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DEPARTMENT OF HEALTH AND HUMAN SERVICES

RIN 0945-AA18

Safeguarding the Rights of Conscience as Protected by Federal Statutes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Department proposes 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.” 76 FR 9968 (“2011 Final Rule”). The Department also proposes to retain, with some modifications, certain provisions of the 2019 Final Rule regarding federal conscience protections but eliminate others because they are redundant or confusing, because they undermine the balance Congress struck between safeguarding conscience rights and protecting access to health care access, or because significant questions have been raised as to their legal authorization. Further, the Department seeks to determine what additional regulations, if any, are necessary to implement certain conscience protection laws. The Department is seeking public comment on the proposal to retain certain provisions of the 2019 Final Rule, including on any alternative approaches for ensuring compliance with the conscience protection laws.

DATES: Written comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) [RIN 0945-AA18] by any of the following methods. The first is the preferred method. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions.

1. *Federal eRulemaking Portal.* You may submit comments electronically to <https://www.regulations.gov>. Submit your comments as an attachment to your message or cover letter. [Attachments should be in Microsoft Word, WordPerfect, or Excel; however, Microsoft Word is preferred.] Follow the instructions for sending comments contained in the Web site link “Comment or Submission” and enter the keywords, “Conscience Recission NPRM.”
2. *By regular, express or overnight mail.* You may mail written comments to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: Conscience NPRM, RIN 0945-AA18, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW, Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.
3. *Delivery by hand (in person or by courier).* If you prefer, you may deliver your written comments before the close of the comment period to the same address: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: Conscience NPRM, RIN 0945-AA18, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW, Washington, DC 20201.

Because of staffing and resource limitations, and to ensure that no comments are misplaced, the agency cannot accept comments by facsimile (FAX) transmission. All comments

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received on a timely basis will be posted without change to <https://www.regulations.gov>, including any personal information provided.

Docket: For complete access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and search for Docket ID number HHS-OCR-0945-AA18.

FOR FURTHER INFORMATION CONTACT:

Pamela Barron at (800) 368-1019 or (800) 537-7697 (TDD).

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) urges all interested parties to examine this regulatory proposal carefully and to share your views with us, including any data to support your positions. If you have questions before submitting comments, please see the “For Further Information” box for the name and contact information of the Office for Civil Rights point of contact for this proposed regulation.

If you are a person with a disability and/or a user of assistive technology who has difficulty accessing this document, please contact the Office for Civil Rights using the name and contact information provided in the “For Further Information” box to obtain this information in an accessible format. Please visit <https://www.HHS.gov/regulations> for more information on HHS rulemaking and opportunities to comment on proposed and existing rules.

I. Background

Statutory Background

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Several provisions of federal law prohibit recipients of certain federal funds from coercing individuals and entities in the health care field into participating 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 at various times during the 1970s in response to debates over whether receipt of federal funds required the recipients of such funds to perform abortions or sterilizations. The first conscience provision in the Church Amendments, 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 conscience provision in the Church Amendments, 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

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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 conscience provision, contained in 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 conscience 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 final conscience provision contained in the Church Amendments, 42 U.S.C. 300a–7(e), prohibits any entity that receives a grant, contract, loan, loan guarantee, or interest subsidy

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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 [42 U.S.C. 238n] (Coats-Snowe Amendment)

Enacted in 1996, section 245 of the Public Health Service Act (PHS Act) prohibits the federal government and any State or local government 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 government 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

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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 include certain conscience provisions as well. In particular, the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251 (1997), prohibits Medicaid managed care-managed organizations and Medicare Advantage plans from prohibiting or restricting a physician from informing a patient about his or her health and full range of treatment options. *See id.* § 40011852(j)(3)(A), 111 Stat. at 295 (codified at 42 U.S.C. § 1395w–22(j)(3)(A)) (Medicare Advantage); *id.* § 4704(b)(3)(A), 111 Stat. at 496 (codified at 42 U.S.C. § 1396u–2(b)(3)(A)) (Medicaid managed care). However, it also 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). And finally, they contain provisions related to religious nonmedical health care providers and

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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).

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 by reference) in each subsequent legislative measure appropriating funds to HHS. *See, e.g.*, Consolidated Appropriations Act, 2022, P.L 117-103, div. H, title V General Provisions, § 507(d)(1) (Mar. 15, 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.”

