and other covered entities about their rights and obligations under the conscience statutes, including through education and outreach efforts.

8. Comment on Whether the Provisions Added by the 2019 Final Rule Are Necessary, Collectively or With Respect to Individual Provisions, To Serve the Statutes' or the Rule's Objectives, Including With Regard to Whether the Department Accurately Evaluated the Need for Additional Regulation in the 2019 Final Rule, and Whether Those Provisions Should Be Modified, or Whether the Rule's Objectives May Also Be Accomplished Through Alternative Means, Such as Outreach and Education

Whether the Provisions Added by the 2019 Final Rule Are Necessary and Whether the Department Accurately Evaluated the Need for Additional Regulation in the 2019 Final Rule

Comment: Some commenters, including a reproductive health group, stated that the Department did not accurately evaluate the need for additional regulation in its promulgation of the 2019 Final Rule, stating that the paucity of data on conscience complaints or allegations of conscience statute violations, and the decision by three federal district courts to vacate the 2019 Final Rule, illustrates that the provisions of the 2019 Final rule were not actually necessary. One legal organization agreed that the 2019 Final Rule made significant changes to the conscience statutes and argued the Department did not need to engage in rulemaking given that there were less than a dozen conscience complaints filed with OCR between 2011 and 2017 and instances in which providers are required to violate their conscience are rare. Some commenters noted that, as the Southern District of New York found, the number of conscience complaints received by OCR was significantly less than the 2019 Final Rule stated, which undermined one key argument for it. These commenters said that this lack of data means HHS has no justification for the assertion in the 2019 Final Rule that HHS otherwise lacks the capacity to enforce the provisions of the Federal conscience statutes. These commenters stated that the provisions of the 2019 Final Rule are not necessary because (1) Congress did not delegate to HHS rulemaking authority to promulgate the substantive components of the 2019 Final Rule and (2) Congress did not delegate to OCR the ultimate enforcement power to cut off all of a recipient's funding for the breach of a conscience provision.

Response: The Department acknowledges that the litigation surrounding the 2019 Final Rule raised questions regarding the complaints of statutory violations that served as a predicate for the 2019 Final Rule, and

thanks the commenters for sharing their other thoughts regarding this issue. The Department notes that OCR's overall caseload has multiplied in recent years, increasing to over 51,000 complaints in 2022—an increase of 69 percent between 2017 and 2022—with 27 percent of those complaints alleging violations of civil rights, 66 percent alleging violations of health information privacy and security laws, and 7 percent alleging violations of conscience/religious freedom laws.²³ The Department has concluded that this final rule will enable OCR to effectively process and resolve complaints related to the Federal health care conscience statutes.

Comment: One commenter stated that the 300 complaints filed with OCR within a month of the announcement of the new Conscience and Religious Freedom Division within OCR are evidence of the need for broader conscience protections, and another commenter defended the 2019 Final Rule in part due to an increase in complaints filed with OCR.

Response: Among other things, the litigation over the 2019 Final Rule raised significant questions regarding the complaints of statutory violations that served as a predicate for the 2019 Final Rule. As noted above, OCR's caseload has increased,²⁴ but the Department has concluded that this final rule will enable OCR to effectively process and resolve complaints related to the Federal health care conscience statutes.

Comment: Some commenters, including a faith-based organization, expressed opposition to the removal of the compliance requirements at § 88.6 of the 2019 Final Rule, stating that removal of these requirements is contradictory to the stated goal of protecting conscience rights and will hinder the Department's ability to prevent discrimination. Commenters explained that compliance requirements would provide clarity on how conscience rights are expected to be enforced, would aid in the fact-intensive investigations conscience complaints can require, and would fit in with the general practices for other for civil rights laws. One commenter elaborated that in the absence of these requirements, recipients may under- or

over-record, incurring laborious administrative costs and enormous legal fees. Additionally, some commenters expressed opposition to the rescission of the applicable requirements and prohibitions that appeared at § 88.3 in the 2019 Final Rule because this rescission creates issues with enforcement. Without this provision's language, several commenters said that the rule fails to provide information to covered entities about which statutes apply to them, removes helpful context, and imposes increased costs on covered entities who now have to research over two dozen separate statutes instead of having one place to learn about them.

Response: The Department thanks the commenters for their recommendations. The Department declines to retain, among other provisions, the applicable requirements and prohibitions that appeared at § 88.3 and the compliance requirements at § 88.6. Specifically, the applicable requirements and prohibitions that appeared at § 88.3 were unnecessary because they simply repeated the language of the underlying statutes.²⁵ Some commenters also raised concerns in response to both the 2018 Proposed Rule²⁶ and the proposed rule for this rulemaking that the compliance requirements at § 88.6 were overly burdensome on covered entities and not authorized by the conscience statutes. The concerns raised by commenters highlight significant questions that warrant additional consideration, and in the Department's view, these provisions are not necessary to clarify OCR's processes by which it enforces these statutes. This final rule specifies the Department's procedures for handling conscience complaints in a manner that allows the Department to address conscience complaints on a case-by-case basis to ensure the balance struck by Congress is respected. Finally, the Department notes, as it has already elsewhere, that in response to comments received on the proposed rule, this rule is being finalized with additional enforcement provisions similar to provisions in the 2019 Final Rule that

did not raise the same issues as were raised by the other provisions noted above.

Comment: One commenter stated that the potential withdrawal of federal funds or the potential for a lawsuit needs to remain in the rule to ensure that there is effective enforcement; and that requirements for reporting incidents of discrimination from § 88.6 of the 2019 Final Rule need to be left in place. One commenter said, "The courts that vacated the 2019 Final Rule did not find that the use of such formal means was impermissible per se, but only that the 2019 rule's text deviated from those existing frameworks in specific ways." The commenter also said that the final rule should therefore retain OCR's authority to pursue formal as well as informal means of enforcing the conscience statutes.

Response: As discussed in response to other comments, the Department is adding regulatory language to clarify the Department's and OCR's authority to enforce the Federal health care conscience statutes, including through compliance reviews (§ 88.2(a) and a new § 88.2(c)), coordinating other appropriate remedial action (§ 88.2(a)), and OCR's authority to utilize existing enforcement regulations, such as those that apply to grants, contracts, or other programs and services, or withhold relevant funding to the extent authorized under the Federal health care conscience statutes where a matter cannot be resolved by informal means (§ 88.2(g)(3)).

As the Department has already noted in response to other comments, the Department determined not to retain, among other provisions, compliance requirements at § 88.6. In the Department's view, this provision is not necessary to clarify OCR's processes by which it enforces these statutes. The Department has concluded that the final rule's enforcement provisions, which set out procedures for the Department to handle conscience complaints on a case-by-case basis as they arise, appropriately permit the Department to ensure compliance with the conscience statutes without raising certain potential concerns commenters identified in connection with compliance provisions included in the 2019 final rule.

Comment: Some commenters, including several faith-based organizations and a couple non-profits, expressed concern regarding the rescission of the rule of construction and severability provisions at § 88.9 and § 88.10 of the 2019 Final Rule, arguing that they provided much needed clarity as to the Department's interpretation and enforcement of the conscience

²⁵ The Department notes that the model notice text includes a link to the HHS web page where additional resources can be accessed for covered entities and the public to better understand their obligations and rights under the Federal health care conscience statutes. See U.S. Dep't of Health and Human Servs., Off. for Civil Rights, *Conscience and Religious Nondiscrimination*, <https://www.hhs.gov/conscience/conscience-protections/index.html>. As noted elsewhere in this preamble, the Department agrees it is important to ensure the public is aware of the Federal conscience statutes and remains committed to educating patients, providers, and other covered entities about their rights and obligations under the conscience statutes, including through education and outreach efforts.

²⁶ See 84 FR 23170, 23219 (May 21, 2019).

²³ See Press Release, U.S. Dep't of Health and Human Servs., Off. for Civil Rights, HHS Announces New Divisions Within the Office for Civil Rights to Better Address Growing Need of Enforcement in Recent Years (Feb. 27, 2023), <https://www.hhs.gov/about/news/2023/02/27/hhs-announces-new-divisions-within-office-civil-rights-better-address-growing-need-enforcement-recent-years.html>.

²⁴ *Id.*

protection laws. Three commenters cited caselaw to elaborate that courts and administrative agencies have long recognized that non-discrimination laws should be construed broadly to give full effect to their remedial purposes, and so it would be entirely appropriate for HHS to announce a rule of broad construction in the final rule.

Response: The Department notes that the language from the severability provision from § 88.10 of the 2019 Final Rule is retained at § 88.4 of the proposed rule and in this final rule. Additionally, as noted in the proposed rule, the enactment of the Federal health care conscience protection statutes represents Congress' attempt to strike a careful balance, and the Department will respect that balance. The conscience statutes each contain particular requirements that must be met in order for them to apply. The Department is committed to meeting its obligations and ensuring compliance with all relevant federal law, including under the Federal conscience statutes.

Comment: One commenter stated that the proposed rule does not provide any justification for rescinding the 2019 Final Rule other than by citing *New York v. U.S. Dep't of Health & Human Servs.*, 414 F. Supp. 3d 475, 513–14, 535 (S.D.N.Y. 2019), without explaining why HHS is deferring to the court's decision. Many other commenters argued that the Department should not rely on the *New York* decision because the district court's ruling was based on an incomplete and incorrect understanding of the underlying legislation. Other commenters maintained that, because only certain provisions of the 2019 Final Rule were held unlawful, the proposed rule over-relied on the finding of the court as to the other provisions in the 2019 Final Rule and did not clearly articulate the reasoning for rescissions in general to specific rescinded provisions.