Affordable Care Act

In 2010, Congress passed the Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified at 42 U.S.C. § 18001, et seq.). This statute also

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includes certain other provisions including specific conscience provisions in sections 1553, 1303 (a)(3)-(b)(2), and 1411 (b)(5)(A).

Section 1553 provides that the federal government, any state or local government, and any health care provider that receives federal funding under the ACA, or any health plan created under the ACA, may not subject an individual or health care entity to discrimination 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 provides that a State may choose to prohibit abortion coverage in its qualified health plans, 42 U.S.C. § 18023(a)(1), and that such a plan is not required to provide abortion coverage as part of its “essential health benefits,” *id.* § 18023(b)(1)(A)(i). However, a qualified health plan that declines to provide abortion coverage must provide notice of this exclusion to potential enrollees. *Id.* § 18023(b)(3)(A). And no qualified health plan may discriminate against any health care provider or facility because it refuses to provide, pay for, cover, or refer for abortions. *Id.* § 18023(b)(4). Section 1303 states that nothing in the ACA shall be construed to preempt state laws on abortion or federal laws on conscience protection, willingness or refusal to provide abortion, and discrimination based on that 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)(1)-(2), or to relieve health care providers of their obligations to provide emergency services under federal or state laws, including the Emergency Medical Treatment and

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Labor Act, *id.* § 18023(d). Section 1303 also states that it does not “alter the rights and obligations of employees and employers” under Title VII. *See id.* § 18023(c)(3).

Section 1411 addresses exemptions to the ACA’s “individual responsibility requirement.” 42 U.S.C. § 18081(b)(5)(A). 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.”¹

Other Provisions

A number of additional provisions relating to conscience and religious liberty have also been the subject of previous HHS rulemaking. These include provisions related to compulsory health care services generally (42 U.S.C. 1396f and 5106i(a)), under hearing screening programs (42 U.S.C. 280g-1(d)), occupational illness testing (29 U.S.C. 699(a)(5)), vaccination programs (42 U.S.C. 1396s(c)(2)(B)(ii)), and mental health treatment (42 U.S.C. 290bb-36(f)). These also include conscience and nondiscrimination provisions tied to certain funding in global health programs and other funds administered by the Secretary. *See* 22 U.S.C. 7631(d) and 22 U.S.C. 2151b(f).

Rulemaking

No statutory provision requires the promulgation of rules to implement the conscience provisions outlined above. On August 26, 2008, however, the Department exercised its discretion

¹ In 2017 Congress effectively nullified the practical effect of this provision by setting the related payment associated with noncompliance to \$0. *See* Tax Cuts and Jobs Act of 2017, Pub. L. 115–97, § 11081, 131 Stat. 2092 (codified in 26 U.S.C. § 5000A(c)).

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

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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, after receiving more than 300,000 comments, 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 rule proposed reinstating several rescinded provisions of the Final 2008 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.

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In response to the 2018 Proposed Rule, the Department received more than 242,000 comments, from a wide variety of individuals and organizations, including private citizens, individual and institutional health care providers, religious 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 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.

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Following the issuance of the 2019 Final Rule, a number of States, localities, and non-governmental parties filed suit 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 and on a nationwide basis. *See Washington v. Azar*, 426 F. Supp. 3d 704 (E.D. Wash. 2019), *appeal pending*, No. 20-35044 (9th Cir.); *City & Cnty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001 (N.D. Cal. 2019), *appeal pending*, Nos. 20-15398 et al. (9th Cir.); *New York v. HHS*, 414 F. Supp. 3d 475 (S.D.N.Y. 2019), *appeal pending*, Nos. 19-4254 et al. (2d Cir.).² The courts' rationales were not identical, but they collectively concluded that the rule was defective in a number of respects. One or more courts held that: (i) the rule exceeded the Department's authority; (ii) its provisions were 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) the rule 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) a particular definitional provision of the rule was not promulgated in compliance with the notice-and-comment requirements of the

² Each court held that the portions of the rule deemed unlawful were so intertwined with any lawful portions that the entire rule would be vacated, rather than individual provisions. *See City & Cnty. of San Francisco v. Azar*, 411 F. Supp. 3d at 1024–25 (“When a rule is so saturated with error, as here, there is no point in trying to sever the problematic provisions. The whole rule must go.”); *New York v. HHS.*, 414 F. Supp. 3d at 577 (“[T]he rulemaking exercise here was sufficiently shot through with glaring legal defects as to not justify a search for survivors.”).