Response: The Department respectfully disagrees with commenters that the sole proffered justification for rescinding the 2019 Final Rule was the *New York* decision. As the Department noted in the proposed rule, 88 FR 820, 825–26, “[t]he Department proposes to rescind the other portions of the 2019 Final Rule because those portions are *redundant, unlawful, confusing or undermine the balance Congress struck* between safeguarding conscience rights and protecting access to health care, or because significant questions have been raised as to their legal authorization.” (Emphasis added). For example, the applicable requirements and prohibitions that appeared at § 88.3 were unnecessary because they simply

repeated the language of the underlying statute.²⁷ Additionally, the Department received comments in response to the 2018 Proposed Rule and the proposed rule for this final rule that stated that many of the definitions at § 88.2 were confusing or undermined the balance struck by Congress between safeguarding conscience rights and protecting access to care. Likewise, commenters in response to the 2018 Proposed Rule and the proposed rule for this final rule stated that the assurance and certification requirements that appeared at § 88.4 were overly burdensome. The Department also determined that the requirements at § 88.4 are not necessary as the Department has updated the HHS Form 690 Assurance of Compliance (which OCR maintains) independent of the 2019 Final Rule and this rulemaking to include reference to the Federal conscience statutes.²⁸ Further, the compliance requirements at § 88.6, the relationship to other laws provision at § 88.8, and rule of construction at § 88.9 (which was echoed in § 88.1) were flagged by commenters to both the 2018 Proposed Rule and the proposed rule for this final rule as, in their view, unlawful or having created confusion or risk of harm by undermining the balance struck by Congress. Finally, as noted in the proposed rule, in the view of the court in the *New York* decision, the purpose provision at § 88.1, several of the definitions at § 88.2, and the assurance and certification requirements at § 88.4 were found to be unlawful since the court understood them to impose new substantive duties on regulated entities in the health care sector, beyond the Department's Housekeeping Authority. The district court decisions overlapped with concerns raised by commenters regarding the provisions at § 88.1, several of the definitions at § 88.2, and the assurance and certification requirements at § 88.4, and so the Department determined these concerns

²⁷ The Department notes that the model notice text includes a link to the HHS web page where additional resources can be accessed for covered entities and the public to better understand their obligations and rights under the Federal health care conscience statutes. See U.S. Dep't of Health and Human Servs., Off. for Civil Rights, *Conscience and Religious Nondiscrimination*, <https://www.hhs.gov/conscience/conscience-protections/index.html>. As noted elsewhere in this preamble, the Department agrees it is important to ensure the public is aware of the Federal conscience statutes and remains committed to educating patients, providers, and other covered entities about their rights and obligations under the conscience statutes, including through education and outreach efforts.

²⁸ See U.S. Dep't of Health and Human Servs., Off. for Civil Rights, “Assurance of Compliance,” HHS Form 690, OMB Control Number 0945–0008 (Last updated Nov. 2019), <https://www.hhs.gov/sites/default/files/form-hhs690.pdf>.

warrant additional consideration. In the current instance, however, the Department does not view these provisions as necessary to clarify OCR's processes by which it enforces these statutes. This final rule specifies the Department's procedures for handling conscience complaints in a manner that allows the Department to address conscience complaints on a case-by-case basis to ensure the balance struck by Congress is respected.

The Department notes as well, as it has already elsewhere, that in response to comments received on the proposed rule, this rule is being finalized with additional enforcement provisions similar to provisions in the 2019 Final Rule that did not raise the same issues as were raised by the other provisions noted above.

Comment: One commenter argued that the specified reasons for the removal of § 88.4 are not rational and weaken the argument proffered by the Department that the proposed rule strengthens conscience rights. Some commenters requested that the Department maintain assurance and certification requirements in the final rule as it is a common mechanism for preventing discrimination used in civil rights regulations. Another commenter argued that HHS, at a minimum, must replace the assurance and certification requirements with a requirement that the names of all conscience statutes that a grantee may be subject to be included in the terms of any grant agreements. One commenter argued that the purpose provision of the 2019 Final Rule was necessary evidence of the Department's commitment to ensuring that conscience rights are respected and protected to the furthest extent of the law, and that the rule in general was a vital expression of the need to protect conscience rights in health care, where, in the commenter's view, discrimination against “pro-life” persons is evident.

Response: The Department believes the final rule clearly demonstrates the Department's commitment to ensuring that the federal conscience statutes are given full effect. The Department determined that the requirements at § 88.4 are not necessary as the Department has updated the HHS Form 690 Assurance of Compliance (which OCR maintains) independent of the 2019 Final Rule and this rulemaking to include reference to the Federal conscience statutes. The purpose provision from § 88.1 of the 2019 Final Rule similarly is not necessary for this rule as this rule is not intended to “implement” the conscience statutes. The final rule is the result of the Department's careful efforts to design an

effective system of enforcement that is fully supported by the authority Congress has granted the Department, and these determinations likewise avoid potential concerns raised by the court decisions and commenters regarding §§ 88.4 and 88.1 of the 2019 rule. As noted in the proposed rule, the district court for the Southern District of New York found that, in its view, the 2019 Final Rule's purpose and assurance and certification requirements, among others, "impose[d] new substantive duties on regulated entities in the health care sector" and did not fall within the agency's Housekeeping Authority. *New York*, 414 F. Supp. 3d at 523. The court's decision raised similar concerns as those raised by commenters in response to both the 2018 Proposed Rule and the proposed rule for this final rule, who stated concerns that those provisions were overly burdensome or overly broad.

Comment: Two commenters noted that HHS has explicit rulemaking authority to engage in substantive rulemaking on the conscience protections set out in Sections 1303, 1411, and 1553 of the Affordable Care Act, 42 U.S.C. 18023, 18081, and 18113; and certain Medicare and Medicaid provisions, 42 U.S.C. 1320a-1(h), 1320c-11, 1395i-5, 1395w-22(j)(3)(B), 1395x(e), 1395x(y)(1), 1395cc(f), 1396a(a), 1396a(w)(3), 1396u-2(b)(3)(B), 1397j-1(b), and 14406. The commenters argued that the Department should retain as applicable to those statutes the provisions of the 2019 Final Rule requiring assurances and certifications of compliance, establishing compliance requirements comparable to those applicable to other civil rights laws, and defining terms.

Response: The Department has carefully considered these comments but declines to make these substantive changes in this final rule at this time. This rule addresses statutes beyond those mentioned by the commenters, and none of the statutes mentioned by the commenters requires the Department to enact regulations for the respective statute's implementation. The Department maintains that addressing all of the statutes listed in § 88.1 uniformly under this rule outweighs the benefits of including piecemeal provisions for certain statutes but not others. The Department will consider, however, whether further rulemaking on the statutes recommended by commenters is needed.

Whether the Rule's Objectives May Also Be Accomplished Through Alternative Means, Such as Outreach and Education

Comment: One professional health care organization stated that they believe physicians are aware of their legal obligations under the conscience statutes, and so the proposed rule is not necessary to enforce the conscience provisions under existing law. A few commenters urged HHS to pursue education and outreach to entities and individuals instead, with some commenters requesting the Department do so as an alternative to rulemaking and others requesting that the Department do so in addition to rulemaking. Commenters stated that such efforts would ensure that physicians and other providers and health care entities are fully aware of their rights and responsibilities under the numerous federal conscience protection laws, especially in light of the proposal to remove the assurance of compliance requirement and to only require voluntary notice.

Response: The Department thanks the commenters for their recommendations. The Department agrees it is important to ensure the public is aware of the Federal conscience statutes and remains committed to educating patients, providers, and other covered entities about their rights and obligations under the conscience statutes, including through education and outreach efforts. The Department looks forward to working with covered entities and stakeholders to increase outreach activities and ensure awareness. The Department notes as well that it has updated the HHS Form 690 Assurance of Certification (which OCR maintains) to include reference to the Federal conscience statutes as another means of increasing awareness. The Department maintains that that this rule is also an important component of educating the public about these statutes.

9. Comment on the Proposal To Retain a Voluntary Notice Provision, Including Comments on Whether Such Notice Should Be Mandatory, and What a Model Notice Should Include
Opposition To Retention of Voluntary Notice

Comment: One local government agency argued that having a voluntary notice provision was inconsistent with the scope of the Housekeeping Authority as explained in *City and County of San Francisco v. Azar*, 411 F. Supp. 3d 1001 (N.D. Cal. 2019), and argued in favor of returning to the 2011 Final Rule in full. A commenter that provides Skilled Nursing & Assisted

Living services opposed the rule's inclusion of a voluntary notice, arguing that there is already overregulation, and adding additional notices would only add confusion and increase anxiety.

Response: While the court in *San Francisco v. Azar* determined that some provisions in the 2019 Final Rule were "substantive" provisions that were not authorized by the Department's Housekeeping Authority, it did not address that rule's voluntary notice provision. 411 F. Supp. 3d at 1023. This rule lacks the provisions that the *San Francisco v. Azar* court identified as substantive, and, as the notice is voluntary, the rule does not impose new responsibilities on health care providers. The Department maintains that providing notice is an important way for covered entities to promote compliance and ensure the public, patients, and workforce, which may include students or applicants for employment or training, are aware of their rights under the health care conscience protection statutes. The Department declines to remove the voluntary notice provision on the bases cited by the commenters and encourages all covered entities to provide the voluntary notice. As stated in this final rule, the Department will consider posting a notice as a factor in an investigation or compliance review.

Whether the Notice Should Be Mandatory

Comment: Some commenters, including some faith-based organizations, elected officials, and professional health care organizations, argued that the voluntary notice provision should be mandatory instead, citing a variety of reasons. A couple of commenters argued that making the notice mandatory would increase awareness of the conscience statutes. Another commenter relied on the concept of notice in many other areas of law to argue that a mandatory notice provision should be applied here. Other commenters, including a professional health care organization, argued that a mandatory notice would increase access to services that providers might object to and supported changes that would ensure that the notice offered information about access to such services. A commenter proposed the notice should include the words "religious and moral beliefs" along with "conscience."

Response: The Department declines to make the notice mandatory, and notes that the 2019 Final Rule notice was also voluntary. The Department also notes that the wide variety of entities subject to the Federal health care conscience

protection statutes would make it difficult to mandate a notice with text that would be relevant to each of those entities. In the Department's view, a voluntary notice with recommended text does a better job of giving covered entities the flexibility to post a notice that is relevant to their obligations without increasing regulatory burden on the Department and covered entities. The Department nonetheless is clarifying in the rule text that posting a notice will be considered as a factor in any relevant OCR investigation or compliance review. Lastly, in response to the commenter's request, the Department has added "religious beliefs or moral convictions" in the model notice.

10. Comment on the Proposal To Retain Portions of the 2019 Final Rule's Enforcement Provisions in the Proposed § 88.2

General Support

Comment: Numerous commenters, including some faith-based organizations, expressed general support for retaining the complaint handling and investigation provisions in § 88.2 on the grounds that it is an improvement over the 2011 Final Rule, noting that OCR is best equipped to be the central HHS office for receiving and investigating complaints.

Response: The Department thanks the commenters for sharing their views and agrees that maintaining OCR as the centralized HHS office tasked with receiving and investigating complaints under these provisions will aid the public by increasing awareness of the rights protected by the various statutes and where to file complaints alleging violations of those rights.

Requests for Clarification

Comment: Many commenters, including reproductive health organizations and legal organizations, expressed support for the rescission of several portions of the 2019 Final Rule, especially what they characterized as overly broad enforcement provisions, but urged HHS to provide more clarity on the limits of the retained enforcement provisions and on OCR's enforcement authority generally. Some commenters recommended that the Department provide a more detailed justification for the proposal to retain procedural elements from the 2019 Final Rule's § 88.7, which includes the authority to conduct interviews and issue "written data or discovery requests." 88 FR at 829–30.

Response: The Department thanks the commenters for sharing their views.

Section 88.2(a)(5) makes clear that OCR's authority is to "[c]onsult and coordinate with the relevant Departmental funding component, and utilize existing enforcement regulations."²⁹ These existing enforcement regulations could include, for example, the Department's authority under the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (UAR; 45 CFR part 75). Second, the ability to conduct interviews and issue written data requests are standard components of OCR's function as an enforcement agency. The Department considers these elements to be part and parcel of the Department's compliance powers, and, as the commenter notes, procedural elements that fall within the Department's Housekeeping Authority. As with its other authorities, OCR may also use the provision of technical assistance or voluntary resolution agreements in an effort to achieve voluntary compliance. The Department's approach to enforcing the Federal health care conscience statutes will continue to rely on the Department's existing compliance and enforcement authority. Finally, the Department notes that, as discussed in response to other comments, the Department is adding regulatory language to clarify the Department's and OCR's authority to enforce the Federal health care conscience statutes, including through compliance reviews (§ 88.2(a) and a new § 88.2(c)), coordinating other appropriate remedial action (§ 88.2(a)), and OCR's authority to utilize existing enforcement regulations or withhold relevant funding to the extent authorized under the Federal health care conscience statutes (§ 88.2(g)(3)) or to refer to the Attorney General (§ 88.2(g)(4)) where a matter cannot be resolved by informal means.

Comment: Many commenters expressed concern that the modifications to § 88.7 of the 2019 Final Rule (§ 88.2 of the proposed rule) remove assurances that OCR will conduct a prompt investigation of complaints and investigate complaints involving a potential or threatened failure to comply with the conscience statutes. One individual commenter specifically pointed to the change of verb from "should" to "may" with regard to the investigatory and fact-finding methods the proposed rule

²⁹ Section 88.2(a)(5) of the proposed rule stated, "Consult and coordinate with the relevant Departmental funding component, and utilize existing regulations enforcement." (emphasis added). 88 FR 820, 829. This typo has been corrected in this final rule to "enforcement regulations" instead.

stated OCR would employ, which the commenter felt left the Department with too much discretion in the complaint handling process. The commenter stated that the proposed rule fails to clarify which, if any, complaints are accepted, and fails to clarify how complaints are to be handled by OCR, making it uncertain who is allowed to file a complaint.

Response: OCR reviews all complaints received as a matter of course in its normal business operations and may use some or all of the investigatory tools outlined in § 88.2 in evaluating and investigating a complaint. As noted in the proposed rule, the Department remains committed to educating patients, providers, and other covered entities about their rights and obligations under the conscience statutes and remains committed to ensuring compliance. In addition, the Department is finalizing proposed § 88.2(b) as § 88.2(d) with a revision to state that OCR shall make a *prompt* investigation of a complaint alleging failure to comply with the Federal health care conscience protection statutes, and adding a new § 88.2(b) explaining that any entity or individual may file a complaint with OCR alleging a potential violation of Federal health care conscience protection statutes, and that the entity filing does not have to be the entity whose rights have been violated. The Department declines to modify the language of § 88.2(d) to mandate the use of certain investigation methods as not all the investigatory and fact-finding methods available to OCR are appropriate or necessary to be used in all cases. Any relevant complaints filed with the Department will be routed to OCR if they are not initially filed directly with OCR, and OCR will review all received complaints and make a determination regarding the allegations raised.

Comment: Numerous commenters criticized the proposed rule and HHS for rescinding portions of the 2019 Final Rule's enforcement provisions and only retaining some, stating it would make it difficult for HHS to protect conscience rights and would lead to discrimination against health care entities and individual providers. Many commenters, including a professional health care organization and a think tank, requested the Department include explicit authority for OCR to pursue formal rather than just informal enforcement and a clear statement on how the Department will interpret the conscience laws in relation to other laws, similar to the language provided in §§ 88.7 and 88.8 of the 2019 Final Rule.

Response: OCR works to achieve voluntary compliance with all of its authorities, including HIPAA Privacy, Security, Breach Notification, and Enforcement Rules³⁰ and Title VI.³¹ As finalized in this rule, the Department states that matters of noncompliance will “be resolved by informal means whenever possible.” (Emphasis added). This is consistent with OCR’s approach to enforcement across the authorities it has been delegated and does not preclude the Department from using appropriate formal means at its disposal to achieve compliance whenever it is not possible to resolve a matter through informal means. As well, as discussed in response to other comments, the Department is adding regulatory language to clarify the Department’s and OCR’s processes and authority to enforce the Federal health care conscience statutes, including through compliance reviews (§ 88.2(a) and a new § 88.2(c)), coordinating other appropriate remedial action (§ 88.2(a)), and OCR’s authority to utilize existing enforcement regulations or withhold relevant funding to the extent authorized under the Federal health care conscience statutes where a matter cannot be resolved by informal means (§ 88.2(g)(3)). The Department declines, however, to add § 88.8 from the 2019 Final Rule into this rule as this is a procedural rule that does not address the scope of any substantive right, and thus there is no need to clarify how the rule interacts with laws that do establish protections for religious freedom or moral convictions. Moreover, in the Department’s view, it is appropriate to proceed with case-by-case enforcement of the conscience statutes. The Department has determined therefore that additional guidance is not necessary at this point.

III. Statutory Authority

The Secretary is partially rescinding the May 21, 2019, Final Rule entitled “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority.” As discussed above, the Church Amendments, section 245 of the PHS Act, the Weldon Amendment, and the Affordable Care Act require, among other things, that the Department and recipients of Department funds (including State and local governments) refrain from discriminating against institutional and individual health care entities for their participation in,

abstention from, or objection to certain medical procedures or services, including certain health services, or research activities funded in whole or in part by the federal government. No statutory provision, however, requires promulgation of regulations for their interpretation or implementation. This rule is being issued pursuant to the authority of 5 U.S.C. 301, which empowers the head of an Executive department to prescribe regulations “for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.”

IV. Overview and Section-by-Section Description of the Final Rule

Section 88.1 describes the purpose of the Final Rule. The language is revised from the 2019 Final Rule, and states that the purpose of this Part 88 is to provide for the enforcement of the Church Amendments, 42 U.S.C. 300a–7; the Coats-Snowe Amendment, section 245 of the Public Health Service Act, 42 U.S.C. 238n; the Weldon Amendment, *e.g.*, Consolidated Appropriations Act, 2023, Public Law 117–328, div. H, title V General Provisions, section 507(d)(1) (Dec. 29, 2022); Sections 1303(b)(1)(A), (b)(4), and (c)(2)(A), and 1411(b)(5)(A), and 1553 of the ACA, 42 U.S.C. 18023(b)(1)(A), (b)(4), and (c)(2)(A), 18081(b)(5)(A), and 18113; certain Medicare and Medicaid provisions, 42 U.S.C. 1320a–1(h), 1320c–11, 1395i–5, 1395w–22(j)(3)(B), 1395x(e) 1395x(y)(1), 1395cc(f), 1396a(a), 1396a(w)(3), 1396u–2(b)(3)(B), 1397j–1(b), and 14406; the Helms, Biden, 1978, and 1985 Amendments, 22 U.S.C. 2151b(f); *accord.*, *e.g.*, Consolidated Appropriations Act, 2023, Public Law 117–328, div. H, section 209, div. K, title VII, section 7018 (Dec. 29, 2022); 22 U.S.C. 7631(d) 42 U.S.C. 280g–1(d), 290bb–36(f), 1396f, 1396s(c)(2)(B)(ii); 5106i(a); and 29 U.S.C. 669(a)(5), referred to collectively as the “Federal health care conscience protection statutes.” The Department is finalizing this provision with two changes. First, in response to a comment, the Department is removing the word “provider” from the proposed rule’s collective reference of the “federal health care conscience protection statutes.” Second, the Department identified and corrected an error in the citations to the Medicare and Medicaid statutes. The proposed rule cites 42 U.S.C. 1395w–22(j)(3)(A) and 1396u–2(b)(3)(A) as conscience provisions when 42 U.S.C. 1395w–22(j)(3)(B) and

1396u–2(b)(3)(B) are the relevant conscience provisions.