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Administrative Procedure Act; and (v) the rule’s penalties for non-compliance with conscience provisions violated the separation of powers and the Spending Clause.

Because the 2019 Final Rule never took effect, HHS has been operating under the 2011 Final Rule continuously since it was finalized. It currently accepts, investigates, and processes complaints under the framework created by the 2011 Final Rule. There are no significant reliance interests stemming from the 2019 Final Rule because the rule was vacated before it became effective. Because the 2019 Final Rule never went into effect, no person or entity could have reasonably relied on its provisions. It is possible that health care providers or individuals have reasonably relied on the 2011 Final Rule because it has remained operational.

As part of this proposed rulemaking, HHS seeks comments on the approach contemplated by the 2019 Final Rule as well as comments on the general framework that OCR has been employing since 2011 – applying the plain text of the underlying statutes to the facts at issue on a case-by-case basis.

II. Proposed Rule

The Department is proposing to partially rescind 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), while leaving in effect the framework created by the February 23, 2011, Final Rule and retaining, with some modifications, certain provisions of the 2019 Final Rule.

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Though the Department received comments supporting and opposing the 2018 Proposed Rule (the basis for the 2019 Final Rule), the overwhelming majority of comments were in opposition to the rule.

Groups supporting the 2018 Proposed Rule said it would provide needed clarity and strengthen protections for conscience rights in health care. For example, a comment jointly filed by the U.S. Conference of Catholic Bishops, the National Association of Evangelicals, the Southern Baptist Ethics & Religious Liberty Commission, the Christian Legal Society, the Catholic Medical Association, and the Family Research Council commended the Department on the breadth of the proposed regulations, saying they would “provide much needed guidance as to the meaning of the conscience statutes.”³ The Catholic Health Association (CHA) filed a separate comment supporting the proposed rule, noting its belief that “[a]ccess to health care is essential to promote and protect the inherent and inalienable worth and dignity of every individual,” and that “organizations and individuals should not be required to participate in, pay for, provide coverage for or refer for services that directly contradict their deeply held religious or moral beliefs and convictions.”⁴ According to CHA, “[t]he lack of implementing regulations and of clarity concerning enforcement mechanisms for these laws has stymied their effectiveness.” Thus, CHA welcomed the proposed rule, saying it “effectively reflects the intent and content of the underlying laws”⁵

³ Letter from USCCB , NAE, CMA, CLS, ELRC, and FRC to HHS (Mar. 16, 2018) *available at* <https://www.regulations.gov/comment/HHS-OCR-2018-0002-27795>. The American Association of Pro-Life Obstetricians and Gynecologists also filed comments in support of the proposed rule. Letter from AAPLOG to HHS (Mar. 26, 2018), *available at* <https://www.regulations.gov/comment/HHS-OCR-2018-0002-67019>.

⁴ Letter from the Catholic Health Association to HHS (Mar. 27, 2018), *available at* <https://www.regulations.gov/comment/HHS-OCR-2018-0002-70534>.

⁵ *Id.*

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Other commenters opposed to the 2018 Proposed Rule raised a number of concerns, including that the rule would create confusion, place unnecessary burdens on covered entities, limit access to patient care, and result in individuals being denied access to services, with vulnerable populations being particularly affected. The American Medical Association, for example, commented that the proposed rule would undermine patients' access to care and information, impede research, and create confusion among providers about their legal and ethical obligations to treat patients.⁶ The American Academy of Family Physicians, American Nurses Association, American Academy of Nursing, American Congress of Obstetricians and Gynecologists, American College of Emergency Physicians and American Academy of Pediatrics, similarly raised concerns about the rule's effect on patients' abilities to access critical care.⁷ The American Psychological Association raised concerns about the rule's potential harm to women and sexual and gender minorities.⁸ The Association of American Medical Colleges commented that the rule was overly expansive and incongruous with medical professionalism, among other concerns.⁹ A coalition of state attorneys general commented that the rule would, among other things, undermine state health care laws and policies that protect patients, and lead to discrimination against patients.¹⁰ Several reproductive health organizations similarly

⁶ Letter from the AMA to HHS (Mar. 27, 2018), *available at* <https://www.regulations.gov/comment/HHS-OCR-2018-0002-70564>.