Sections 88.2 through 88.4 of the 2019 Final Rule have been removed. The language of § 88.7 of the 2019 Final Rule has been revised and redesignated as § 88.2 in this final rule. Section 88.2 in this final rule states under paragraph (a) that OCR has been delegated the authority to facilitate and coordinate the Department’s enforcement of the Federal health care provider conscience protection statutes and includes a list of related authorities. This includes three authorities that did not appear in the proposed rule, but which the Department is finalizing at § 88.2(a)(2), (7), and (8) addressing OCR’s authority to initiate compliance reviews, “coordinate other appropriate remedial action as the Department deems necessary and as allowed by law and applicable regulation,” and “make enforcement referrals to the Department of Justice.” In response to comments, the Department is finalizing this rule with a new § 88.2(b) and (c) to clarify OCR’s authority to conduct compliance reviews and to clarify who may file a complaint with OCR regarding the Federal health care conscience protection statutes. Section 88.2(b) of the proposed rule has been redesignated in this final rule as § 88.2(d) and describes OCR’s investigation process. In response to comments, the Department is finalizing § 88.2(d) with a revision to state that OCR shall make a *prompt* investigation of a complaint alleging failure to comply with the Federal health care conscience protection statutes. The Department is also making a technical edit to remove the term “discovery” from § 88.2(d) as that term is generally used in litigation, but is keeping the term “data request.” The Department is also finalizing this rule with a new § 88.2(e) that did not appear in the proposed rule, but which now notes that, “OCR may adopt a negative inference if, absent good cause, an entity that is subject to the Federal health care conscience protection statutes fails to respond to a request for information or to a data or document request within a reasonable timeframe.” Proposed § 88.2(c) has been redesignated as § 88.2(f) and describes OCR’s role in providing supervision and coordination of compliance where OCR makes a determination as a result of an investigation that an entity is not compliant with their responsibilities under the Federal health care conscience protection statutes. Proposed § 88.2(d) has been redesignated as § 88.2(g) and describes OCR’s process for achieving resolution of matters. In

³⁰ See 45 CFR 160.304.

³¹ See 28 CFR 42.411 (“Effective enforcement of title VI requires that agencies take prompt action to achieve *voluntary* compliance in all instances in which noncompliance is found.” (emphasis added)).

response to comments, the Department is finalizing § 88.2(g) with a new paragraph (3) that describes OCR's authority to "coordinate with the relevant Departmental component to (1) utilize existing enforcement regulations, such as those that apply to grants, contracts, or other programs and services, or (2) withhold relevant funding to the extent authorized under the statutes listed under § 88.1" where informal means of achieving compliance have failed to resolve a given matter. In response to comments, the Department is also finalizing § 88.2(g) with a new paragraph (4) that describes OCR's authority to "in coordination with the Office of the General Counsel, refer the matter to the Department of Justice for proceedings to enforce the statutes listed under § 88.1" where informal means of achieving compliance have failed to resolve a given matter.

Section 88.5 of the 2019 Final Rule has been revised and redesignated as § 88.3 of this final rule. In response to comments, section 88.3(a) in this final rule now states that OCR considers the posting of a notice consistent with this part "as a best practice towards achieving compliance with and educating the public about the Federal health care conscience protection statutes, and encourages all entities subject to the Federal health care conscience protection statutes to post the model notice provided in Appendix A." In addition, we have also added to section 88.3(a) language to explain that "OCR will consider posting a notice as a factor in any investigation or compliance review under this rule." Section 88.3(b) describes places where the model notice in Appendix A should be posted. Section 88.3(c) describes the format of the notice. Section 88.3(d) describes the content of the notice text. Section 88.3(e) provides that the Department and each recipient may post the notice text along with the content of other notices (such as other nondiscrimination notices). The language from Appendix A to Part 88 in the 2019 Final Rule has been revised but is still designated as Appendix A to Part 88 in this final rule. The Department is finalizing the text of Appendix A with one change in response to commenters to include a statement for clarity that "You may have rights as a provider, patient, or other individual under these Federal statutes, which prohibit coercion or other discrimination on the basis of conscience in certain circumstances."

V. Regulatory Impact Analysis

A. Introduction

The Department has examined the impacts of this Final Rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct agencies 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 Office of Information and Regulatory Affairs has designated this final rule significant under Section 3(f)(1) of Executive Order 12866, as amended by Executive Order 14094. The Department addresses the Regulatory Flexibility Act below.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires agencies 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 1 year." The current threshold after adjustment for inflation is approximately \$177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not create an unfunded mandate under the Unfunded Mandates Reform Act because it does not impose any new requirements resulting in unfunded expenditures by state, local, and tribal governments, or by the private sector.

Congress enacted the Paperwork Reduction Act of 1995 to "maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal government" and to minimize the burden of this collection. 44 U.S.C. 3501(2). This final rule does not require new collections of information under the Paperwork Reduction Act of 1995. See generally 44 U.S.C. 3501–3520.

The Department made several changes to this Regulatory Impact Analysis (RIA) in response to public comment to the RIA that was published with the proposed rule in January 2023. In response to multiple comments regarding potential cost savings against a baseline of the 2019 Final Rule, the Department reviewed all RIA cost categories from the 2019 Final Rule to

determine if they will be potentially recoverable by virtue of the rescission of the 2019 Final Rule. The Department concluded that regulatory familiarization costs likely happened immediately following the publication of the 2019 Final Rule and would not be recoverable as a result of this final rule. The Department determined that all other cost categories might be considered as potential savings in a rescission scenario. We also added regulatory familiarization costs in response to concerns about the need of various stakeholders to review the provisions of this rule. Finally, the Department addressed comments about the impacts to small businesses by including a separate regulatory flexibility analysis section.

B. Requests for Comment

The Department solicited comments on the proposed rule's RIA, including whether the non-quantified impacts identified in the 2019 Final Rule's RIA would likely be realized, absent any further regulatory action. The Department responds to those comments here.

Comment: A commenter said that the 2019 Final Rule would have been burdensome because providers would have had to: obtain legal counsel to determine whether and how policies must be altered; revise employment manuals and training programs; maintain the records the Rule requires; and provide the mandated assurances and certifications.

Response: The Department thanks the commenter for insight into potential burdens.

Comment: A commenter stated that HHS did not "adequately or accurately" consider the costs of the proposed rulemaking. The commenter elaborated that the RIA did not show that the proposed rule is justified "when evaluated reasonably," stating that the primary baseline used is "irrational and self-contradictory." The commenter disagreed that the Department's explanation of the proposed rescissions of the 2019 Final Rule could be considered a savings, since the rule was not put into effect. The commenter stated that HHS should use its alternative baseline scenario, which assumes the 2019 Final Rule to be unimplemented, instead of the primary baseline to avoid arbitrariness. The commenter also said that the Department underestimates the impact of the proposed rule because the calculations under the alternative baseline in the RIA leave out the familiarization costs included with the 2019 Final Rule's RIA.

Response: The Department acknowledges the commenter's concern. The two baselines in question—the primary baseline that the 2019 Final Rule would go into effect and the alternative baseline that it would never go into effect—involve different ways of looking at the economic impact of the rule, not the justification for the rule. The Department continues to use the primary baseline but presents the alternative baseline as well.

Comment: A commenter stated that the RIA published with the proposed rule excludes the impact of the rulemaking on voluntary remedial efforts. The commenter cited the 2019 Final Rule's RIA statement that "some recipients will institute a grievance or similar process to handle internal complaints raised to the recipient's or sub-recipient's attention," and concluded that "an additional undiscounted 5-year cost of \$36 million at minimum must be added to the total cost of the proposed rule." The commenter stated that there is no reason to suggest that the proposed rule will not cause adoption of the same number of grievance processes as the 2019 Final Rule would have.

Response: The Department has reviewed this comment and disagrees. The commenter did not provide any new data to support the argument that the Department should adopt a particular view regarding how many entities will adopt a grievance or other remedial process. The Department does have reason to disagree with the remedial costs being identical, as significant provisions from the 2019 Final Rule that would likely have incentivized entities to voluntarily adopt grievance processes are removed. The rule rescinds significant portions of the 2019 Final Rule including required assurance and compliance provisions. Absent new data, the Department continues to believe that the rescissions in this final rule will generate \$8.3 million per year in savings through less grievance costs.

Comment: One commenter claimed that if the assurance and certification requirements of the 2019 Final Rule were "redundant and unnecessary" as HHS described them in the proposed rule, then "there would likely not be any costs within the first five years of publication" since "entities were already fully taking steps to be educated on, and comply with, all the laws that are the subject of this rule," as stated in the 2019 Final Rule's RIA. Given this assumption, the commenter continued, then the impact of the 2019 Final Rule should be reduced by the \$255.3 million in assurance and certification impact,

bringing the total undiscounted cost of the 2019 Final Rule to \$769.7 million. The commenter argued that this "overall lack of consideration of cost itself" constitutes a failure to meet the demands of *Michigan v. EPA*.

Response: The commenter quotes from the 2019 Final Rule's RIA's statement that there would likely not be "any costs within the first five years of publication" for remedial efforts taken by a recipient to meet the assurance and certification requirements in § 88.4 if "entities were already fully taking steps to be educated on, and comply with, all the laws that are the subject of this rule[.]" In other words, the costs of these remedial efforts would be zero if entities were taking these steps. But this conclusion cannot be extrapolated to the assurance and compliance requirements more generally. Section 88.4(b)(6) of the 2019 Final Rule required annual assurance and certification to OCR. These assurance and certification costs were projected to occur regardless of whether entities were already educated about the health care conscience protection statutes.

Comment: Some commenters suggested that, because a pandemic has occurred since the 2019 Final Rule, various estimates in the RIA are unreliable because of the strain on the health care community, including from loss of staffing.

Response: The Department agrees with the commenter that the impact estimates of the final rule are subject to several sources of uncertainty, including any impacts of the COVID-19 pandemic on covered entities. However, the comment did not provide any new data to explain which numbers in the 2019 RIA should be changed because of the noted strain due to the pandemic. The comment also did not provide a recommended approach for projecting these impacts over the 5-year time horizon of the analysis of the final rule. The Department notes that, while the analysis does not modify its estimates based on impacts related to the COVID-19 pandemic, it does address uncertainty, including by assessing a secondary baseline scenario.

Comment: Several commenters urged HHS to consider additional costs in the calculation of the final rule. These included: the impact of turnover, increased agency costs, increased litigation, and risk management costs; the costs of potential increased conscience and religious freedom complaints; the Federalism implications associated with impacts on state hospitals, medical facilities, and insurance plans, as well as the interaction with state and local laws

regarding conscience and religious freedom; specific costs, such as: the stresses placed on the nation's infrastructure of health care as a whole, and the public health consequences of "conscientious providers" leaving the workforce; the loss of access to certain providers; the costs that may result from companies that choose to ignore conscience protections, and thus lose employees and patients as a result; the compound effect of the rule's impact on existing labor shortages, among others.

Response: The Department is unable to quantify most of these costs, as the necessary data are not provided by the commenter and are not available in any data sources that the Department has reviewed. This approach is consistent with the 2019 Final Rule, in which these potential effects were discussed qualitatively but were also not quantified.

In response to the concerns about federalism, some of the Federal laws that this rule implements and enforces, such as the Weldon and Coats-Snowe Amendments, directly regulate States and local governments that receive Federal funding by conditioning the receipt of such funding on the governments' commitments to refrain from discrimination on certain bases or by imposing certain requirements on States and local governments that receive Federal funding. This impact, however, is a result of the statutory prohibitions and requirements themselves and are not due to the mechanisms provided by this rule.

Comment: A commenter pointed out that a premise of the 2019 Final Rule was that the 2019 Final Rule would expand access to health care, specifically by reducing barriers to the entry of certain health professionals and delaying the exit of certain health professionals from the field, by reducing discrimination or coercion that health professionals anticipate or experience. The commenter suggested that the proposed rule's disagreement with this conclusion means the Department (which continues to rely on the 2019 RIA) now underestimates the effects of reversing the 2019 Final Rule, as the commenter agrees with the 2019 Final Rule's assessment of its effects.

Response: The Department has reviewed this comment and found that it does not provide any new data or other actionable information relevant to the economic analysis. Consistent with numerous comments received on the 2018 proposed rule, the Department has no reason to conclude that the 2019 Rule would have resulted in more providers entering the workforce or

would have resulted in greater patient access to care.

Comment: Commenters had varying views regarding what percent of providers would post the voluntary notice. One commenter, who suspected the percent of covered entities posting voluntary notices would be minimal, requested that OCR better estimate the percentage of entities that will comply with the proposed posting notice on a voluntary basis. Another commenter suggested it would be reasonable for the Department to assume that all entities will provide voluntary notices, and, therefore, the overall cost to covered entities from posting the voluntary notices will be higher than the RIA states.

Response: The Department has reviewed this issue but disagrees that nearly all entities will post a voluntary notice. No commenter provided data to support their assertion that all covered entities or else a minimal number of covered entities will post the voluntary notice. After consideration, the Department in this final rule maintains the 2019 Final Rule RIA's estimate that half of all entities would post a voluntary notice in this final rule. If all entities posted a voluntary notice, the costs associated would be equivalent to the costs of a mandatory notice summarized in Policy Option 3 (this final rule, modified to include a mandatory notice). This final rule adopts a voluntary notice provision, and the cost is the same as the cost of the 2019 Final Rule's voluntary notice provision summarized in Policy Option 2 (this final rule).

C. Detailed Economic Analysis

HHS considered several policy alternatives, in addition to the approach of this final rule. This economic analysis considers the likely impacts associated with the following three policy options: (1) rescinding the 2019 Final Rule without exceptions; (2) adopting the approach of this final rule, which partially rescinds the 2019 Final Rule, and modifies other provisions; and (3) adopting the approach of this final rule, except further modifying the notice provision to require mandatory notices instead of voluntary notices. To simplify the narrative of this RIA, we present the impacts of rescinding the 2019 Final Rule in its entirety first, and then present the impacts of a partial rescission with modifications. These modifications correspond to the policy option of the final rule, and the policy option of mandatory notices. This RIA then summarizes the impacts of each policy option against common

assumptions about the baseline scenario of no further regulatory action.

Policy Option 1: Rescinding the 2019 Final Rule

Rescinding the final rule entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," published in the **Federal Register** on May 21, 2019 (84 FR 23170, 45 CFR part 88) (hereafter, "2019 Final Rule") would prevent the realization of many of the anticipated impacts of the 2019 Final Rule. For the purposes of this economic analysis, we provisionally adopt the characterization and quantification of these impacts that were presented in the regulatory impact analysis (RIA) of the 2019 Final Rule. The potential impacts identified and estimated in the RIA covered a five-year time horizon following the effective date of the 2019 Final Rule. However, because the 2019 Final Rule has been vacated by three federal district courts, these impacts have mostly not occurred and are not likely to occur. The litigation status of the 2019 Final Rule introduces substantial analytic uncertainty into any characterization of the baseline scenario of no further regulatory action. We address this uncertainty directly by analyzing the potential impacts of Policy Option 1 under two discrete baseline scenarios. First, for the purposes of this economic analysis, we adopt a primary baseline scenario that the 2019 Final Rule would take effect. Second, we adopt an alternative baseline scenario that the 2019 Final Rule would never take effect, even without any subsequent regulatory action.

Under our primary baseline scenario, Policy Option 1 would entirely reverse the impacts of the 2019 Final Rule. To analyze the impacts of Policy Option 1 under this scenario, we provisionally adopt the estimates of the likely impacts of the 2019 Final Rule in its RIA, although we understand that commenters raised questions whether, for example, certain of the non-quantified benefits that the 2019 Final Rule anticipated would in fact be realized. The RIA identified five categories of quantified costs: (1) familiarization; (2) assurance and certification; (3) voluntary actions to provide notices of rights; (4) voluntary remedial efforts; and (5) OCR enforcement and associated costs. The narrative of the RIA described an approach for estimating each of these costs, and Table 6 of the RIA summarized the timing and magnitude of these quantified costs (84 FR 23240). In addition to identifying quantified costs, the RIA identified non-quantified

costs associated with compliance procedures and non-quantified costs associated with seeking alternative providers of certain objected to medical services or procedures.

The 2019 Final Rule's RIA did not identify any quantified benefits, but identified non-quantified benefits associated with compliance with the law; protection of conscience rights, the free exercise of religion and moral convictions; more diverse and inclusive providers and health care professionals; improved provider-patient relationships that facilitate improved quality of care; equity, fairness, nondiscrimination; and increased access to care. The District Court in *New York*, however, also identified some non-quantified costs of the 2019 Final Rule, including: "that the Rule could potentially impose liability on an employer . . . for insisting that an ambulance driver complete a mission of transporting a patient to a hospital for an emergency procedure," that the Rule "would authorize individuals [to leave] the operating theater or medical procedure [and] withhold their services," and other instances of failing to provide care in life-threatening situations. 414 F.Supp.3d at 539, 519, 514 (citing *Shelton v. Univ. of Med. & Dentistry of N.J.*, 223 F.3d 220, 222–23, 224–28 (3d Cir. 2000)). The Department has no reason to conclude that, consistent with numerous comments received on the 2018 proposed rule, the 2019 Rule would have resulted in more providers entering the workforce or would have resulted in greater patient access to care, and acknowledges the potential harms raised by the *New York* decision. In addition, the Department notes that there are non-quantifiable benefits of this revised rule, including respecting Congress' attempt to strike a careful balance between patient and provider rights, ensuring patient access to health care, notifying the public of OCR's existing authorities on conscience laws, and clarifying to the public what OCR's process is for handling complaints under these authorities.

Table 1 of the 2019 Final Rule's RIA reported the present value and annualized value of the quantified costs and summarized the non-quantified costs and benefits of the 2019 Final Rule (84 FR 23227). That RIA reported estimates of the present value of the total costs over a 5-year time horizon of \$900.7 million using a 3-percent discount rate and \$731.5 million using a 7-percent discount rate. That RIA also reported annualized estimates of the costs of \$214.9 million under a 3-percent discount rate and \$218.5 million using a 7-percent discount rate.