⁷ See Letter from AAFP to HHS (Mar. 20, 2018) *available at* <https://www.regulations.gov/document/HHS-OCR-2018-0002-34646>; Letter from ANA-AAN to HHS (Mar. 23, 2018) *available at* <https://www.regulations.gov/document/HHS-OCR-2018-0002-55870>; Letter from ACOG to HHS (Mar. 27, 2018) *available at* <https://www.regulations.gov/document/HHS-OCR-2018-0002-70647>; Letter from ACEP to HHS (Mar. 27, 2018); and Letter from AAP to HHS (Mar. 27, 2018) *available at* <https://www.regulations.gov/document/HHS-OCR-2018-0002-71022>.

⁸ Letter from APA to HHS (Mar. 26, 2018) *available at* <https://www.regulations.gov/document/HHS-OCR-2018-0002-71056>.

⁹ Letter from AAMC to HHS (Mar. 26, 2018) *available at* <https://www.regulations.gov/document/HHS-OCR-2018-0002-67592>.

¹⁰ Letter from Attorneys General to HHS (Mar. 27, 2018) *available at* <https://www.regulations.gov/comment/HHS-OCR-2018-0002-70188>.

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commented that the proposed rule would upset the statutory balance between protecting providers' conscience rights and patients' ability to access reproductive care.¹¹ The National Coalition for LGBTQ Health commented that the proposed rule would lead to increased discrimination and denials of care for vulnerable members of the LGBTQ community.¹²

Comments received on the 2018 Proposed Rule made valuable points about the importance of federal conscience protections as well as the importance of access to care free from discrimination. For this and other reasons, the Department is proposing to retain certain provisions from the 2019 Final Rule with modifications while rescinding others, and generally reinstating 2011 framework that has been in effect for some time.

The Department proposes to retain three aspects of the 2019 Final Rule: (1) the application to statutes first referenced in the 2019 Final Rule; (2) several enforcement provisions; and (3) a voluntary notice provision. The provisions proposed to be retained have been modified to address concerns raised by many of the commenters – and echoed in federal district court decisions – about the Department's underlying rulemaking authority.¹³ The new proposed rule relies on the Department's housekeeping authority under 5 U.S.C. 301, which permits the Department to issue regulations concerning its own internal procedures and operations, and therefore allows for the modifications in this proposed rule.

¹¹ *E.g.*, Letter from Nat'l Family Planning and Reproductive Health Assoc. to HHS (Mar. 27, 2018) *available at* <https://www.regulations.gov/comment/HHS-OCR-2018-0002-70260>

¹² Letter from The Nat'l Coalition for LGBT Health to HHS (Mar. 27, 2018) *available at* <https://www.regulations.gov/comment/HHS-OCR-2018-0002-71195>.

¹³ *See, e.g., New York v. United States Dep't of Health & Hum. Servs.*, 414 F. Supp. 3d 475, 521-22 (S.D.N.Y. 2019) (neither housekeeping authority nor general compliance powers are a basis for substantive rulemaking).

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First, the Department proposes to expand the category of “federal health care provider conscience protection statutes” covered by the rule to include the statutes that HHS added to § 88.3 in the 2019 Final Rule. Those statutes, which are described above, include conscience protections embedded in a wide range of Department programs, including Medicare and Medicaid, the administration of the Affordable Care Act, global health programs, health screenings, and more. 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, 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.

Second, the Department proposes to retain a number of provisions from the 2019 Final Rule related to complaint handling and investigations. In the proposed § 88.2, the Department expands upon the 2011 Final Rule’s description of complaint handling and investigation. Paragraph (a) describes OCR’s authority to receive and handle complaints, seek voluntary compliance, and work with relevant Department components to ensure compliance through existing enforcement mechanisms. Paragraph (b) describes how OCR will conduct investigations. Paragraph (c) describes how OCR will proceed if an investigation reveals a violation of a federal health care provider conscience protection statute, and paragraph (d) provides that OCR will seek voluntary resolution of violations and will inform relevant parties if it has found no violation.

Finally, the Department proposes to retain the 2019 Final Rule’s voluntary notice provisions, with some modifications to address concerns identified above. Notice of conscience protections and nondiscrimination laws under those provisions is an important means of

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promoting compliance. Such notices inform the public, patients, and workforce, which may include students or applicants for employment or training, of protections under the Federal conscience and nondiscrimination laws and this rule.