Both sets of these cost estimates were reported in year 2016 dollars. We updated these estimates to year 2022 dollars using the Implicit Price Deflator for the Gross Domestic Product. We removed the regulatory familiarization costs for the 2019 Final Rule from the potential costs savings, as we believe these were incurred in full upon publication of the rule and will therefore be non-recoverable despite the partial rescission of the 2019 Final Rule. Likewise, we added regulatory familiarization costs for this final rule following the general methodology of the 2019 Final Rule updated with the most recent available data. We estimate that 513,627 entities will spend 2 hours of legal professional time to review the document. To determine the cost of legal professional time, we use the average wage for Lawyers (OES 23-1011) and load it with the factor for all civilian workers.³² As Table 1 notes below, the present value of these

familiarization costs add up to \$114 million using a 3-percent discount rate, or \$106 million using a 7-percent discount rate; they will also partially offset any cost savings in the first year of this current rule. The annualized costs are \$24.8 million, and \$23.2 million, respectively.

HHS next estimated the Policy Option 1 cost savings by calculating the total potentially recoverable costs from fully rescinding the 2019 Final Rule and adjusting them with the new regulatory familiarization costs. The present value of potentially recoverable costs from fully rescinding the 2019 Final Rule is \$1,026.0 million using a 3-percent discount rate and \$856.8 million using a 7-percent discount rate; these cover assurance and certification, voluntary notice and remedial efforts, and OCR enforcement costs (see Table 1 below for detailed breakdown of individual costs), and annualized costs of \$224.0 million using a 3-percent discount rate and

\$187.1 million using a 7-percent discount rate. Under our primary baseline scenario, the cost savings of Policy Option 1 would be approximately the inverse of the impacts contained in the 2019 potentially recoverable costs from the 2019 Final Rule's RIA plus the newly incurred regulatory familiarization cost. These cost savings sum up to a total discounted value of \$912.3 million at a 3-percent discount rate, or \$750.5 million using a 7-percent discount rate; the annualized values are, \$199.2 million, and \$163.9 million, respectively. Table A in the Summary of Impacts section of this preliminary regulatory impact analysis reports the summary impacts of the Policy Option 1 under this baseline scenario in millions of 2022 dollars, covering a 5-year time horizon, including annualized values, and Table 1 reports the detailed impacts in this primary baseline scenario, by cost category.

TABLE 1—COSTS AND COST SAVINGS—OPTION 1 (PRIMARY BASELINE)

[Discounted 3% and 7% in millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Costs and Cost Savings—Option 1						
Familiarization (undiscounted)	\$117.2	\$0.0	\$0.0	\$0.0	\$0.0	\$117.1
Familiarization (3%)	113.8	0.0	0.0	0.0	0.0	113.7
Familiarization (7%)	106.3	0.0	0.0	0.0	0.0	106.3
Assurance and Certification (undiscounted)	-187.2	-171.1	-171.1	-171.1	-171.1	-871.5
Assurance and Certification (3%)	-181.7	-161.3	-156.6	-152.0	-147.6	-799.1
Assurance and Certification (7%)	-169.8	-140.8	-127.8	-116.0	-105.2	-659.6
Voluntary Notice (undiscounted)	-112.3	-17.0	-17.0	-17.0	-17.0	-180.3
Voluntary Notice (3%)	-109.1	-16.0	-15.5	-15.1	-14.6	-170.4
Voluntary Notice (7%)	-101.9	-14.0	-12.7	-11.5	-10.4	-150.6
Voluntary Remedial Efforts (undiscounted)	-8.8	-8.8	-8.8	-8.8	-8.8	-43.9
Voluntary Remedial Efforts (3%)	-8.5	-8.3	-8.0	-7.8	-7.6	-40.2
Voluntary Remedial Efforts (7%)	-8.0	-7.2	-6.6	-5.9	-5.4	-33.1
OCR Enforcement Costs (undiscounted)	-3.6	-3.6	-3.6	-3.6	-3.6	-17.9
OCR Enforcement Costs (3%)	-3.5	-3.4	-3.3	-3.2	-3.1	-16.4
OCR Enforcement Costs (7%)	-3.3	-3.0	-2.7	-2.4	-2.2	-13.5
Total Costs (undiscounted)	-194.6	-200.4	-200.4	-200.4	-200.4	-996.4
Total Costs (3%)	-189.0	-188.9	-183.4	-178.1	-172.9	-912.3
Total Costs (7%)	-176.6	-165.0	-149.7	-135.8	-123.3	-750.5

Notes: Negative costs indicate the Policy Option, if finalized would result in cost savings.

Under our alternative baseline scenario, we assume that the 2019 Final Rule would never take effect, even without any additional regulatory action. Under this baseline scenario, Policy Option 1 would maintain the current status quo, which is characterized by the 2011 Final Rule (76 FR 9968). Thus, for this baseline scenario, we conclude that adopting

Policy Option 1 would result in the new regulatory familiarization costs (discussed above) plus other *de minimis* impacts that we do not quantify, such as resolving any regulatory uncertainty associated with the 2019 Final Rule, which has been vacated by three federal courts but not rescinded. We report the summary impacts of Policy Option 1 under this alternative baseline scenario

in Table A in the Impacts Summary section.

Policy Option 2: The Final Rule

The final rule partially rescinds the 2019 Final Rule, with certain exceptions. Specifically, this final rule retains three aspects of the 2019 Final Rule: (1) the addition to part 88 of statutes included in the 2019 Final Rule;

³² U.S. Dep't of Labor, Bureau of Labor Statistics, *May 2022 State Occupational Employment and Wage Estimates* (Last visited October 30, 2023),

<https://www.bls.gov/oes/current/oesrcst.htm>; U.S. Dep't of Labor, Bureau of Labor Statistics, *Employer Costs for Employee Compensation*, Quarter 1, 2023

(Last visited October 30, 2023), <https://www.bls.gov/eceec/data.htm>.

(2) several enforcement provisions; and (3) a voluntary notice provision.³³ However, as described in greater detail in the Preamble, the Department is also modifying each of these provisions of the 2019 Final Rule. For example, the voluntary notice provision in the proposed rule would clarify that providing these voluntary notices would not satisfy an entity’s substantive obligations imposed upon covered entities by the underlying statutes.

We considered the likely impacts of each of the three retained aspects of the 2019 Final Rule. The Department estimates that maintaining the statutes from the 2019 Final Rule will not impact costs. For the remaining two aspects of the 2019 Final Rule, we identify quantifiable impacts associated with retaining the aspects of the 2019 Final Rule related to the enforcement provisions and quantifiable impacts related to the voluntary notice provision. We adopt the analytic approach contained in the 2019 Final Rule’s RIA to quantify these impacts, including an assumption in that RIA

that about half of covered entities would provide notices voluntarily. For the provisions related to enforcement, the 2019 RIA estimated an annual impact of about \$3 million in costs to the Department and \$15 million in total costs over five years. For the provisions related to voluntary notices, that RIA estimated an impact of about \$93.4 million in costs in the first year of the analysis, and about \$14.1 million in costs in subsequent years, or about \$150 million over five years. Combined, the 2019 RIA estimated 5-year costs for these two provisions of \$165 million; in present value terms, these estimates are \$142 million using a 3-percent discount rate and \$118 million using a 7-percent discount rate. The 2019 RIA reported these costs in 2016 dollars.

To quantify the net impact of this rule, we fully remove the costs associated with enforcement and voluntary notice provisions from our earlier estimates of the total cost savings of rescinding the 2019 Final Rule. Since the voluntary notice requirement will not be rescinded, and some enforcement

provisions will be retained, we anticipate that there will be no cost savings against the 2019 Final Rule under these cost categories. As an intermediate step, we converted the 2016 dollar estimates from the previous paragraph to 2022 dollars using the Implicit Price Deflator for the Gross Domestic Product. Compared to our primary baseline, we estimate that over the first five years of this rule, this rule will result in total cost savings in 2022 dollars of \$725.5 million using a 3-percent discount rate and \$586.4 million using a 7-percent discount rate (as shown in Table 2); the corresponding annualized cost savings are \$158.4 million using a 3-percent discount rate and \$128.0 million using a 7-percent discount rate. We report these estimates in Table A in the Summary of Impacts section, which also reports comparable estimates corresponding to our alternative baseline scenario, and include a detailed breakdown of primary baseline costs in Table 2 below.

TABLE 2—COSTS AND COST SAVINGS—OPTION 2 (PRIMARY BASELINE)
[Discounted 3% and 7% in millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Costs and Cost Savings—Option 2						
Familiarization (undiscounted)	\$117.2	\$0.0	\$0.0	\$0.0	\$0.0	\$117.1
Familiarization (3%)	113.8	0.0	0.0	0.0	0.0	113.7
Familiarization (7%)	106.3	0.0	0.0	0.0	0.0	106.3
Assurance and Certification (undiscounted)	-187.2	-171.1	-171.1	-171.1	-171.1	-871.5
Assurance and Certification (3%)	-181.7	-161.3	-156.6	-152.0	-147.6	-799.1
Assurance and Certification (7%)	-169.8	-140.8	-127.8	-116.0	-105.2	-659.6
Voluntary Notice (undiscounted)	0.0	0.0	0.0	0.0	0.0	0.0
Voluntary Notice (3%)	0.0	0.0	0.0	0.0	0.0	0.0
Voluntary Notice (7%)	0.0	0.0	0.0	0.0	0.0	0.0
Voluntary Remedial Efforts (undiscounted)	-8.8	-8.8	-8.8	-8.8	-8.8	-43.9
Voluntary Remedial Efforts (3%)	-8.5	-8.3	-8.0	-7.8	-7.6	-40.2
Voluntary Remedial Efforts (7%)	-8.0	-7.2	-6.6	-5.9	-5.4	-33.1
OCR Enforcement Costs (undiscounted)	0.0	0.0	0.0	0.0	0.0	0.0
OCR Enforcement Costs (3%)	0.0	0.0	0.0	0.0	0.0	0.0
OCR Enforcement Costs (7%)	0.0	0.0	0.0	0.0	0.0	0.0
Total Costs (undiscounted)	-78.7	-179.8	-179.8	-179.8	-179.8	-798.2
Total Costs (3%)	-76.4	-169.5	-164.6	-159.8	-155.1	-725.5
Total Costs (7%)	-71.4	-148.1	-134.4	-121.9	-110.6	-586.4

Negative costs indicate the Policy Option, if finalized would result in cost savings.

Policy Option 3: The Final Rule With an Alternative Notice Provision

The Department analyzed a third policy option, which is similar to the final rule, but would further modify the notice provision by requiring covered entities to post these notices in designated places. The 2019 Final

Rule’s RIA assumes that about half of covered entities would provide these notices on a voluntary basis, and we carried this assumption through in this analysis, including in our analysis of the costs of the proposed rule. Under Policy Option 3, we anticipate that all covered entities would provide notices, and

therefore estimate that the costs of mandatory notices would be double that of our estimates of the costs of voluntary notices.

To quantify the net impact of Policy Option 3, we subtract the costs associated with enforcement and mandatory notice provisions from our

³³ The Department also keeps the severability clause from the 2019 Final Rule.

earlier estimates of the total cost savings of rescinding the 2019 Final Rule. Compared to our primary baseline, we estimate that Policy Option 3 would result in annualized cost savings in

2022 dollars of \$121.2 million using a 3-percent discount rate and \$95.2 million using a 7-percent discount rate. We report these estimates in Table A in the Summary of Impacts section, which

also includes comparable estimates corresponding to our alternative baseline scenario; a detailed breakdown of primary baseline impacts is included in Table 3 below.

TABLE 3—COSTS AND COST SAVINGS—OPTION 3 (PRIMARY BASELINE)

[Discounted 3% and 7% in millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Costs and Cost Savings—Option 3						
Familiarization (undiscounted)	\$117.2	\$0.0	\$0.0	\$0.0	\$0.0	\$117.1
Familiarization (3%)	113.8	0.0	0.0	0.0	0.0	113.7
Familiarization (7%)	106.3	0.0	0.0	0.0	0.0	106.3
Assurance and Certification (undiscounted)	-187.2	-171.1	-171.1	-171.1	-171.1	-871.5
Assurance and Certification (3%)	-181.7	-161.3	-156.6	-152.0	-147.6	-799.1
Assurance and Certification (7%)	-169.8	-140.8	-127.8	-116.0	-105.2	-659.6
Mandatory Notice (undiscounted)	112.3	17.0	17.0	17.0	17.0	180.3
Mandatory Notice (3%)	109.1	16.0	15.5	15.1	14.6	170.4
Mandatory Notice (7%)	101.9	14.0	12.7	11.5	10.4	150.6
Voluntary Remedial Efforts (undiscounted)	-8.8	-8.8	-8.8	-8.8	-8.8	-43.9
Voluntary Remedial Efforts (3%)	-8.5	-8.3	-8.0	-7.8	-7.6	-40.2
Voluntary Remedial Efforts (7%)	-8.0	-7.2	-6.6	-5.9	-5.4	-33.1
OCR Enforcement Costs (undiscounted)	0.0	0.0	0.0	0.0	0.0	0.0
OCR Enforcement Costs (3%)	0.0	0.0	0.0	0.0	0.0	0.0
OCR Enforcement Costs (7%)	0.0	0.0	0.0	0.0	0.0	0.0
Total Costs (undiscounted)	\$33.6	-162.9	-162.9	-162.9	-162.9	-617.9
Total Costs (3%)	\$32.6	-153.5	-149.0	-144.7	-140.5	-555.2
Total Costs (7%)	\$30.5	-134.1	-121.7	-110.4	-100.2	-435.9

Notes: Negative costs indicate the Policy Option, if finalized would result in cost savings.

D. Summary of Impacts

This analysis estimates the costs associated with the final rule and for two policy alternatives. For the final rule, we estimate the present value of the costs of -\$725.5 million using a 3-percent discount rate and -\$586.4 million using a 7-percent discount rate. Alternatively stated, we estimate that the final rule would generate cost savings of \$725.5 million using a 3-percent discount rate and \$586.4 million using a 7-percent discount rate.

Table A reports cost estimates for the Final Rule and for the two policy alternatives. These estimates are reported in millions of 2022 dollars over a 5-year time horizon. Table A presents these cost estimates in present value terms and as annualized values for both a 3-percent and a 7-percent discount rate. Table A reports these estimates for our primary baseline scenario that the 2019 Final Rule would take effect, and for an alternative baseline scenario that the 2019 Final Rule would never take

effect, even without any subsequent regulatory action. We do not identify any quantified benefits for the Final Rule or for the two policy alternatives.

The Department has selected Policy Option 2 despite Policy Option 1 generating the most savings because Policy Option 2 both rescinds the 2019 Final Rule and maintains several of its provisions. This approach better clarifies OCR's existing authorities and processes for enforcing the conscience statutes, as explained above.

TABLE A—ACCOUNTING TABLE OF COSTS

[Millions of 2022 dollars over a 5-year time horizon]

Baseline scenario and policy option	Present value by discount rate		Annualized value by discount rate	
	3 Percent	7 Percent	3 Percent	7 Percent
Primary Baseline:				
Option 1 (Rescinding the 2019 Final Rule)	-\$912.3	-\$750.5	-\$199.2	-\$163.9
Option 2 (The Final Rule)	-725.5	-586.4	-158.4	-128.0
Option 3 (The Final Rule with an Alternative Notice Provision)	-555.2	-435.9	-121.2	-95.2
Alternative Baseline:				
Option 1 (Rescinding the 2019 Final Rule)	113.7	106.3	24.8	23.2
Option 2 (The Final Rule)	300.5	270.4	65.6	59.0
Option 3 (The Final Rule with an Alternative Notice Provision)	470.8	420.9	102.8	91.9

Notes: Negative costs indicate the Policy Option, if finalized would result in cost savings.

E. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. HHS has examined the economic implications of this final rule as required by the RFA. The RFA requires an agency to describe the impact of a rulemaking on small entities by providing an initial regulatory flexibility analysis unless the agency expects that the rule will not have a significant impact on a substantial number of small entities, provides a factual basis for this determination, and to certify the statement. 5 U.S.C. 603(a), 605(b). If an agency must provide an initial 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 considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact of revenue on at least five percent of small entities.

One commenter said that HHS also needs to assess and certify the impact on small businesses and all non-profits under the RFA, using the above analysis on costs and explaining its reasoning. The commenter pointed to non-profit organizations, including many religiously affiliated hospitals and health-care facilities, and small health-care practitioners as entities and individuals affected by this rule.

Based on its examination, the Department has concluded that this rule does not have a significant economic impact on a substantial number of small entities. The entities that would be affected by this final rule, in industries described in detail in the RIA, are considered small by virtue of either nonprofit status or having revenues of less than between \$7.5 million and \$38.5 million in average annual revenue, with the threshold varying by industry. Persons and States are not included in the definition of a small entity. The Department assumes that most of the entities affected meet the threshold of a small entity.

Although this final rule will apply to and affect small entities, this rule's per-entity effects are relatively small. The Department estimates that this rule would result in average cost savings of \$307 per entity in the primary baseline scenario, or an average cost of \$129 per entity in the alternative baseline

scenario, over the first five years of compliance (both annualized with a 3-percent discount rate). Furthermore, any costs would generally be proportional to the size of an entity, so that the smallest affected entities will face lower average costs. Given the thresholds discussed in the preceding paragraphs, the average costs are below the Department's default threshold for significance.

Because this final rule would result in either a small reduction in costs to small entities or minimal to no impact on costs to small entities, this analysis concludes, and the Secretary certifies that the rule will not have a significant economic impact on a substantial number of small entities. This finding and certification is consistent with the regulatory flexibility analysis of the 2019 Final Rule that would be partially rescinded by this regulatory action, which "concluded that this rule does not have a significant economic impact on a substantial number of small entities" (84 FR 23255).

List of Subjects in 45 CFR Part 88

Adult education, Authority delegations (Government agencies), Civil rights, Colleges and universities, Community facilities, Conflicts of interest, Educational facilities, Employment, Family planning, Freedom of information, Government contracts, Government employees, Grant programs—health, Grants administration, Health care, Health facilities, Health insurance, Health professions, Hospitals, Immunization, Indians—Tribal government, Insurance, Insurance companies, Intergovernmental relations, Laboratories, Maternal and child health, Medicaid, Medical and dental schools, Medical research, Medicare, Mental health programs, Nursing homes, Occupational safety and health, Prescription drugs, Public assistance programs, Public health, Religious discrimination, Reporting and recordkeeping requirements, Research, Scholarships and fellowships, Schools, Scientists.

Xavier Becerra,

Secretary, Department of Health and Human Services.

■ For the reasons set forth in the preamble, the Department revises 45 CFR part 88 to read as follows:

PART 88—ENSURING THAT DEPARTMENT OF HEALTH AND HUMAN SERVICES FUNDS DO NOT SUPPORT COERCIVE OR DISCRIMINATORY POLICIES OR PRACTICES IN VIOLATION OF FEDERAL LAW

Sec.