This proposed notice would advise persons and covered entities about their rights and the Department's and/or recipients' obligations under Federal conscience and nondiscrimination laws. The notice may also provide information about how to file a complaint with OCR if an individual believes that these laws have been violated, and may provide additional information to the patient on how to seek care.

Proposed paragraph (b) sets forth locations where the notice should appear: on the Department's and recipient's website(s), and in a physical location of each Department and recipient establishment where notices to the public and notices to their workforce are customarily posted. Proposed paragraph (c) would encourage covered entities to utilize the model notice and, if the recipient does not have a conscience-based objection to doing so, to provide information about alternative providers that may offer patients services the recipient does not provide for reasons of conscience. The Department proposes that recipients should be permitted to tailor their notice to their particular circumstances and communities, and paragraph (d) of § 88.3 proposes to permit recipients to combine the text of the notice specified in paragraph (a) with other notices.

The 2019 Final Rule, at § 88.5(A), provided that the OCR director would consider whether a covered entity posted OCR's model notice as non-dispositive evidence of compliance with the underlying federal conscience protection statute where relevant. This proposed rule modifies that provision to avoid implying that covered entities can substantively comply with the

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underlying statute by simply posting a notice. The Department believes such an implication could undermine the conscience and nondiscrimination protections provided by the underlying statutes themselves, and therefore the goal of this rule. While the Department considers posting a notice to be a best practice and encourages covered entities to post the model notice included in the proposed rule, we wish to avoid the implication that a covered entity can satisfy the substantive obligations imposed upon it by the underlying statutes by taking an action that none of the underlying statutes designates as a method of demonstrating compliance with their substantive provisions. Covered entities must comply with the requirements of each of the federal health care provider conscience protection statutes identified in § 88.1 of the proposed rule, regardless of whether the notice is posted. We solicit comments on these voluntary notice provisions and specifically seek comment on whether posting a notice should be mandatory as contemplated by the 2018 Proposed Rule.

We encourage any relevant comments, including those that will assist the Department in assessing alternatives and reevaluating the necessity for additional regulations implementing the statutory requirements.

The 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. This includes the purpose provision at § 88.1, the definitions that appeared at § 88.2, the applicable requirements and prohibitions that appeared at § 88.3, the assurance and certification requirements at § 88.4, compliance requirements at § 88.6, the relationship to other laws provision at § 88.8, and the rule

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of construction and severability provisions at § 88.9 and § 88.10. Those portions of the 2019 Rule were either: (1) redundant and unnecessary, because they simply repeated the language of the underlying statute; (2) have been deemed unlawful in district court decisions that raise significant questions as to whether they exceed the scope of the Department’s housekeeping authority; or (3) created confusion or harm by undermining the balance struck by Congress in the statutes themselves. For example, the district court for the Southern District of New York found that the 2019 Final Rule’s purpose, definitions, and assurance and certification requirements “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 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.” *City and Cty. of San Francisco*, 411 F. Supp. 3d at 1023. The “expansive definitions,” which departed from the federal statutes, coupled with the termination of all HHS funding as a consequence of noncompliance, deemed the rule “undoubtedly substantive.” *Id.*

The proposed partial rescission is informed by the three district court decisions that vacated the 2019 Final Rule prior to it taking effect and identified a number of serious questions that warrant additional careful consideration. Among other things, the litigation has raised significant questions regarding the complaints of statutory violations that served as a predicate for the 2019 Final Rule.

The Federal health conscience protection and nondiscrimination statutes represent Congress’ attempt to strike a careful balance. Some doctors, nurses, and hospitals, for example, object for religious or moral reasons to providing or referring for abortions or assisted suicide,

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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, sometime urgent ones. Our health care systems must effectively deliver services—including safe legal abortions—to all who need them in order to protect patients’ health and dignity.

Congress sought to balance these considerations through a variety of statutes. The Department will respect that balance. 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 light of the decisions discussed above, issues raised by commenters, and concerns about how the 2019 Final Rule approached the balance struck by Congress in the underlying statutes, the Department proposes to partially rescind the 2019 Final Rule, while maintaining some of its provisions, but otherwise preserve the status quo from 2011, which continues to be in effect. We solicit public comment to aid our consideration of the many complex questions surrounding the issue and the need for regulation in this area.

III. Statutory Authority

The Secretary proposes to partially rescind 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

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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 proposed 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 his employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.”