88.1 Purpose

88.2 Complaint handling and investigating.

88.3 Notice of Federal conscience and nondiscrimination laws.

88.4 Severability.

Appendix A to Part 88—Model Text: Notice of Rights Under Federal Conscience and Nondiscrimination Laws

Authority: 5 U.S.C. 301.

§ 88.1 Purpose.

The purpose of this part is to provide for the enforcement of the Church Amendments, 42 U.S.C. 300a–7; the Coats-Snowe Amendment, section 245 of the Public Health Service Act, 42 U.S.C. 238n; the Weldon Amendment, *e.g.*, Consolidated Appropriations Act, 2023, Public Law 117–328, div. H, title V General Provisions, section 507(d)(1) (Dec. 29, 2022); Sections 1303(b)(1)(A), (b)(4), and (c)(2)(A), and 1411(b)(5)(A), and 1553 of the ACA, 42 U.S.C. 18023(b)(1)(A), (b)(4), and (c)(2)(A), 18081(b)(5)(A), and 18113; certain Medicare and Medicaid provisions, 42 U.S.C. 1320a–1(h), 1320c–11, 1395i–5, 1395w–22(j)(3)(B), 1395x(e), 1395x(y)(1), 1395cc(f), 1396a(a), 1396a(w)(3), 1396u–2(b)(3)(B), 1397j–1(b), and 14406; the Helms, Biden, 1978, and 1985 Amendments, 22 U.S.C. 2151b(f), *accord, e.g.*, Consolidated Appropriations Act, 2023, Public Law 117–328, div. K, title VII, section 7018 (Dec. 29, 2022); 22 U.S.C. 7631(d); 42 U.S.C. 280g–1(d), 290bb–36(f), 1396f, 1396s(c)(2)(B)(ii); 5106i(a); and 29 U.S.C. 669(a)(5), referred to collectively as the "Federal health care conscience protection statutes."

§ 88.2 Complaint handling and investigating.

(a) *Delegated authority.* The Office for Civil Rights (OCR) has been delegated the authority to facilitate and coordinate the Department's enforcement of the Federal health care conscience protection statutes, which includes the authority to:

- (1) Receive and handle complaints;
- (2) Initiate compliance reviews;
- (3) Conduct investigations;
- (4) Consult on compliance within the Department;
- (5) Seek voluntary resolutions of complaints;
- (6) Consult and coordinate with the relevant Departmental funding component, and utilize existing

enforcement regulations, such as those that apply to grants, contracts, or other programs and services;

(7) In coordination with the relevant component or components of the Department, coordinate other appropriate remedial action as the Department deems necessary and as allowed by law and applicable regulation; and

(8) In coordination with the relevant component or components of the Department, make enforcement referrals to the Department of Justice.

(b) *Complaints.* Any entity or individual may file a complaint with OCR alleging a potential violation of Federal health care conscience protection statutes. OCR shall coordinate handling of complaints with the relevant Department component(s). The complaint filer is not required to be the entity whose rights under the Federal health care conscience protection statutes have been potentially violated.

(c) *Compliance reviews.* OCR may conduct compliance reviews of an entity subject to the Federal health care conscience protection statutes, where authorized for the funding at issue, to determine whether they are complying with Federal health care conscience protection statutes. OCR may initiate a compliance review of an entity subject to the Federal health care conscience protection statutes based on information from a complaint or other source that causes OCR to suspect non-compliance by such entity with the Federal health care conscience protection statutes.

(d) *Investigations.* OCR shall make a prompt investigation of a complaint alleging failure to comply with the Federal health care conscience protection statutes. This investigation may include a review of the pertinent practices, policies, communications, documents, compliance history, circumstances under which the possible noncompliance occurred, and other factors relevant to determining whether the Department, Department components, recipient, or sub-recipient has failed to comply. OCR may use fact-finding methods including site visits; interviews with the complainants, Department components, recipients, sub-recipients, or third parties; and written data requests. OCR may seek the assistance of any State agency.

(e) *Failure to respond.* OCR will adopt a negative inference if, absent good cause, an entity that is subject to the Federal health care conscience protection statutes fails to respond to a request for information or to a data or document request within a reasonable timeframe.

(f) *Supervision and coordination.* If, as a result of an investigation, OCR makes a determination of noncompliance with responsibilities under the Federal health care conscience protection statutes, OCR will coordinate and consult with the Departmental component responsible for the relevant funding to undertake appropriate action with the component to assure compliance.

(g) *Resolution of matters.* (1) If an investigation reveals that no action is warranted, OCR will in writing so inform any party who has been notified by OCR of the existence of the investigation.

(2) If an investigation indicates a failure to comply with the Federal health care conscience protection statutes, OCR will so inform the relevant parties and the matter will be resolved by informal means whenever possible.

(3) If a matter cannot be resolved by informal means, OCR will coordinate with the relevant Departmental component to:

(i) Utilize existing enforcement regulations, such as those that apply to grants, contracts, or other programs and services, or

(ii) Withhold relevant funding to the extent authorized under the statutes listed under § 88.1.

(4) If a matter cannot be resolved by informal means, OCR may, in coordination with the Office of the General Counsel, refer the matter to the Department of Justice to the extent permitted by law for proceedings to enforce the statutes listed under § 88.1.

§ 88.3 Notice of Federal conscience and nondiscrimination laws.

(a) *In general.* OCR considers the posting of a notice consistent with this part as a best practice towards achieving compliance with and educating the public about the Federal health care conscience protection statutes, and encourages all entities subject to the Federal health care conscience protection statutes to post the model notice provided in Appendix A to this part. OCR will consider posting a notice as a factor in any investigation or compliance review under this rule.

(b) *Placement of the notice text.* The model notice in Appendix A to this part should be posted in the following places, where relevant:

(1) On the Department or recipient's website(s);

(2) In a prominent and conspicuous physical location in the Department's or covered entity's establishments where notices to the public and notices to its workforce are customarily posted to permit ready observation;

(3) In a personnel manual, handbook, orientation materials, trainings, or other substantially similar document likely to be reviewed by members of the covered entity's workforce;

(4) In employment applications to the Department or covered entity, or in applications for participation in a service, benefit, or other program, including for training or study; and

(5) In any student handbook, orientation materials, or other substantially similar document for students participating in a program of training or study, including for postgraduate interns, residents, and fellows.

(c) *Format of the notice.* The text of the notice should be large and conspicuous enough to be read easily and be presented in a format, location, and manner that impedes or prevents the notice being altered, defaced, removed, or covered by other material.

(d) *Content of the notice text.* A recipient or the Department should consider using the model text provided in Appendix A to this part for the notice but may tailor its notice to address its particular circumstances and to more specifically address the Federal health care conscience protection statutes covered by this rule that apply to it. Where possible, and where the recipient does not have a conscience-based objection to doing so, the notice should include information about alternative providers that may offer patients services the recipient does not provide for reasons of conscience.

(e) *Combined nondiscrimination notices.* The Department and each recipient may post the notice text provided in Appendix A of this part, or a notice it drafts itself, along with the content of other notices (such as other nondiscrimination notices).

§ 88.4 Severability.

Any provision of this part held to be invalid or unenforceable either by its terms or as applied to any entity or circumstance shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be severable from this part, which shall remain in full force and effect to the maximum extent permitted by law. A severed provision shall not affect the remainder of this part or the application of the provision to other persons or entities not similarly situated or to other, dissimilar circumstances.

**Appendix A to Part 88—Model Text:
Notice of Rights Under Federal
Conscience and Nondiscrimination
Laws**

[Name of entity] complies with applicable Federal health care conscience protection statutes, including the Church Amendments, 42 U.S.C. 300a–7; the Coats-Snowe Amendment, section 245 of the Public Health Service Act, 42 U.S.C. 238n; the Weldon Amendment, *e.g.*, Consolidated Appropriations Act, 2023, Public Law 117–328, div. H, title V General Provisions, section 507(d)(1) (Dec. 29, 2022); Sections 1303(b)(1)(A), (b)(4), and (c)(2)(A), and 1411(b)(5)(A), and 1553 of the ACA, 42 U.S.C. 18023(b)(1)(A), (b)(4), and (c)(2)(A), 18081(b)(5)(A), and 18113; certain Medicare

and Medicaid provisions, 42 U.S.C. 1320a–1(h), 1320c–11, 1395i–5, 1395w–22(j)(3)(B), 1395x(e), 1395x(y)(1), 1395cc(f), 1396a(a), 1396a(w)(3), 1396u–2(b)(3)(B), 1397j–1(b), and 14406; the Helms, Biden, 1978, and 1985 Amendments, 22 U.S.C. 2151b(f), *accord, e.g.*, Consolidated Appropriations Act, 2023, Public Law 117–328, div. K, title VII, section 7018 (Dec. 29, 2022); 22 U.S.C. 7631(d); 42 U.S.C. 280g–1(d), 290bb–36(f), 1396f, 1396s(c)(2)(B)(ii); 5106i(a); and 29 U.S.C. 669(a)(5). More information to help entities determine which statutes are applicable to them is available at <https://www.hhs.gov/conscience/conscience-protections/index.html>. You may have rights as a provider, patient, or other individual under these Federal statutes, which prohibit coercion or other discrimination on the basis of conscience, whether based on religious

beliefs or moral convictions, in certain circumstances. If you believe that [Name of entity] has violated any of these provisions, you may file a complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://www.hhs.gov/ocr/complaints/index.html> or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW, Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD) or by email at ocrmail@hhs.gov. Complaint forms and more information about Federal conscience protection laws are available at <https://www.hhs.gov/conscience>.

[FR Doc. 2024–00091 Filed 1–9–24; 8:45 am]

BILLING CODE 4153–01–P