IV. Request for Comment

The Department seeks comments in order to determine whether or not to rescind the 2019 Final Rule in part or in its entirety or to modify that rule or parts of it, as well as to determine whether or not to leave in place the framework created by 2011 Final Rule, with additional authorities added to that framework, or otherwise to modify it. In particular, the Department seeks 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;

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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;

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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.

V. Preliminary Regulatory Impact Analysis

Introduction

We have examined the impacts of the proposed 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 us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is an economically significant regulatory action as defined by Executive Order 12866.

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The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule would result in either a small reduction in costs to small entities or no impact on costs to small entities, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. This finding is consistent with the regulatory flexibility analysis of the 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).

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$165 million, using the most current (2021) 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.

Detailed Economic Analysis

HHS considered several policy alternatives, in addition to the approach of the proposed 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 the proposed rule, which partially rescinds the 2019 Final Rule, and modifies other provisions;

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and (3) adopting the approach of the proposed 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 proposed 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 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.

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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 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; increased access to care. We request public comment on whether the non-quantified benefits and costs identified in the 2019 Final Rule's RIA would likely be realized, absent any further regulatory action.

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-

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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 2021 dollars using the Implicit Price Deflator for the Gross Domestic Product and report the present value of costs of \$1,008.0 million using a 3-percent discount rate and \$818.6 million using a 7-percent discount rate; and annualized costs of \$240.5 million using a 3-percent discount rate and \$244.5 million using a 7-percent discount rate. Under our primary baseline scenario, the impacts of Policy Option 1 would be approximately the inverse of the impacts contained in the 2019 Final Rule's RIA. Table A in this preliminary regulatory impact analysis reports the impacts of the Policy Option 1 under this baseline scenario in millions of 2021 dollars, covering a 5-year time horizon.

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 Policy Option 1 would result in only *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 impacts of Policy Option 1 under this alternative baseline scenario in Table A.

Policy Option 2: The Proposed Rule

The proposed rule would partially rescind the 2019 Final Rule, with certain exceptions. Specifically, the Department proposes to retain three aspects of the 2019 Final Rule: (1) the

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addition to part 88 of statutes included in the 2019 Final Rule; (2) several enforcement provisions; and (3) a voluntary notice provision. However, as described in greater detail in the Preamble, the Department is also proposing to modify 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. 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 the proposed rule, we subtract the costs associated with enforcement and voluntary notice provisions from our earlier estimates of the total cost savings of rescinding the 2019 Final Rule. As an intermediate step, we converted the 2016 dollar

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estimates to 2021 dollars using the Implicit Price Deflator for the Gross Domestic Product.

Compared to our primary baseline, we estimate that the proposed rule, if finalized, would result in annualized cost savings in 2021 dollars of \$202.5 million using a 3-percent discount rate and \$205.2 million using a 7-percent discount rate. We report these estimates in Table A, which also reports comparable estimates corresponding to our alternative baseline scenario.

Policy Option 3: The Proposed Rule with an Alternative Notice Provision

We analyzed a third policy option, which is similar to the proposed 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 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 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 2021 dollars of \$168.0 million using a 3-percent discount rate and \$169.2 using a 7-percent discount rate. We report these estimates in Table A, which also reports comparable estimates corresponding to our alternative baseline scenario.

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Summary of Impacts

This analysis estimates the costs associated with the proposed rule and for two policy alternatives. For the proposed rule, we estimate the present value of the costs of -\$834.2 million using a 3-percent discount rate and -\$657.2 million using a 7-percent discount rate. Alternatively stated, we estimate that the proposed rule would generate cost savings of \$834.2 million using a 3-percent discount rate and \$657.2 million using a 7-percent discount rate. Table A reports cost estimates for the proposed rule and for the two policy alternatives. These estimates are reported in millions of 2021 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 proposed rule or for the two policy alternatives.

Table A - Accounting Table of Costs (Millions of 2021 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	-\$1,008.0	-\$818.6	-\$240.5	-\$244.5
Option 2	-\$834.2	-\$657.2	-\$202.5	-\$205.2
Option 3	-\$675.7	-\$509.6	-\$168.0	-\$169.2
Alternative Baseline				
Option 1	\$0.0	\$0.0	\$0.0	\$0.0
Option 2	\$173.8	\$161.4	\$37.9	\$39.4
Option 3	\$332.2	\$309.0	\$72.5	\$75.4

Notes: Option 2 corresponds to the Proposed Rule. Negative costs indicate the Policy Option, if finalized would result in cost savings.

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The RIA of the 2019 Final Rule also identified certain non-quantifiable impacts. That RIA discussed potential impacts related to compliance with the law; impacts related to conscience rights; impacts related to the composition of providers and health care professionals; impacts related to provider-patient relations; impacts related to equity, fairness, and nondiscrimination; impacts related to access to care; and additional non-quantified cost savings associated with compliance procedures (recordkeeping and compliance reporting) and seeking of alternative providers of certain objected to medical services or procedures. We request public comment on whether the non-quantified impacts identified in the 2019 Final Rule’s RIA would likely be realized, absent any further regulatory action; and request comment on the extent to which each of the Policy Options, including the proposed rule, would result in comparable impacts.

We also request comment on whether covered entities have incurred costs attributable to the 2019 Final Rule that would not be averted by the proposed rule, if it is finalized; and further request data that would allow us to refine our quantified cost-savings estimates. For example, we request information that would allow us to quantify costs that covered entities previously incurred and are not recoverable, such as the costs associated with familiarization of the 2019 Final Rule.

VI. List of Subjects

For the reasons set forth above, the Department proposes to amend 45 CFR part 88 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

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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, Consolidated Appropriations Act, 2022, P.L 117-103, div. H, title V General Provisions, § 507(d)(1) (Mar.15, 2022); Sections 1303, 1411, and 1553 of the ACA, 42 U.S.C. 18023, 18081, and 18113; certain Medicare and Medicaid provisions, 42 U.S.C. 1320a-1(h), 1320c-11, 1395i-5, 1395w-22(j)(3)(A)-(B), 1395x(e), 1395x(y)(1), 1395cc(f), 1396a(a), 1396a(w)(3), 1396u-2(b)(3)(A)-(B), 1397j-1(b), and 14406; Consolidated Appropriations Act, 2022, Pub. L. 115-245, div. H, § 209, div. K, title VII, § 7018; 22 U.S.C. 7631(d); 22 U.S.C. 2151b(f); 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 provider conscience protection statutes.”

§ 88.2 Complaint handling and investigating

(a) OCR has been delegated the authority to facilitate and coordinate the Department’s enforcement of the Federal health care provider conscience protection statutes, which includes the authority to:

- (1) Receive and handle complaints;
- (2) Conduct investigations;
- (3) Consult on compliance within the Department;
- (4) Seek voluntary resolutions of complaints; and
- (5) Consult and coordinate with the relevant Departmental funding component, and utilize existing regulations enforcement, such as those that apply to grants, contracts, or other programs and services..

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(b) Investigations. An OCR investigation of a complaint alleging failure to comply with the Federal health care provider conscience protection statutes 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 component, recipient, or sub-recipient has failed to comply. OCR may use fact-finding methods including site visits; interviews with the complainants, Department component, recipients, sub-recipients, or third-parties; and written data or discovery requests. OCR may seek the assistance of any State agency.

(c) Supervision and coordination. If as a result of an investigation OCR makes a determination of noncompliance with responsibilities under the Federal health care provider 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.

(d) 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 provider conscience protection statutes, OCR will so inform the relevant parties and the matter will be resolved by informal means whenever possible.

§ 88.3 Voluntary Notice of Federal conscience and nondiscrimination laws.

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(a) In general. OCR considers the posting of a notice consistent with this part as a best practice, and encourages all entities subject to the federal health care provider statutes to post the model notice provided in Appendix A.

(b) Placement of the notice text. The model notice in Appendix A 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, or manner that impedes or prevents the notice being altered, defaced, removed, or covered by other material.

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(d) Content of the notice text. A recipient or the Department should consider using the model text provided in Appendix A for the notice, but 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. 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.

(d) 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 provider conscience protection statutes, including [list applicable conscience statutes]. If you believe that [Name of entity] has violated any of these provisions, you can file a complaint with the U.S. Department of Health

Note: The official version of this document is the document published in the Federal Register. This document has been sent to the Office of the Federal Register and is being scheduled for publication.

and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf> 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). Complaint forms and more information about Federal conscience protection laws are available at <http://www.hhs.gov/conscience>.

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Dated: _____

Xavier Becerra,

Secretary,

Department of Health and Human Services.